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Framework for Benefit Sharing Guidelines for India

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Abstract: The paper elaborates on principles and issues relevant to ''benefit sharing" within access and benefit sharing provisions in the context of the implementation of relevant provisions within India's Biological Diversity Act and Rules. By focusing on a typical bioprospecting scheme from access to end-product using appropriate examples, discussions centre on various scenarios that can be anticipated in the process and the need for a proportional, efficient and equitable approach to devise appropriate benefit schemes.

Keywords: Access and Benefit Sharing, Biological Diversity Act, India, Convention on Biodiversity, implementation, benefit sharing principles

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Introduction

According to various estimates, the potential value of biological diversity and genetic resources range anywhere between US$ 800 billion to US$ 1 trillion.[1] However, this potential is not available in a form for us to use directly but is based on careful prospecting of genetic resources for products, derivatives and services. Though these biological resources have been used in many forms since the birth of civilization, as they are available in nature or in its other variable conditions, with the advent of new technologies we can add value to existing biological diversity and genetic resources. These value additions can convert the genetic resources into new products

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of biotechnological food and medicines, other pharmaceutical products, etc. But one of the key issues in such use and value additions is how to regulate the access to such resources? Questions of who gains access to such resources, how such access is made available, how the benefits accrue to the providers, how the benefits will be shared with the providers and users of the resources, etc., are relevant in the above respect.

The Convention on Biological Diversity (CBD) is an international agreement (with 191 countries being Parties to the Convention) that provides countries a set of principles and protocol on how access to genetic resources be provided and benefits arising from use of such resources be shared. The Convention is by far the most widely accepted as it attempts to facilitate such access and benefit sharing arrangements, rather than being restrictive in its approach. Within the CBD process, at the Conference of Parties (COP) meetings, important initiatives related to access to genetic resources and fair and equitable sharing of benefits arising from the commercial utilization of genetic resources (ABS) have been taken. These are (a) adoption of the Bonn Guidelines in 2002 for developing legislations and contracts for establishing access and benefit sharing regimes at national levels;[2] (b) proposal for an international certificate of origin source/legal provenance;[3] and (c) development of a road map to establish an international regime on ABS.[4]

But despite such road map and intent, not much headway seems to have been made in the effective implementation of regulations related to fair and equitable benefit sharing.[5] Several reasons could be adduced to such delay. These are, among others, normally long gap between bio-prospecting and discovery of the biological resources and development and commercialization of products, asymmetric information in the market, inability to foresee the potential of genetic resources in realizing benefits by the community that may be the holder of the resources – biological and traditional knowledge, high transactions costs of negotiating and enforcing contracts, and the absence of clear principles on equity and ethics (asymmetry of resources for negotiations between the holder of the resources and the developer and marketer of the final product) .

India's National Biodiversity Act (hereinafter Act) does provide policy guidance on issues of ABS, but much still remains to be done so to ensure operationalability of ABS arrangements. Towards this, clear guidelines that account for various potential national scenarios which factor in various property rights that exist in India are required. This paper intends to draw attention to what issues need to be addressed in the implementation of

principles surrounding benefit sharing. This is especially relevant in the light of the global discussions on developing an international regime on ABS by 2010.

Given the above, the paper provides an analysis of various provisions under the Act and the related Rules with regard to benefit sharing principles to commensurate with access provisions and details under mutually agreed terms (MATs) and material transfer agreements (MTAs).The paper is constructed in a manner that suggests specific issues to be considered while developing the national benefit sharing guidelines as well as available options to be considered based on the experiences outside and within India.

India, CBD and TRIPS - Implementation

India has taken a number of legal and administrative measures to ensure compliance with the CBD and Article 27.3(b) of the TRIPS Agreement.[6]

Legal Instruments

- The Biological Diversity Act 2002 (Act No.18 of 2003)
- The Biological Diversity Act 2002 (Act No.18 of 2003)
- The Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001 (Act 53 of 2001)
- The Patent (Amendment) Act 2002 (Act 38 of 2002)

The Biological Diversity Act, 2002[7]

The aim of the Biological Diversity Act is to provide for the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto.

The Act refers to India being a party to the CBD and underscores the need for legislation to realize the Convention's objectives. Chapter II is on regulation of access to biological resources and traditional knowledge.

It regulates access:

(i) For foreigners, non-resident Indians, a body corporate, association or organization not incorporated or registered in India, or incorporated or registered in India, which has any non-India participation in the share capital or management. The access is based on approval of the National Biodiversity Authority (NBA) (Section 3(2).

(ii) For Indian citizens, companies, associations and other organizations registered in India, access to any biological resource for commercial

utilization or bio-survey and bio-utilization for commercial utilization is based on prior intimation to the concerned State Biodiversity Board (Section 7).

(iii) For local people and communities of the area, including growers and cultivators of biodiversity, and *vaid*s and *hakim*s, who have been practicing indigenous medicine, exemption of prior approval or prior intimation is given (Section 7).

