

Benefit Sharing: Reframing India's Policy

Anitha Ramanna-Pathak



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Abstract

Benefit sharing is part of the larger concept of Access and Benefit Sharing (ABS) nested within such international agreements as the Convention on Biological Diversity (CBD), the 2010 Nagoya Protocol (NP) and the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Benefit sharing establishes legal mechanisms to ensure that those who access genetic resources do so only with prior permission and on mutually agreed terms. India has been a frontrunner in the move for effective benefit-sharing agreements at the international level, and was also among the first countries to frame legislation on benefit sharing. However, domestic implementation has remained weak: few benefit-sharing arrangements with local communities have been concluded, and although the focus has been on revenue generation, very little actual revenue has accrued as a result of these agreements. The distribution of real benefits to communities under benefit sharing in India remains unclear, as do the developmental effects on local communities. This study examines India's policy on benefit sharing, seeking to explain the difficulties in implementation. At the domestic level, the lack of a clearly defined objective has been a major reason for weak implementation. At the international level, the existence of a regime complex has affected decision-making and policy strategies. Poor implementation of benefit sharing in India emerges as the result of domestic factors combined with international regime complexity.

Key Words

access, benefit sharing, Convention on Biological Diversity, genetic resources, implementation, India, International Treaty on Plant Genetic Resources for Food and Agriculture, regime complex

About the Author

Dr. Anitha Ramanna-Pathak is Assistant Professor and Manager, Quality Assurance, S P Jain School of Global Management. This study is part of the project “International Objectives for Adaptation, Access and Benefit-Sharing: Effects on the Management of Plant Genetic Resources in India and Nepal” (Project number 217258/H30) conducted by FNI in collaboration with Indian experts and South Asian Watch on Trade, Economics and Environment (SAWTEE). The project was funded by Globmek under the Norglobal program of the Research Council of Norway. The author would like to thank Kristin Rosendal and Tone Winge, for their insightful comments and immense support. The other members of the project also provided valuable guidance at various stages of the project. Thanks to SAWTEE and the FNI team for their assistance and to Susan for her editorial assistance. Any errors remain solely those of the author.

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Acronyms

| | |
|---------|--|
| ABS | Access and Benefit Sharing |
| AICRPE | All India Coordinated Research Project on Ethnobiology |
| AVP | Arya Vaidya Pharmacy |
| BMCs | Biodiversity Management Committees |
| CBD | Convention on Biological Diversity |
| COP | Conference of Parties |
| CSIR | Council for Scientific and Industrial Research |
| FAO | Food and Agriculture Organization of the United Nations |
| GMP | Good Manufacturing Process |
| INR | Indian Rupees |
| IPRs | Intellectual Property Rights |
| ITPGRFA | International Treaty on Plant Genetic Resources for Food and Agriculture |
| KIRTADS | Kerala Institute for Research, Training and Development of Scheduled Castes and Scheduled Tribes |
| MAT | Mutually Agreed Terms |
| MLS | Multilateral System (of the ITPGRFA) |
| MOEF | Ministry of Environment and Forests |
| MPSBB | Madhya Pradesh State Biodiversity Board |
| NGT | National Green Tribunal |
| NBA | National Biodiversity Authority/National Biodiversity Act |
| NP | Nagoya Protocol |
| NRIs | Non-Resident Indians |
| PIC | Prior Informed Consent |
| RRL | Regional Research Laboratory |
| SBB | State Biodiversity Board |
| SC/ST | Scheduled Caste/Scheduled Tribe |
| TBGRI | Tropical Botanic and Research Institute |
| TK | Traditional Knowledge |
| TRIPs | Agreement on Trade-Related Intellectual Property Rights |
| WTO | World Trade Organization |

1 Introduction

Benefit sharing establishes legal mechanisms to ensure that those who access genetic resources do so only with prior permission and on mutually agreed terms. Benefit sharing is part of the larger concept of Access and Benefit Sharing (ABS) nested within various international agreements such as the CBD, the 2010 Nagoya Protocol (NP) and the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and is closely linked to debates within the UN Food and Agriculture Organization (FAO) and the 1995 TRIPs (Agreement on Trade-Related Intellectual Property Rights) of the World Trade Organization (WTO). The two concepts of the CBD that link the legal ABS to the national level and the provider country are Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Prior informed consent (PIC) refers to permission given by the competent national authority of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework (Union for Ethical BioTrade, 2010). Mutually agreed terms (MAT) refer to agreements reached between the providers of genetic resources and users on the conditions of access and use of the resources, and the benefits to be shared between both parties (Union for Ethical BioTrade, 2010).

India has been seen as one of the leaders of the developing world in promoting benefit sharing at the international level. India played a key role in ensuring that benefit sharing was enshrined in the 1992 Convention on Biological Diversity (CBD) (see McConnell, 1996), and was also among the first countries to enact legislation on benefit sharing and farmers' rights. However, India's active role globally and its proactive stance in framing legislation have not resulted in effective implementation of benefit sharing domestically. While India has been able to fulfil the international legal obligations required under the global regime, it has not managed to ensure tangible domestic distribution. Although one of the first countries in the world to establish laws on benefit sharing and farmers' rights, it has not been able to set up an efficient operative system for ensuring sharing of benefits with local communities. The National Biodiversity Authority (NBA), the regulatory agency established to implement ABS in India, notes that it had signed over a hundred ABS agreements as of 2012 (NBA, 2002). However, very few cases of benefit sharing have been concluded that have resulted in tangible benefits for communities in India. The focus has been on revenue generation, but very little actual revenue has accrued to domestic stakeholders. The distribution of real benefits to communities remains unclear, as does the effects on local community development. It is also uncertain whether the system actually serves to promote conservation, a major aim of the ABS. There are clear discrepancies between the aim of the policy and practice on the ground.