The Act does not permit any person to transfer the results of research relating to biological resources obtained from India for monetary consideration to foreign nationals, companies or non-resident Indians without prior approval of the NBA. Prior approval is necessary for application of a patent or any other intellectual property rights (IPRs). Prior approval is also needed for transfer of accessed biological resources or traditional knowledge (TK) to a third party. Section 21 of the Act deals with determination of equitable benefit sharing by the NBA. Biodiversity Rules 2003 spell out the procedures for implementing ABS provisions.

Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act) 2001

The PPVFR Act deals with the protection of plant breeders' rights over the new varieties developed by them and the entitlement of farmers to register new varieties and to save, breed, use, exchange or share or sell the plant varieties, which the latter have developed, improved, and maintained over generations. It is an alternate (to the 1991 UPOV Model) *sui generis* system. It protects farmers' rights and suggests mechanisms for compensation or benefit-sharing for the contributions of local communities or farmers in the development of a new plant variety.

The Patent (Amendment) Act, 2002

This Act has been enacted to meet India's obligations arising out of the Agreement on Trade Related Intellectual Property Rights (TRIPS Agreement). It excludes plants and animals from the purview of the Act. It stipulates disclosure of the source and geographical origin of biological materials in the specification, when used in an invention. A patent can be revoked if (i) the complete specification does not disclose or wrongly mentions the source, and (ii) if the invention so far as cleared in any claims of the complete specification is anticipated to have incorporated knowledge oral or otherwise, available with any local or indigenous community in India or elsewhere. However, the law does not require

evidence of prior informed consent (PIC) of the relevant authorities, or benefit-sharing with the relevant TK holder, to be disclosed in the patent application. While India has been quite progressive in incorporating issues that overlap between CBD and TRIPS through appropriate legislation, it has to contend with trans-jurisdictional issues that arise when such provisions are not recognized elsewhere. It is therefore useful to summarize the positions of countries, especially those that are influential in the negotiating process, towards the relationship between TRIPS and CBD (Box).

Positions of some developed countries on the TRIPS-CBD Relationship

- Objectives of the TRIPS Agreement and the CBD are distinct and there is no conflict between them.
- Provisions regarding disclosure of source of biological resources and evidence of PIC and benefit sharing are neither necessary nor desirable for implementing the PIC and benefit sharing provisions of the CBD, and would be unnecessarily burdensome.
- It is not easy to determine with certainty the origin of the biological resources.
- These obligations would increase costs of acquiring patents. It could also encourage inventors to keep their inventions secret rather than apply for patents and come into public domain.
- The proposed obligations are not consistent with TRIPS Agreement. Existing disclosure requirement under Article 29 of TRIPS Agreement are directly related to determining whether an invention meets the standards of patentability and disclosure of technology to enable others skilled in the art to reproduce the invention. Proposed obligations would also be contrary to Article 27.1 which provides for non-discrimination in patent availability among fields of technology.
- Intellectual Property Rights do not aim to regulate the access and use of genetic resources. This could best be done through contracts between the authorities competent for granting access to genetic resources and/or traditional knowledge and those intending to make use of such resources and traditional knowledge.
- In accordance with the provisions of the CBD, countries could incorporate in their national legislation requirements for the conclusion of such contracts and the terms and conditions under which access and use may be granted including provisions for transfer of technology that might result from such use of genetic resources and/or traditional knowledge to which access is to be granted. Criminal and /or Civil remedies could also be provided for in the event of breach of obligations on either side and contracts can be litigated in the specified jurisdiction and judgments passed thereon could be enforced around the world under international agreements on recognition of judgments.

Box continued

Box continued

- Disclosure requirement in the patent applications with regard to evidence of PIC will not prevent misappropriation.
- Disclosure requirement with regard to evidence of benefit sharing cannot transfer benefits because such requirement would merely convey the information required. It would have no mechanism to transfer benefits between parties.
- If the country of origin and /or traditional knowledge has no benefit sharing infrastructure in place for the use of biological resources and/or traditional knowledge, any compensation to the custodians of such resources and/or traditional knowledge would not be possible even if a patent relates to these materials. So, first a mechanism to transfer benefits must be established.
- A new disclosure requirement could have significant, unintended consequences. For example, if improper disclosure results in revocation of a patent due to litigation by a third party which is not affiliated with a biological resources and/or traditional knowledge, this could actually upset the benefit-sharing agreement arrived at before grant of the patent.
- If an inventor fails to get patent on an invention which is associated with biological resources and /or traditional knowledge because of his inability to properly fulfill disclosure requirements or even if a patent is granted but later it is revoked owing to wrongful disclosure, the inventor may still be able to commercialize the invention outside the patent system without disclosing the invention to the public and without any obligation to share benefits. In either case, the invention having been disclosed to the public, third parties are most likely to use and commercialize the resources and/or traditional knowledge so disclosed without any obligation of sharing benefits.
- The disclosure requirements will be ineffective in having a better assessment by patent examiners of novelty and inventive step; rather these would only complicate an already overburdened patent system.
- New patent disclosure requirement may lead to significant administrative burdens for the patent offices of Member countries that would in turn create additional costs, with regard to those requirements which demand compliance with foreign laws.
- It does not seem possible that patent examiners could examine, with legal certainty, decisions involving interpretations of foreign laws to determine the validity of PIC or benefit sharing. This would only compound the uncertainties both in granted patent rights and in the process of granting patents.