This study examines India's policy on benefit sharing in order to explain the difficulties in implementation. An interplay of domestic and international factors has affected the shape of the benefit sharing frame-

work in India. At the domestic level, the lack of a clearly defined objective has been a major reason for weak implementation. At the international level, we examine how the existence of a regime complex has affected decision-making and policy strategies, noting how regime complexity has shaped actor interests and enabled powerful groups to promote their views. We find that fragile implementation of benefit sharing in India is the result of domestic factors combined with international regime complexity.

A “regime complex” refers to various partially overlapping institutions governing a specific area (Raustiala and Victor, 2004). It is characterized by the existence of several agreements where rules may overlap, but with no hierarchy to resolve conflicts between the rules (Raustiala and Victor, 2004) The study of regime complexes has focused on explaining the origins and characteristics of regime complexity in international relations and global environmental governance, but less attention has been paid to the impact of the regime complexes on national policy implementation. Focusing on benefit sharing in India, this report explores how the existence of a regime complex affects the nature of policy framing and outcomes in the national realm. How does a regime complex impact decision-making and policy strategies? How does it shape actors’ interests and/or enable powerful groups to promote their views?

The lack of effective mechanisms for benefit sharing in India cannot be fully explained in terms of regime complexity alone. Account must also be taken of domestic factors that may be linked to regime complexity but can have emerged for other reasons. The lack of a clearly defined objective for benefit sharing, a focus on regulating access rather than on benefit sharing as such, stakeholder interests, and administrative difficulties have all been pointed out as factors hampering the implementation of benefit sharing in India. Explanations for these domestic factors should also be sought within the political economy of India’s framework for benefit sharing.

2 International Agreements Relating to Benefit Sharing

The international regime relating to benefit sharing rests mainly within the 1992 CBD, the 2010 NP, and the 2001 ITPGRFA. It is also closely linked to debates within FAO and TRIPs. Here we outline the main provisions relating to benefit sharing within these three agreements.

2.1 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) is the starting point for understanding the global regime on ABS (UNCTAD, 2014). The CBD, which entered into force in 1993, has three main objectives: 1) the conservation of biological diversity 2) the sustainable use of the components of biological diversity 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (UNCTAD, 2014). The major provisions in the CBD focusing on benefit sharing can be found in Article 15 and Article 8 (j).

Article 15 states: “Each Contracting Party shall take legislative, administrative or policy measures... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.”

Article 8(j) of the CBD promotes the sharing of benefits arising out of the utilization of such traditional knowledge but leaves any measures to achieve this objective to the domestic policies of the CBD members: “Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”

Two main concepts are meant to guide ABS: Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). PIC concerns explicit permission from the authorities of the provider country before access or use of plant material may take place (Union for Ethical BioTrade, 2010). In practice, PIC is an administrative process established by national legislation on ABS; actors seeking access to biodiversity generally submit an application to the competent authorities in the provider country, which may then grant a permit, license or accord for such access to take place (Union for Ethical BioTrade, 2010). MAT is the “ABS agreement”—the arrangement reached on the terms and conditions of access and use of genetic resources between the users seeking plant material for research and development, and the country providing the material (Union for Ethical BioTrade, 2010). These contractual agreements are subject to specific procedural and substantive principles. In addition to the parties to the contract, for example, the involvement of other stakeholders—local communities, civil society organizations and authorities—may be relevant (Union for Ethical BioTrade, 2010).

With regard to benefit sharing, the CBD essentially establishes that national governments are to frame laws and policies to ensure that benefits are shared equitably. The guidelines provided for such policies are prior informed consent (PIC) and Mutually Agreed Terms (MAT). Through the CBD, states can regulate access to their resources and negotiate the conditions for benefit sharing. ABS serves as a compensation mechanism between the providers and the users of plant genetic resources. With new developments in biotechnology and stricter intellectual property regulations, genetic resources became increasingly valuable, but the benefits went largely to the developed countries (Jonge, 2013). The ABS framework of the CBD addresses this imbalance by requiring a part of the benefits that users derive from genetic resources to flow back to the original providers, offering a win-win situation between the “North” and the “South”— and, ideally, these measures would promote the conservation and sustainable use of biodiversity (Jonge, 2013).

2.2 Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol, NP) was adopted in 2010 as a supplementary agreement to the CBD. It emerged as the result of the call for an international regime to promote equitable benefit sharing. Implementation of ABS provisions under the CBD was slow, particularly with regard to user measures and support for user compliance with ABS legislation in provider countries and negotiated MAT conditions (UNCTAD, 2014). Many of the provisions of the Nagoya Protocol draw on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, a set of voluntary non-binding guidelines on access and benefit sharing endorsed by the CBD Conference of the Parties (COP) at its Sixth Session in 2002 (UNCTAD, 2014).

The Nagoya Protocol sets out the rules and mechanisms for access to genetic resources and associated traditional knowledge (TK), and supports the fair and equitable sharing of benefits arising from their utilization. Along with the basic provisions of the CBD on ABS, it forms the central body of law that defines how the ABS system operates. The Nagoya Protocol rephrases and makes more concrete the objectives of the CBD (IEEP, Ecologic and GHK, 2012). Article 1 clarifies that such benefit sharing includes appropriate access to genetic resources, appropriate transfer of relevant technologies, and appropriate funding. Accordingly, benefit sharing entails more than sharing a certain percentage of the profits when a product is developed on the basis of a genetic resource (Griber et al., 2012). The Nagoya Protocol specifies that benefit sharing arrangements shall be established through MAT between the provider and user of genetic resources, thus on a contract basis.

Each party is obliged to take legislative, administrative, and/or policy measures to ensure that the benefits arising from the utilization of genetic resources as well as any subsequent application and commercialization are shared fairly and equitably with the providing party (Kamau et al., 2010). Benefits listed under the Protocol include monetary as well as non-monetary benefits; the Protocol prescribes collaboration and cooperation in technical and scientific research and development (R&D) programmes, preferably with the participation of provider parties (Kamau et al, 2010). Key areas identified by the Protocol that require capacity-building include implementation of the Protocol, negotiation of MAT development and enforcement of domestic legislation, and endogenous research capabilities (Kamau et al., 2010).

Article 5(5) addresses benefit sharing in relation to TK associated with genetic resources. Parties are required to take appropriate measures to ensure that the benefits arising from the utilization of such TK are shared fairly and equitably with the local communities holding the knowledge, and such benefit sharing shall be upon MAT (Griber et al., 2012).

The Nagoya Protocol also foresees two mechanisms for handling ABS in relation to special branches of genetic resources: 1) sectoral and cross-sectoral model contracts that can serve special purposes; 2) a possible Global Multilateral Benefit-sharing Mechanism (Tvedt, 2014). As Tvedt explains, "Among other aims, the mechanism could essentially act as a 'catch' in instances where it is unclear who should benefit, or indeed if the genetic resource in question has multiple beneficiaries, as would be the case with transboundary genetic resources" (Tvedt, 2014).

2.3 ITPGRFA

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA; here: the Treaty), entered into force in 2004. The Treaty focuses on conservation and sustainable use of plant genetic resources for food and agriculture. It establishes a multilateral system of access and benefit sharing for plant genetic resources, whereby contracting parties agree to virtually pool a subset of the genetic resources of 64 crops and forages to be used for "utilization and conservation for research, breeding and training for food and agriculture" (Article 12.3(a)) (see also Jonge, 2013). Benefit sharing under the Treaty is based on a multilateral system where "facilitated access" is itself viewed as a major benefit (Moore and Tymowski, 2005). The benefits from use of plant genetic resources are to be shared fairly through methods such as exchange of information, access to technology, capacity building, sharing of monetary and other benefits of commercialization (Moore and Tymowski, 2005). The Treaty establishes a multilateral system (MLS) where parties who benefit monetarily from materials from the MLS are to make a payment to a joint fund which can be shared so that all parties benefit; further, a Material Transfer Agreement (MTA) has been proposed in the Treaty, which should contain the benefit-sharing requirement (Moore and Tymowski, 2005).

3 Institutional and Legal Framework for Implementing ABS in India¹

The National Biodiversity Act of 2002 and the Biodiversity Rules of 2004 comprise the main legal framework for implementing ABS in India. Both have been established to conform to the Convention on Biological Diversity. Additionally, the 2014 Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations have been framed in order to further clarify ABS based on the Nagoya Protocol. Benefit sharing is also found in India's Protection of Plant Varieties and Farmers' Rights Act, 2001, where the aim is to ensure implementation of farmers' rights in harmony with the International Treaty on Plant Genetic Resources for Food and Agriculture. The Patent Amendment Act (2002) also contains provisions relevant for implementing ABS in India. Here we outline the main policies concerning access and benefit sharing in India under these acts.

¹ Information in this section is drawn mainly from <http://www.nabaindia.org>.

3.1 Regulatory Framework for Accessing Biological Resources in India

3.1.1 Three-Tier Structure

The National Biodiversity Act 2002 establishes a three-tier system for regulating access to biological resources in India, with governing bodies at the national, state and local levels. This is in accordance with India's federal structure, with the national (central) government, state governments, and the local-level units known as *panchayats*. The National Biodiversity Authority (NBA) is the national level body established under the Ministry of Environment and Forests (MOEF) to implement the Act, with the State Biodiversity Board (SBB) and Biodiversity Management Committees (BMCs) set up at the state and local levels.

The NBA is the main body for granting approval for access to biological resources, for intellectual property rights (IPRs) based on biological resources, and for transferring the results of research based on biological resources. It has the power to oppose, in any country, IPRs that are based on biological resources obtained in India. It has been given the responsibility to ensure equitable sharing of benefits with regard to access of biological resources, as well as advising on matters related to biodiversity conservation, sustainable use and benefit sharing.

The State Biodiversity Boards are to regulate by granting approvals for commercial utilization, bio-survey and bio-utilization of any biological resource by Indian citizens; and to advise the state government on conservation of biodiversity, sustainable use and sharing of benefits.² The Biodiversity Management Committees are to prepare People's Biodiversity Registers in consultation with the local population and to advise on any matters referred to it by the Authority or the State Biodiversity Board. The National Biodiversity Authority and the State Biodiversity Boards are expected to consult the Biodiversity Management Committees regarding the use of biological resources occurring within the territory of the Biodiversity Management Committees. Each of these is to be interconnected for decision-making on various issues, including access and benefit sharing (ABS).³ According to the NBA, 29 states have established State Biodiversity Boards.⁴

² <http://nbaindia.org/text/13/StateBiodiversityBoards.html>

³ <http://nbaindia.org/content/19/16/1/faq.html>

⁴ <http://nbaindia.org/text/13/StateBiodiversityBoards.html>

Table 1: Three-Tier Structure

| | |
|----------|--|
| National | <p>National Biodiversity Authority</p> <p>Established to deal with all matters relating to implementation of the Act and the Rules at national level.</p> |
| State | <p>State Biodiversity Board</p> <p>Established to deal with all matters relating to implementation of the Act and the Rules at State level.</p> |
| Local | <p>Biodiversity Management Committees</p> <p>Established by institutions of local self-government for implementation of specific provisions of the Act and Rules.</p> |

As of September 2015, there were over 30,000 Biodiversity Management Committees. Table 2 lists the number of Biodiversity Management Committees as of September 2015.