***Source*:** Adapted from the Website of the Ministry of Commerce & Industry, Government of India**:** www.commerce.nic.in.

India's National Biological Diversity Act and Related Rules and Benefit Sharing

The National Biological Diversity Act (BDA), 2002 and related Rules (2004) deal with issues of biodiversity conservation, sustainable use and equitable benefit sharing through the National Biodiversity Authority and State Biodiversity Boards (SBB) at the provincial level and the Biodiversity Management Committees (BMCs) at the local level.

Since the enactment of the Rules, the National Biodiversity Authority (NBA) has been implementing provisions of the Act meticulously, especially those related to ABS,. Till 2008, the NBA has approved 24 applications for access to biological resources for commercial utilization, nine applications for transfer of research results, 266 applications approving intellectual property rights claims, 16 third party transfers and 40 collaborative research projects (from http://www.nbaindia.org/approvals/status_approvals.htm accessed 23 April, 2009)

However, the principles and rules governing benefit sharing, referred together as benefit sharing guidelines are in the process of being developed by the NBA pursuant to Section 20 of the Biological Diversity Rules.

We attempt here to use the provisions under the National Biodiversity Act and Rules of India as an example to expand, assess and analyze the issues related to benefit sharing, the entry points for discussions on issues and the possible considerations NBA should make before deciding on the benefit sharing principles and rules while developing benefit sharing guidelines.

The following provides an explanation of the provisions of the Biodiversity Act of India arranged on the basis of issues of relevance to benefit sharing going through a typical bio-product development framework - from access to value addition to ownership over final product. In the process, issues related to benefit sharing will be discussed under five major topics: access to and ownership of genetic resources, development of by-products/derivatives, benefit sharing, third party transfers and issues related to intellectual property rights. Each section of the Act and Rules are identified so as provide the important topics that need to be addressed in the development of benefit sharing guidelines. The paper makes use of relevant case studies related to utilization of genetic resources and implications for ABS, to highlight possible scenarios for the different topics. By juxtapositioning the provisions of the Act and Rules with the indicative scenarios and issues that would crop up during a bioprospecting chain of events, the paper provides a framework for the development of guidelines that are anticipatory and proactive in nature.

Access to and Ownership of Genetic Resources

Some of the relevant sections of the BDA are being summarised below:

Section 3

3. (1) No person referred to in sub section (2) shall, without previous

approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio survey and bio utilization.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub section (1) are the following, namely:

(a) a person who is not a citizen of India;

(b) a citizen of India, who is a non resident as defined in clause (30) of section 2 of the Income tax Act, 1961;

(c) a body corporate, association or organization-

(i) not incorporated or registered in India; or

(ii) incorporated or registered in India under any law for the time being in force which has any non Indian participation in its share capital or management.

Results of research not to be transferred to certain persons without approval of National Biodiversity Authority

Section 7

7. No person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio survey and bio utilization for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned:

Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*, who have been practicing indigenous medicine.

12. General functions of the Authority:

The Authority may perform the following functions, namely:

- lay down the procedure and guidelines to govern the activities provided under sections 3, 4 and 6

Issues that need consideration

1. *Defining ownership*

The transfer of Genetic Resources (GRs), which occurs in accordance with the Act, involves the transfer of only the possession and not the ownership of the material. While the CBD clearly specifies sovereign rights over genetic resources, it would be in place to state

how ownership over 'species' and 'samples of species' will be dealt with by the National Authority.

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.
Reaching agreement on how to share benefits from exploitation of 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 for 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 NBA provide for options to deal with PIC, MATs and MTAs that are based on resource and associated knowledge?

3. *Defining possible solutions for transboundary similarities and thereby ownership issues in resources and/ or knowledge*
This issue is critical to effective implementation of NBA especially with issues related to ABS discussions across states. Ownership of material vested with communities that are residing in more than one state, and negotiation on benefit sharing arrangements by State Biodiversity Boards need careful consideration to ensure no confusion exists with respect to benefit sharing arrangements. It is also pertinent to make provisions for circumstances where resources/related knowledge are shared between communities across countries. Countries such as Bangladesh have made provisions for recognizing such co-ownership across countries (see Appendix for a listing of examples of country legislations related to ABS)

By-products (Derivatives)

Some of the relevant sections of the BDA are being summarised below:

Section 21

21.(1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

Relevant Sections of the Biological Diversity Rules

Section 14

Procedure for access to biological resources and associated traditional knowledge:

(1) Any person seeking approval of the Authority for access to biological resources and associated knowledge for research or for commercial utilization shall make an application in Form I.