Table 2: Biodiversity Management Committees

| Biodiversity Management Committees | | |
|------------------------------------|-------------------|--------|
| 1. | Andhra Pradesh | 928 |
| 2. | Arunachal Pradesh | 43 |
| 3. | Assam | 171 |
| 4. | Bihar | -- |
| 5. | Chhattisgarh | 27 |
| 6. | Goa | 54 |
| 7. | Gujarat | 3405 |
| 8. | Himachal Pradesh | 155 |
| 9. | Haryana | -- |
| 10. | Jammu & Kashmir | -- |
| 11. | Jharkhand | 66 |
| 12. | Karnataka | 4,636 |
| 13. | Kerala | 1043 |
| 14. | Madhya Pradesh | 23,743 |

| | | |
|-----|---------------|---------------|
| 15. | Maharashtra | 890 |
| 16. | Manipur | 52 |
| 17. | Meghalaya | 94 |
| 18. | Mizoram | 221 |
| 19. | Nagaland | 10 |
| 20. | Odisha | 230 |
| 21. | Punjab | 55 |
| 22. | Rajasthan | 31 |
| 23. | Sikkim | 13 |
| 24. | Tamil Nadu | 16 |
| 25. | Telangana | 710 |
| 26. | Tripura | 217 |
| 27. | Uttarkhand | 751 |
| 28. | Uttar Pradesh | 32 |
| 29. | West Bengal | 176 |
| | Total | 37,769 |

Source: <http://nbaindia.org/content/20/35//bmc.html>

3.1.2 Distinction between foreigners and Indians under the Act

The Act makes a clear distinction between Indians and foreign nationals regarding the application procedure, and this distinction is followed by the National Biodiversity Authority (NBA) and the State Biodiversity Boards. While foreigners require the prior approval of the NBA to access biological resources, Indian citizens need only to inform the relevant State Biodiversity Board. In other words, access to biological resources and TK for foreign citizens or companies and non-resident Indians (NRIs) requires prior approval of the NBA. Indian citizens, companies and associations are required to inform the State Biodiversity Board concerned for access to resources; NBA approval is not required for accessing biological resources but its approval *is* required for transferring the results of research to foreigners and applying for IPRs based on biological resources obtained from India. There are exemptions from the approval process for presenting papers in conferences and collaborative research projects. With regard to IPRs, those applying for protection under the Plant Variety Act in India are exempt from this provision.⁵ There is also an exemption for local people and communities: permission

⁵ <http://www.nbaindia.org>

is not required, nor it is necessary to inform the SBB in order to access biological resources.

3.1.3 Application Process

The application process established under the Act consists of four different types of activities that require approval: 1) access to biological resources for research or commercial utilization 2) transfer of results of research 3) approval for obtaining IPRs 4) third-party transfer. A different form is outlined for each of these activities. A main function of the NBA is to scrutinize these applications and decide on whether to grant or deny approvals. In the process, the NBA is also supposed to ensure that fair and equitable sharing of benefits occurs. In this section, we elaborate on the application process, and benefit sharing is covered in section II.

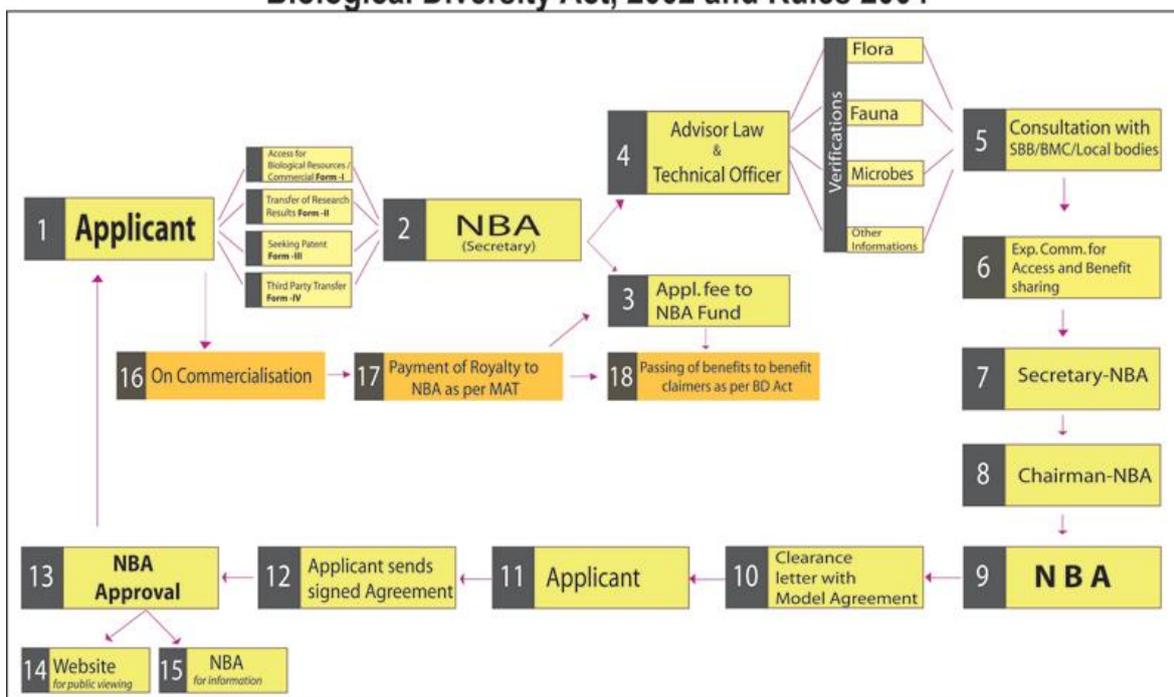
Table 3 outlines the various application forms under the NBA.

Table 3: Application Forms under NBA

| | |
|--|---|
| Form 1— Access to Bioresources for Research/Commercial Purpose | |
| Form 2— Transfer of Research Results | Any party wishing to transfer the results of research relating to biological resources obtained in India to foreign nationals, companies and Non-resident Indians must apply to the NBA for approval. |
| Form 3— Approval for Obtaining IPRs | Any party applying for a patent or any other intellectual property right based on research on biological material obtained from India shall make an application with this form |
| Form 4— Third-Party Transfer | Any party who has been granted access for biological resources and wishes to transfer it to another person or organization. |

Table 4: Application process

Schematic Presentation of Processing of Applications under Biological Diversity Act, 2002 and Rules 2004



* For details please go through Biological Diversity Act, 2002 & Rules, 2004

Source: <http://nbaindia.org/content/684/62/1/applicationprocess.html>

As of October 2015, a total of 1100 applications had been received, approval had been granted for 203 applications, and 277 were under process.⁶

4 Benefit-Sharing Structure

Various laws in India deal with benefit sharing focusing on: non-monetary benefit sharing, monetary benefit sharing, and benefit sharing through a National Biodiversity Fund. While certain aspects are found in all these laws, the type of benefit sharing and the calculation of the amount of benefit sharing are elaborated in different ways, reflecting how the issue has been framed and shaped within the Indian policymaking system.

4.1 Legislation and Benefit Sharing

The modalities for benefit sharing in India have been outlined in various policies, including the National Biodiversity Act (2002), the Biological Diversity Rules (2004), and the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations

⁶ <http://nbaindia.org/content/333/25/1/applicationstatus.html>

(2014). The Protection of Plant Varieties and Farmers' Right Act was established to conform with TRIPs as regards the provision of plant breeders' rights. It also sets out 'Farmers' Rights' in accordance with the International Treaty on Plant Genetic Resources for Food and Agriculture. Various aspects of the Protection of Plant Varieties and Farmers' Rights Act are relevant for ABS. The Act also contains provisions for benefit sharing. India's Patent Act has also been revised in order to encompass certain aspects of benefit sharing.

4.1.1 National Biodiversity Act

The National Biodiversity Act vests the National Biodiversity Authority (NBA) with responsibility for ensuring benefit sharing and for determining what is to be understood as "fair and equitable benefit sharing". Benefit sharing is linked with the various types of applications listed in section 3.1.3 (Application Process) above. In considering the applications, the NBA must ensure "equitable sharing of benefits...in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers" (National Biodiversity Act, 2002). Benefit claimers are defined in the Act as "the conservers of biological resources their byproducts, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application." With applications concerning IPR, the NBA can "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." (National Biodiversity Act, 2002)

4.1.2 Biological Diversity Rules⁷

The Biological Diversity Rules framed in 2004 provide further elaboration on the Act. Regarding benefit sharing the Rules state that guidelines will be framed to describe the amount of benefit sharing to be levied, with the specific formula to be determined on a case-by-case basis. The Rules state that the Authority may impose terms and conditions for ensuring equitable sharing of benefits, and that the amount of benefit sharing is to be mutually agreed upon by the applicant and the Authority in consultation with local bodies and benefit claimers. This shall be done with due regard to the defined parameters of access, the extent of use, sustainability, impact and expected outcome levels, including measures to ensure the conservation and sustainable use of biological diversity. Depending on the case the Authority can also decide whether the benefit sharing is to be short-, medium- or long-term. Consideration is to be given to the conservation and sustainable use of biodiversity. If biological resources are accessed from a specific individual or group, the amount can be paid directly to them through the district administration. If the individual or group cannot be identified, the monetary benefits shall be deposited in the National Biodiversity Fund.

⁷ <http://nbaindia.org/uploaded/Biodiversityindia/Legal/33.%20Biological%20Diversity%20Rules,%202004.pdf>

4.1.3 *Guidelines on Access to Biological Resources and Associated Knowledge and Benefit-Sharing Regulations*⁸

While the Act and the accompanying Rules set out the general framework for benefit sharing, the actual modalities were left to be spelled out in the Guidelines that were framed in 2014. The Guidelines are based on the Nagoya Protocol, and focus on the financial obligations of users and how benefits are to be shared. Essentially, the Guidelines indicate the percentage of benefit sharing according to the following in relation to the type of application outlined in the Act (see section 3.1.3 Application Process): 1) commercial utilization, 2) transfer of results of research, 3) commercialization of IPR, 4) transfer to third party for research/commercial utilization. The determination of benefit sharing shall be based on such considerations as the commercial utilization of the biological resource, stages of research and development, potential market for the outcome of research, R&D investments already made, nature of technology applied, timelines and milestones from initiation of research to development of the product, and any risks involved in commercialization of the product. The amount of benefit sharing is to remain the same whether the end product contains one or more biological resources.

4.1.4 *Protection of Plant Varieties and Farmers' Rights Act 2001*⁹

The Protection of Plant Varieties and Farmers' Right Act was established to conform with TRIPs in providing plant breeders' rights; it also set out 'Farmers' Rights' in accordance with the International Treaty on Plant Genetic Resources for Food and Agriculture. Various aspects and provisions of the Act are relevant for ABS. After registering a variety, the Authority shall invite claims for benefit sharing. Any person or group of persons, firm, governmental or non-governmental organization may submit claims for benefit sharing provided that the persons are citizens of India and the firms have been formed or established in India. The breeder may oppose the claim for benefit sharing. The Authority will hear both sides and then decide whether any benefit sharing is to be imposed, taking into account the nature of genetic material used in the development of the variety, and the commercial utility and market demand for the variety. The amount of benefit sharing as determined by the Authority is to be placed in the National Gene Fund. This amount shall, on reference by the Authority, be recoverable as an arrear of land revenues within the local jurisdiction where the breeder resides. The National Gene Fund established under the Act is set up to collect the funds owed to the original holders of the genetic resources being accessed.

In practice, benefit sharing under the Plant Varieties and Farmers' Right Act has taken place only in the form of recognition of farmers through the National Genome Saviour Community Award instituted in 2009/2010. There have been very few registrations of Farmers' Varieties (6 out of total 487 as of September 2012).

⁸ http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines.pdf

⁹ <http://lawmin.nic.in/ld/P->

ACT/2001/The%20Protection%20of%20Plant%20Varieties%20and%20Farmers%E2%80%99%20Rights%20Act,%202001.pdf

4.1.5 Patent Act¹⁰

India's Patent Act, revised in 2002, makes disclosure on patent applications a mandatory requirement: the applicant must "disclose the source and geographical origin of the biological material in the specification, when used in an invention". This is an attempt to keep a check on patent applications that are based on Indian biological resources. However, it is not clear how effective this is in practice. The fact that India has not been able to ensure international adoption of this mechanism has weakened it considerably.