(6) The form of the agreement referred to in sub-rule (5) shall be laid down by the Authority and shall include the following, namely:

- general objectives and purpose of the application for seeking approval;
- description of the biological resources and traditional knowledge including accompanying information;
- intended uses of the biological resources (research, breeding, commercial utilization, etc.)
- conditions under which the applicant may seek intellectual property rights;
- quantum of monetary and other incidental benefits. If need be, a commitment to enter into a fresh agreement particularly in case if the biological material is taken for research purposes and later on sought to be used for commercial purposes, and also in case of any other change in use thereof subsequently.
- restriction to transfer the accessed biological resources and the traditional knowledge to any third party without prior approval of Authority;
- submitting to the Authority a regular status report of research and other developments;

- independent enforceability of individual clauses, provision to the extent that obligations in benefit sharing clauses survive the termination of the agreement, events limiting liability (natural calamities), arbitration, any confidentiality clause.

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 need to better understand 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 for a MTA and benefit sharing agreement. For instance, 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 biological and genetic resource such as blood, oils, resins, genes, seeds, spores, pollen and the like taken from or modified from a product. These are not standard definitions, and the authors are aware that discussions on defining by-products and derivatives are ongoing within the CBD process, and countries and different stakeholders have different understanding of the terms. The definitions will also have implications for trade in bio-products within the World Trade Organization (WTO) context.

2. *Terms for unmodified by-products (from original material and/or from leads from traditional knowledge).*
   It has to be clarified what will be the status of by-products that are unmodified from the original 'biochemical' form or when a resource is used for same purpose as in traditional knowledge that is accessed. In the absence of this, the status of use of un-modified products and the relationship with traditional knowledge will remain unclear. Consider the following examples from India that highlight the terms 'unmodified' by-products, and how local initiatives have attempted at benefit sharing. The first is a case study of how 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 based exclusively on TK on resources and processes of product development, using modern technologies and markets.

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 along 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. The scientists 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 per cent of its receipts with the Kani community through a Trust Fund established in the name of the community[8].
2. The Gram Mooligai Company Limited (GMCL) is a Public Ltd. Company registered in India. Its shareholders are made up of small groups comprising 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 for harvesting. The company also promotes sustainable harvesting practices among the communities. The company sells the herbs and shares 70 per cent 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.[9] Similarly, the Honey Bee Network also has examples of domestic benefit sharing with indigenous local innovators.[10]

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

Modified by-products refer to changes in information encoded in the resource, either as a synthetic or an analogue, or for use which differs from purpose in TK. The MTAs and benefit sharing discussion should deal with such modified by-products clearly.

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 over the original resource and related knowledge.

The indigenous communities of Madagascar used 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.[11] 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.

Benefit Sharing

Some of the relevant sections of the BDA are being summarised below:

Section 21

21.(1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

21. (2) The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:

- grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
- transfer of technology;
- location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;
- association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio survey and bio utilization;
- setting up of venture capital fund for aiding the cause of benefit claimers;
- payment of monetary compensation and non monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

21. (3) Where any amount of money is ordered by way of benefit sharing, the National Biodiversity Authority may direct the amount to be deposited in the National Biodiversity Fund:
Provided that where biological resource or knowledge was a result of access from specific individual or group of individuals or organizations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individual or group of individuals or organizations in accordance with the terms of any agreement and in such manner as it deems fit.

21. (4) For the purposes of this section, the National Biodiversity Authority shall, in consultation with the Central Government, by regulations, frame guidelines.

Section 24

24.(1) Any citizen of India or a body corporate, organization or association registered in India intending to undertake any activity referred to in section 7 shall give prior intimation in such form as may be prescribed by the State Government to the State Biodiversity Board.

24. (2) On receipt of an intimation under sub section (1), the State Biodiversity Board may, in consultation with the local bodies concerned and after making such enquires as it's conservation, may deem fit, by order, prohibit or restrict any such activity if it is of

opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity:

Provided that no such order shall be made without giving an opportunity of being heard to the person affected.

24. (3) Any information given in the form referred to in sub section (1) for prior intimation shall be kept confidential and shall not be disclosed, either intentionally or unintentionally, to any person not concerned there to.

Section 27

27.(1) There shall be constituted a Fund to be called the National Biodiversity Fund and there shall be credited thereto any grants and loans made to the National Biodiversity Authority under section 26; all charges and royalties received by the National Biodiversity Authority under this Act; and all sums received by the National Biodiversity Authority from such other sources as may be decided upon by the Central Government.