4.2 Non-monetary benefit sharing

India's laws prescribe various forms of non-monetary benefit sharing, elaborated differently in the National Biodiversity Act, in the Rules and in the recently issued guidelines. However, to date the non-monetary aspects have received very little attention. The National Biodiversity Act (2002) outlines the following forms of non-monetary benefit sharing:

- (a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;
- (b) transfer of technology;
- (c) location of production and R&D units in areas which will facilitate better living standards to the benefit claimers;
- (d) association of Indian scientists, benefit claimers and the local people with R&D in biological resources and bio-survey and bio-utilization;
- (e) setting up of venture capital fund to aid the cause of benefit claimers;
- (f) payment of monetary compensation and non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

The Biodiversity Rules (2004) specify that the guidelines should be issued for monetary and non-monetary benefit sharing such as royalty, joint ventures, technology transfer, product development, education and awareness-raising activities, institutional capacity building and venture capital funds.

The Guidelines (2014) outline various forms of non-monetary benefit-sharing options:

1. providing institutional capacity building, including training on sustainable use practices;
2. transfer of technology or sharing of R&D results within Indian institutions/individuals/entities;

¹⁰ http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf

3. strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative R&D programs with Indian institutions/individuals/entities;
4. contribution/collaboration related to education and training in India on conservation and sustainable use of biological resources;
5. location of production and R&D units, and measures for conservation and protection of species in the area from where biological resource has been accessed, contributions to the local economy and income generation for local communities;
6. sharing of scientific information relevant to the conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies.

While many of these mechanisms could be very useful for designing benefit sharing mechanisms, they unfortunately remain only as policy prescriptions. The focus has been on the monetary aspects, to which we now turn.

4.3 Monetary Benefit Sharing

Monetary benefit sharing is mentioned in the Act as well as the Rules, but it is the Guidelines that set out the formula for calculating benefit sharing, divided into various categories based on the type of application as stated in the Act. Under each of these categories, the applicant must first apply to the NBA (the Authority) and obtain permission for accessing biological resources.

4.3.1 Access to biological resources for research

The Guidelines state that persons wishing access to a biological resource for research are to apply to the Authority. If satisfied with the application, it will then enter into a benefit sharing agreement with the applicant, as such constituting approval. In the case of biological resources of high economic value, an upfront payment may be required, the amount to be decided between the applicant and the Authority.

4.3.2 Access to biological resources for commercial utilization

The applicant should apply to the Authority (NBA) or the State Biodiversity Board (SBB) for access to biological resources for commercial utilization. The Guidelines differentiate between persons who enter into negotiations on benefit sharing with local bodies or persons prior to access, and those who have not conducted any such negotiations, also between a trader and a manufacturer. In cases of biological resources with high economic value such as sandalwood, red sanders (saunderwood), etc. and their derivatives, the benefit sharing may include an upfront payment of not less than 5.0% on proceeds of auction or sale amount, as decided by the NBA or the SSB.

The Guidelines outline the following, depending on whether the applicant has entered into a benefit-sharing agreement prior to access, and give two options:

Option 1 for access to biological resources for commercial utilization

| | | |
|--------------|--|---|
| | Applicant has not entered into benefit-sharing agreement prior to access | Has concluded benefit-sharing agreement prior to access |
| Trader | 1.0–3.0% of purchase price of biological resource | Not less than 3% of purchase prices |
| Manufacturer | 3–5% of the purchase price of the biological resource | Not less than 5% of purchase price |

Option 2 for access to resources for commercial utilization

Applicant may pay benefit sharing ranging from 0.1% to 0.5%, at the following percentages of annual gross ex-factory sale of the product minus taxes:

| Annual gross ex-factory sale of the product | benefit-sharing component |
|--|----------------------------------|
| Up to INR 1,00,00,000 | 0.1% |
| INR 1,00,00,001 to 3,00,00,000 | 0.2% |
| Above INR 3,00,00,000 | 0.5% |

4.3.3 Transfer of results of research

The applicant must pay to the Authority monetary and or non-monetary benefits as agreed by the Authority and the applicant. If the applicant has received any monetary benefit, then the applicant shall to pay to the Authority 3.0% to 5.0% of the monetary consideration.

4.3.4 Obtaining Intellectual Property Rights (IPRs)

In cases that involve commercialization of IPRs obtained on inventions related to genetic resources, the applicant shall pay to the NBA monetary and or non-monetary benefit as agreed upon between the applicant and the NBA, as follows: 1) Where the applicant themselves commercialize the process/product/innovation, the benefit sharing should be in the range

of 0.2 to 1.0% based on sectoral approach, calculated in term of annual gross ex-factory sale minus taxes. 2) Where applicants license the process/product/innovation to a third party for commercialization, they shall pay to the NBA 3.0%–5.0% of the fee received, and 2.0%–5.0% of the royalty amount received annually from the assignee based on sectoral approach.

4.3.5 Transfer of research results to another party

The applicant must pay monetary or non-monetary benefit as agreed between the NBA and the applicant. In the case of monetary benefit, the applicant is to pay 2.0%–5.0% of any amount or royalty received from the transferee throughout the term of the agreement. In case the biological resource has high economic value, an upfront payment may also be mutually agreed upon.

The calculation of monetary benefit sharing requires meticulous attention to detail as prescribed by the guidelines. It is not stated as a simple percentage of sales but is dependent on the type of access, the purpose of access as well as the importance of the resource. However, whether this can become an effective mechanism for ensuring collection of benefits remains to be seen.