27.(2) The Fund shall be applied for channeling benefits to the benefit claimers; conservation and promotion of biological resources and development of areas from where such biological resources or knowledge associated thereto has been accessed; socio-economic development of areas referred to in clause (b) in consultation with the local bodies concerned.

Relevant Sections of the Biological Diversity Rules

Section 14

Procedure for access to biological resources and associated traditional knowledge:

(1) Any person seeking approval of the Authority for access to biological resources and associated knowledge for research or for commercial utilization shall make an application in Form I.

(6) The form of the agreement referred to in sub-rule (5) shall be laid down by the Authority and shall include the following namely:

- quantum of monetary and other incidental benefits. If need be, a commitment to enter into a fresh agreement particularly in case if the biological material is taken for research purposes and later on sought to be used for commercial purposes, and also in case of any other change in use thereof subsequently;
- restriction to transfer the accessed biological resources and the traditional knowledge to any third party without prior approval of

Authority;

- submitting to the Authority a regular status report of research and other developments;
- independent enforceability of individual clauses, provision to the extent that obligations in benefit sharing clauses survive the termination of the agreement, events limiting liability (natural calamities), arbitration, any confidentiality clause.

Section 20

Criteria for equitable benefit sharing (Section 21)

- The Authority shall by notification in the Official Gazette formulate the guidelines and describe the benefit sharing formula.
- The guidelines shall provide for monetary and other benefits such as royalty; joint ventures; technology transfer; product development; education and awareness raising activities; institutional capacity building and venture capital fund.
- The formula for benefit sharing shall be determined on a case-by case basis.
- The Authority while granting approval to any person for access or for transfer of results of research or applying for patent and IPR or for third party transfer of the accessed biological resource and associated knowledge may impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated knowledge.
- The quantum of benefits shall be mutually agreed upon between the persons applying for such approval and the Authority in consultation with the local bodies and benefit claimers and may be decided in due regard to the defined parameters of access, the extent of use, the sustainability aspect, impact and expected outcome levels, including measures ensuring conservation and sustainable use of biological diversity.
- Depending upon each case, the Authority shall stipulate the time frame for assessing benefit sharing on short, medium, and long term benefits.
- The Authority shall stipulate that benefits shall ensure conservation and sustainable use of biological diversity.
- Where biological resources or knowledge is accessed from a specific individual or a group of individuals or organizations, the Authority may take steps to ensure that the agreed amount is paid directly to them through the district administration. Where such individuals

or group of individuals or organizations cannot be identified, the monetary benefits shall be deposited in the National Biodiversity Fund.

- Five percent of the assessed benefits shall be earmarked for the Authority or Board, as the case may be, towards administrative and service charges.
- The Authority shall monitor the flow of benefits as determined under sub rule (4) in a manner determined by it.

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 relevant legislation from countries such as Brazil (see Appendix) provide national treatment to 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 on their research intentions, although they are expected to comply with benefit sharing principles in the event of accessing community resources/knowledge. Hence, benefit sharing norms for different actors need to be appropriately specified.

Such discussion will have implications for linking to the WTO based debates as well.

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 bio-prospector 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 purposes of research, training, education, and so on, 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/process development (different from the original intent) while providing access and in dealing with MATs, and MTAs.

Relevant examples include development of biodiversity registers, and related inventories, herbaria, bioactivity studies are examples of development of products from genetic resources, where the genetic resources accessed is used only for research purpose and do not enter into the commercial stream in the near term. However, it will be necessary to negotiate terms in the event of potential commercialization of the scientific/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. Commercial cultivation, rearing or culturing of a genetic resource from provider country in user country relating to agro-biodiversity, animal and microbial biodiversity are examples of this scenario that negotiators/ national implementing agencies may encounter.

To illustrate with a real example of a genetic resource being used directly for a commercial process: 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*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.[12]

c. *Terms when information on original genetic resource is commercialized*

Development of biodiversity inventories, which are then compiled and developed into a commercial product such as in a CD Rom or commercialization of genetic information, such as genetic sequences that have been identified are some examples of this scenario.

They indicate how databases can be used for commercial gain, and indicates the need for negotiations on compilation of information, who gains access to it, what aspects of the database is open for access to all and other related aspects. For instance, from their interviews with pharmacies using ethnobotanical knowledge, ten Kate and Laird (1999) report that 80 per cent of these companies rely for their data requirements on secondary sources such as databases and published literature over 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*

For instance, powders or aqueous extracts of a plant identified for medicinal properties may be commercialized in foreign markets. Then, 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 as it is obtained 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*

For instance, an active ingredient of a medicinal plant may be identified and later isolated. This isolate may then be synthetically produced through various technological processes. Then, it is 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

A molecule that shows, for instance, anti-cancerous activity is isolated, and 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 will have to take into account the relative contribution of the genetic resource to the development of the final product.

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

In the Kani case study referred to earlier, during the process of bioexploration and related ethnopharmacological work, the TBGRI developed several uncommercialized research products (products developed based on ethno-pharmacological research). The uses of these products were in line with the traditional uses for the genetic resources by the Kani community.[13] 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

The following are examples of research products that were developed from TK and later commercialized. These examples 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. Members of the San tribe of South Africa use 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.[14] 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 of 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.[15] 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 the research is carried out with contributions from TK, but the final uncommercialized research product developed has uses different to the original use in TK. For instance, an antihistaminic drug could be developed from a herb used by a TK community for treating injuries/burns, but 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

A classic example is the case of the development of 'Vincristine' and 'Vinblastine' from *Catharanthes roseus* for use in hypertension, while the plant was originally used by traditional communities as an antidiabetic. While the case did not see any sharing of benefits, it is imperative for negotiators/ implementing agencies to 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 an as yet 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: one, on a commitment for renegotiation of an agreement in the event of commercialization; and two, to enter into a benefit sharing arrangement that will provide a percentage 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 undervalue the share of the resource/ related knowledge. During various stages of the research and product cycle, the quasi-option value (value of the resource due to increased information) increases, 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)*

   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. Some of the various benefit sharing options 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

A good contract template that merits examination is that of the National Institute of Biodiversity of Costa Rica (INBio). Considered a leader in the negotiation and signature of benefit sharing agreements, INBio has signed around 11 agreements of this nature since its inception in 1989. All INBio agreements contain seven basic aspects:

1. Direct payments in cash or knowledge exchanges (equipment, training, technological knowhow).
2. Payment of a significant percentage of the initial budget of the project (10 per cent) and the returns of the commercialization of the products (50 per cent).
3. Cooperation clauses that stipulate the gradual translation of the investigation processes to the supplier country, in order to create new jobs and the achievement of industrial development.
4. Minimum exclusivity.
5. Agreement on the samples property and patents property.
6. The use of chemistry synthesis, semi-synthesis and domestication of the living sources, in order to avoid the continuous extraction of the biotic material.
7. Legal mechanisms that will provide protection to both parties.

Third Party Transfers of Research Results

Some of the relevant sections of the BDA are being summarised below:
Section 4

4. No person shall, without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non resident as defined in clause (30) of section 2 of the Income tax Act, 1961 or a body corporate or organization which is not registered or incorporated in India or which has any non Indian participation in its share capital or management.

Explanation for the purposes of this section, "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government.

5.(1) The provisions of sections 3 and 4 shall not apply to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government

sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions specified in sub section (3).

(3) For the purposes of sub section (1), collaborative research projects shall

(a) conform to the policy guidelines issued by the Central Government in this behalf;

(b) be approved by the Central Government.

Section 19

19. (1) Any person referred to in sub section (2) of section 3 who intends to obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio survey and bio utilization or transfer the results of any research relating to biological resources occurring in, or obtained from, India, shall make application in such form and payment of such fees as may be prescribed, to the National Biodiversity Authority.

Section 20

20.(1) No person who has been granted approval under section 19 shall transfer any biological resource or knowledge associated thereto which is the subject matter of the said approval except with the permission of the National Biodiversity Authority.

20.(2) Any person who intends to transfer any biological resource or knowledge associated thereto referred to in sub section (1) shall make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority.

20.(3) On receipt of an application under sub section (2), the National Biodiversity Authority may, after making such enquiries as it may deem fit and if necessary after consulting an expert committee constituted for this purpose, by order, grant approval subject to such terms and conditions as it may deem fit, including the imposition of charges by way of royalty or for reasons to be recorded in writing, reject the application:

Provided that no such order for rejection shall be made without giving an opportunity of being heard to the person affected.

Relevant Sections of the Biological Diversity Rules

Section 17

Procedure for seeking approval for transferring results of research:

Any person desirous of transferring results of research relating to biological resources obtained from India for monetary consideration to foreign nationals, companies and Non Resident Indians (NRIs), shall make an application to the Authority in the Form II.

Section 19

Procedure for third party transfer under sub-section (2) of Section 20:

The person who have been granted approval for access to biological resources and associated knowledge, intend to transfer the accessed biological resource or knowledge to any other person or organization shall make an application to the Authority in Form IV.

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 of material:
   a. Original material
   b. Publications
   c. Research product
   d. Derivatives/ By-products
   e. Normally traded commodities
   f. Intellectual Property rights (IP)
      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/ implementing authorities will need to arrive at an understanding if the terms are set only in the event of commercial transfers, or any 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 on 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.

Example

Genencor-Kenya case: A micro-organism (that produced enzymes that faded 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 clones it to produce the enzyme which is used for fading jeans and as an ingredient in a detergent.[16]

This case highlights how a research product was transferred for commercial application, indicating the need for a provider country to include in transfer agreements clauses for renegotiation and arbitration in the event of such transfers, and for users to be explicit and transparent in their resource sourcing trails.