4.4 Biodiversity Fund

The benefit sharing framework in India involves not only bilateral methods of payment, but also outlines mechanisms for payment through a Fund. According to the National Biodiversity Act, the Authority may direct the benefit-sharing fee to be deposited in a National Biodiversity Fund. However, if the biological resource is accessed from a specific individual or group, the fee should be paid directly to that individual or group. The Biodiversity Rules also reiterate this. The Act states that the National Biodiversity Authority shall frame guidelines for this, in consultation with the Central Government. The Fund should be used for channeling benefits to benefit claimants, the conservation and promotion of biological resources, and socio-economic development in consultation with local bodies. The Act also envisages the establishment of a State Biodiversity Fund, to focus on management and conservation of heritage sites, conservation of biological resource, and socio-economic development. In addition, Local Biodiversity Funds may be constituted at the local level, for conservation of biodiversity and the benefit of the community. Although the concept of a Fund relates to the International Treaty, in India's framework it is more a mechanism for distributing benefits when a specific owner of the resource cannot be identified. As yet, the Fund has received inadequate attention as a useful tool for benefit sharing in India.

5 Benefit Sharing in Practice

5.1 National Level

Actual practice with regard to benefit sharing in India demonstrates how differently laws actually operate on the ground. Here we focus on cases at the national level. These cases reveal a clear tilt towards monetary benefit sharing, as well as showing how difficult it is to ensure that fair and equitable sharing of benefits takes place with local communities.

Our first case concerns the Kani people. Although it occurred prior to the conclusion of the Biodiversity Act, it is historically important, for it shaped the nature of the benefit sharing in India. The other cases presented have all taken place under the Biodiversity Act.

5.1.1 *Kani Case*¹¹

The benefit-sharing case relating to the Kani tribals is important not only because it was the first well publicized instance of benefit sharing in India, but also because it set a precedent how benefit sharing can take shape. Although the Kani case is an entirely domestic one in terms of access and benefit sharing, it has implications for how benefit sharing has evolved in India. It also revealed the problems that can arise and the difficulties involved in ensuring the participation of local communities.

The Kani tribals (pop. approx. 18,000) live in the forests of the southern Indian state of Kerala (Gupta, 2002). They are extremely impoverished and base their livelihood on handicrafts, and gathering and selling various permitted forest produce. The Kani benefit-sharing case dates back to 1987, when a team of scientists from the All India Coordinated Research Project on Ethnobiology (AICRPE) led by Dr. Pushpangadan arrived on a botanical expedition. The Kani tribals accompanied the scientists as guides. When the scientists noticed that the Kanis ate some fruits to keep their stamina up, they became curious.

When the exhausted scientists were offered these, they also felt a “sudden flush of energy and strength.”¹² When asked about the source of the fruit, however, the *Kani* tribals were reluctant to reveal the same, saying that it was sacred information and a tribal secret, and not to be revealed to outsiders; only after much urging did they show the plant from which the fruit (which they called *Arogyappacha*) was obtained (Anuradha 1998). The scientists then collected some specimens of the plant to conduct scientific studies in their laboratories at Jammu. The fruit of the plant showed anti-fatigue properties that the Kanis had identified; and study of the leaves revealed the presence of certain glycolipids and non-steroidal compounds with anti-stress, anti-hepatotoxic and immunodulatory/-immunorestorative properties (Anuradha 1998).

¹¹ This section summarizes from: Gupta (2002), Chaturvedi (2007), Anuradh (1998).

¹² Quoted in R V Anuradha (1998)

Further research on the plant was then conducted at the Tropical Botanic and Research Institute (TBGRI), Kerala. Scientists from various fields as well as some Kanis were included in the research conducted. This project ultimately led to the development of a drug which they called “Jeevani,” using the leaves of the plant as well as three other medicinal plants. It was ready for marketing in 1994. In November 1996 TBGRI transferred the technology to Arya Vaidya Pharmacy (Coimbatore) Ltd for a period of seven years for a license fee of Rs. ten lakhs (approximately \$25,000) (Anuradha 1998). Arya Vaidya Pharmacy is an Indian pharmaceutical manufacturer that has commercialized ayurvedic herbal formulations since 1948 (Anuradha 1998). It was agreed that TBGRI would receive two percent royalty on future drug sales. In November 1997, with the assistance of TBGRI, the Kanis formed the *Kerala Kani Samudaya Kshema Trust*, registered with nine members, all tribals (Anuradha 1998). The President and Vice-President of the Trust are the two Kanis who imparted knowledge to TBGRI regarding Aarogyappacha (Anuradha 1998). After transfer of the technology for manufacturing *Jeevani* to the AVP, in 1996, the TBGRI earned US\$50,000. Fifty per cent of the license fee as well as fifty per cent of royalties from sale were to go to the Kani tribals, through the Trust: altogether Rs. 519,062 (Chaturvedi 2007). After the transfer of money to the Trust, no Trust meetings were held until 1999, when it was decided that the three Kanis who had passed on the information to the scientists would be rewarded with cash (Chaturvedi 2007).

The Kani case reveals the complexity of negotiating benefit-sharing agreements. Throughout the process, there were criticisms from various stakeholders about how the agreement had emerged. Firstly, opposition political parties in the State of Kerala strongly protested the choice of the company AVP, maintaining that a public-sector and not a private-sector company should be selected. There were also views expressed within the Legislative Assembly in Kerala that, given the economic potential of *Jeevani*, the license fees were very low and should have been set much higher (Anuradha 1998). The TBGRI then investigated the option of transfer to a public-sector body but found none that had the Good Manufacturing Process (GMP) facility as advised by the WHO, and therefore decided on AVP, which had adopted the GMP standard (Chaturvedi 2007). The TBGRI also pointed out that the agreement was for seven years, after which a higher amount could be negotiated and other companies could be selected. Secondly, a research institute in Kerala, KIRTADS (Kerala Institute for Research, Training and Development of Scheduled Castes and Scheduled Tribes), held that the Kanis had got an unfair deal and should have been more actively involved in the process (Anuradha 1998). KIRTADS feels that the Kanis should be encouraged to interact directly with wider society, and administer their medical knowledge on their own terms; further, that the only way tribal medicine can survive is by preserving its original form and premises—otherwise it is liable to be misused as a convenient resource base for other systems of medicine. KIRTADS particularly criticized the TBGRI for not involving Kanis directly in the negotiating process. In the beginning of the negotiations, the Kanis only participated in an informally manner, but they joined the negotiations formally later. The Kanis are no longer a cohesive unit, but live in several different parts

of Kerala. TBGRI interacted mostly with the Kanis from one area, who are supportive of the role of TBGRI. However, Kanis from other areas have voiced strong concerns about the lack of involvement of Kanis from elsewhere in the state (Anuradha 1998). One Kani leader felt the benefit-sharing exercise was a superficial one as the Kanis had not been consulted. In 1995, several Kani traditional doctors wrote to the Chief Minister of Kerala, objecting to the sale of their knowledge to private companies, and expressing fears that private firms would rapidly destroy the existing stocks of the plant. The TBGRI acknowledges that it has not been able to communicate with all Kanis, but hopes that through the Trust more Kanis can become involved (Anuradha 1998). The TBGRI also tried in the second phase of the ABS agreement to make the process more structured, democratic and transparent (Chaturvedi 2007).