Intellectual Property

Some of the relevant sections of the BDA are being summarised below:

Section 6

Application for intellectual property rights not to be made without approval of National Biodiversity Authority.

6. (1) No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.

Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned:

Provided further that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof.

(2) The National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or

impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

(3) The provisions of this section shall not apply to any person making an application for any right under any law relating to protection of plant varieties enacted by Parliament.

(4) Where any right is granted under law referred to in sub section (3), the concerned authority granting such right shall endorse a copy of such document granting the right to the National Biodiversity Authority.

Section 19

(2) Any person who intends to apply for a patent or any other form of intellectual property protection whether in India or outside India referred to in sub section (1) of section 6, may make an application in such form and in such manner as may be prescribed to the National Biodiversity Authority.

Section 21

(2) The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:

- grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;

Relevant Sections of the Biological Diversity Rules

Section 18

Procedure for seeking prior approval before applying for intellectual property protection.

Any person desirous of applying for a patent or any other intellectual property based on research on biological material and knowledge obtained from India shall make an application in Form III

Issues that need consideration

1. *Joint Ownership of IP*

a. Define joint ownership: 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 same use as in accessed TK. Joint ownership is a sensitive issue with product developers and hence needs to be carefully negotiated.

Example

A joint ownership was claimed and assigned on plant anti-malarial knowhow 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) project 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.[17] This particular case indicates the possibility of joint ownership of a product between scientists and local communities.

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. (...)...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.[18] 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.

Concluding Remarks

From the various case studies, the nature of the Indian Act and Rules and from the direction of intergovernmental discussions, it can be stated that India has an opportunity to lead the way on ABS discussions through proactive implementation of ABS measures, especially those related to benefit sharing. Some of the questions that will have to be addressed include:

- What combination of monetary and non-monetary incentives would be optimal for which kind of knowledge systems and innovations and under what institutional arrangements? Unless such a contingent framework is developed through guidelines, it is unlikely that most users of biodiversity will be able to initiate benefit-sharing experiments.
- What alternate models of benefit sharing will be appealing and practical to communities and businesses? To what extent has the generation of awareness about rights of traditional communities and grassroots innovators among various stakeholders been effective in changing the way business is done?
- What are the constitutional guarantees given to Scheduled Tribes (STs) and indigenous groups under the Indian Constitution? Does the recently passed Forest Act contain provisions that empower STs in enforcing their rights (collective and individual) against any sort of unsustainable acts on the biodiversity that directly or indirectly affects their livelihood or deprives them of their rightful share? What is the perception of local communities and innovators themselves on the issues of benefit-sharing?
- What have been the efforts of Non-Governmental Organizations (NGOs) and Governments in developing countries in initiating benefit-sharing measures at a national level and among the various institutions within the country? As some of the successful domestic benefit sharing examples show, it is important to identify such experiments and use them to devise effective implementation strategies involving various stakeholders.
- If international law doesn't come to the aid in solving the trans-jurisdictional issues, particularly the enforcement of foreign awards and judgments, is there a possibility of countering the same, by ensuring stronger national structures and regional agreements that could improve and foster a heterogeneous benefit sharing mechanism?

Endnotes

1 ten Kate and Laird (1999); Balmford *et al*. (2002).
2 http://www.cbd.int/abs/bonn.shtml
3 Decision 8/ 4 C of the CBD-COP 8; Also refer http://www.cbd.int/decisions/cop8/?m=COP-08&id=11016&lg=0
4 http://www.cbd.int/abs/regime.shtml
5 Pisupati (2006); Pisupati (2004).
6 See India Third National Report, https://cbd.int/doc/world/in/in-nr-03-en.doc last accessed on 21 April, 2009
7 http://www.nbaindia.org/act/act_english.htm
8 Pushpangadan (1988).
9 Personal Communication, Mr.MuthuVelayutham, Covenant Centre for Development, Madurai, Partner of GMCL, 2005.
10 Gupta (2004).
11 Reid (1994).
12 McGown, Jay (2006).
13 Personal Communicatin with Dr. S. Rajashekaran, TBGRI, 2001.
14 Suneetha (2004).
15 McGown, Jay (2006).
16 Lacey, Marc (2006).
17 Lewis, Walter H and Veena Ramani (2003).
18 Tobin (2008).

References

Balmford, A., A. Bruner, P. Cooper, R. Constanza, S. Farber, R. E. Green, M. Jerkins, P. Jefferiss, V. Jessamy, J. Madden, K. Munro, N. Myers, S. Naeem, J. Paavola, M. Rayment, S. Rosendo, J. Roughgarden, K. Trumper, K. Turner (2002). 'Economic reason for conserving wild nature', *Science* 297: 950-953.

Gupta, Anil K. (2004). 'The Role Of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge', World Intellectual Property Organization (WIPO) and the United Nations Environment Programme (UNEP).

Lacey, Marc (2006). 'Washday miracle? Kenya wants profit share', *The New York Times*, 21 February.

Lewis, Walter H and Veena Ramani (2003). Ethics and practice in Ethno biology: Analysis of the international cooperative biodiversity group project in Peru, Washington University in St. Louis.

McGown, Jay (2006). 'Out of Africa: Mysteries of Access and Benefit Sharing', Edmonds Institute and African Centre for Biosafety.

Pisupati, Balakrishna (2004). 'Access and Benefit Sharing: Questions for Policy Makers', IUCN Regional Biodiversity Programme, Asia.

Pisupati, Balakrishna (2006). 'Benefit Sharing within ABS'. *Biodiversity*, 12: 34-39.

Pushpangadan,P, S. Rajashekaran, P. K. Ratheshkumar, C. R. Jawahar, V. Velayudhan Nair, N. Lakshmi and L. Sarada Amma (1998). 'Arogyapacha' (*Trichopus zeyalnicus* Gaertn), The 'Ginseng' of Kani Tribes of Agasthyar Hills (Kerala) for Ever green Health and Vitality, *Ancient Science of Life,* 8 (1): 13-16.

Reid, Walter V (1994). 'Biochemical Prospecting, Strategies for Sharing Benefits', *Biopolicy,* International Series No.16, African Centre for Technology Studies (ACTS) Press, Kenya.

Suneetha, M. S. (2004). 'Economic Valuation of Medicinal Plants in the context of Convention on Biodiversity and IPR rights', Ph.D thesis (Unpublished), University of Agricultural Sciences, Bangalore.

ten Kate, Kerry and Sarah Laird (1999). *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing*, Earthscan Publications Ltd, London.

Tobin, Brendan (2008). 'Monitoring Compliance under an International ABS Regime: The Role of an International Certificate Scheme', *Asian Biotechnology and Development Review*, 10(3): 95-111.

'Options for Non-Monetary Benefit-Sharing - An Inventory', *CGRFA Background Study Paper No. 30,* Rome.

WIPO (2004). Genetic Resources: Draft Intellectual Property Guidelines for Access and Equitable Benefit-Sharing, WIPO/GRTKF/IC/7/9, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge And Folklore, Seventh Session, Geneva.

Conventions, Agreements

- National Legislations and Guidelines on ABS (Brazil, Philippines, Costa Rica, Bangladesh, Guyana, Malawi, Kenya, Ethiopia, Bolivia).
- Bonn Guidelines on access to genetic resources and fair and equitable sharing of benefits arising out of their utilization from http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.
- The Patents Act of India, 1970.
- The Biological Diversity Act of India, 2002.
- The Protection of Plant Varieties and Farmers' Rights Act of India, 2001.

Appendix: Examples of Country Legislation related to Benefit Sharing

Country	Legislation/ Relevant Sections of the Biological Diversity Rules	Implementing Agency	Applicable to whom	Monetary elements of Benefit sharing	Non-monetary elements of Benefit sharing	Ownership rights (IPRs/ *sui generis*)	Punitive action
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 institution who make economic use of product/ process from resource/ associated TK (Art 24)	1. Sharing of profits 2. Payment of royalties	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
Bangladesh	Biodiversity and Community Knowledge Protection Act of Bangladesh, 1998 - Articles 7(6), 7(7), 8, 13(9(vi))	National Biodiversity Authority	To all those who seek access for commercial purposes	1. Not less than 50 % of net monetary gain Arts 7(5) , 16(6) 2. Compensation for ecological or environmental costs incurred (Art 7(6))	1. Technology transfers 2. Knowledge transfer (Arts 13(9(vi)) 3. Royalty free access to technology for domestic institutions in case of endemic species access (Art 13(27)	1. Recognizes collective/ community IP rights (Art 7 (7)) 2. Co-ownership rights over biological resources, knowledge and innovation defined between communities, with State and with communities from other countries (Art 8)	Varies from written warnings, fines, revocation of permits, confiscation to perpetual ban, with widespread publicity given in international foras.
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 (Part IV, 20)) of the Environmental Management and Co-ordination Act (1999)	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	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

Appendix continued

Appendix continued

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 (Art 63(3))	1. 10% of research budget to National System of Conservation Areas 2. 50% of bonus to NSCA 3. Administrative costs (Art 76)	1. Technology transfer (Art 76)	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
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	1. Inclusion of local counterparts and institutions or individuals in research activities 2. Co-authorship 3. Periodical reports and final reports on activitiy		Offenders to pay a fine between 300,000 to 750,000 dollars and face imprisonment for one year
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 (Art 9) 2. License fee 3. Upfront payment 4. Milestone payment 5. Royalty 6. Research funding	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 (Art 10) in customary practices and norms	Suspension or termination of Access agreement and prohibit access to GR and associated knowledge
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	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.
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	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.