One major issue revealed in the Kani case was the difficulty in determining the amount of benefit sharing and its distribution. The guidelines established by one of India's top scientific institutes, the CSIR (Council for Scientific and Industrial Research), influenced the way benefit sharing was determined. While CSIR follows a model that designates 60% for scientists and 40% for the institute, in the Kani case it was decided to follow a 50–50 sharing agreement (Chaturvedi 2007). Another factor that shaped the entire process was the fact that Dr. Pushpangadan had been closely involved in national and global discussions on the protection of indigenous knowledge systems (Chaturvedi 2007). The scientists at TBGRI had decided not to take their 50% share but to give it to the Kanis, but then a new problem arose: how to distribute it? (Chaturvedi 2007) Dr. Pushpangadan consulted with experts and pursued the idea of forming a Trust among the Kanis, as suggested by Dr. Anil Gupta (Chaturvedi 2007). This highlights how, even when benefit sharing is framed, actual distribution to local communities becomes an issue that requires careful consideration.

Another main issue concern ensuring sustainable development. The Kani case gave rise to several ethical concerns. The Kani are amongst the poorest communities of the world and the monetary benefits realized under the current benefit-sharing arrangement are not seen as adequate compensation for their knowledge (Chaturvedi 2007). Some of the earnings from the raw material have provided some revenue but the beneficiaries are still limited. According to Chaturvedi (2007), although the Trust is open to all (initially it started with 50 families, it now has 3000 members) the membership has not expanded as expected for achieving 'fair' and 'equitable' sharing of benefits. The funds have enabled the building of a school, buying a vehicle for transport and some training programs. Plant cultivation has enabled some earnings as the AVP purchases leaves at Rs. 150 per kg. For the period 1999–2005, royalties payments to the Trust amounted to Rs. 0.25 million, plus a license fee of Rs. 1 million (Chaturvedi 2007).

Another important issue is that the regular supply of the raw material is not available. The Forest Department puts a limit on the cultivation of leaves. The entire arrangement would have been more beneficial had prior efforts at capacity building, awareness and access to raw materials had been laid down.

IPRs are also important in this case. There are five patents which emanated from the research work at the Regional Research Laboratory (RRL), Jammu, and the TBGRI. The first patent was awarded to the RRL-based research team in 1994 (File No: 88/Del/1994) on the process for isolation of glycolipid in the *Arogyappacha* plant (Chaturvedi 2007). After the research was shifted to the TBGRI, four patents were applied for. Among them one was on the process for *jeevani* titled, 'A process for the preparation of a novel immune-enhancing, anti-fatigue, anti-stress and hepatoprotective herbal drug (*Jeevani*)', received in 1996 (File No: 959/MAS/1996) (Chaturvedi 2007). A patent was also granted on an anti-diabetic herbal drug developed at the TBGRI in 1996 (File No: 957/MAS/1996) (Chaturvedi 2007). Similarly, a herbal sports medicine was developed called '*Vaji*' for which a patent was granted (File No: 958/MAS/1996) (Chaturvedi 2007). The TBGRI also received a patent for herbal medicinal components for cancer treatment from *Janakia arayalpathra* root and *Trichopus zeylanicus* leaf (Patent No. 193609) (Chaturvedi 2007). In 2000, NutriScience Innovations LLC, a US-based supplier of nutritional and functional food ingredients, was granted a trademark on *jeevani* (Serial No. 75692281) (Chaturvedi 2007). This trademark led to TBGRI being criticized for not seeking such protection of *Jeevani*.

5.1.2 PepsiCo India¹³

An important case with regard to benefit sharing after the enactment of the Biodiversity Act in India concerned the company PepsiCo India Holdings Private Limited (a subsidiary of the multinational company PepsiCo Inc.). Benefit-sharing revenues collected so far under the NBA are largely (90%) a result of the PepsiCo agreements. In 2007, the National Biodiversity Authority entered into two agreements with PepsiCo, one for commercial access and the other for third-party transfer of *Kappaphycus alvarezii*, a type of seaweed (a species of red algae). The company paid about \$ 55,000 USD (INR 37.26 lakhs) to the NBA for *Kappaphycus alvarezii* from the Gulf of Munnar area in the southern Indian State of Tamil Nadu; PepsiCo signed a yearlong agreement with the NBA to export this to Indonesia, Malaysia and the Philippines for commercial utilization in the food and cosmetics industry.

The NBA has collected about Rs.39 lakhs (approximately US\$ 65,000) from PepsiCo India Holdings Private Limited for export of this red algae seaweed cultivated by the fishing community in the southern Indian state of Tamil Nadu. Approximately 2000 metric tonnes of seaweed have been exported to Malaysia, the Philippines and Indonesia by PepsiCo. Fishermen/women from the districts of Ramanathapuram, Tuticorin, Pudukottai, and Tanjore in Tamil Nadu cultivated the seaweed; and, with the help of women's self-help groups that have received training by the company, the seaweed has been collected, cleaned, baled and exported.

¹³ This section draws on information provided in Bhutani, Shalini and Kohli, Kanhi, "Unfair Share, Uncertain Futures" 20 September 2010 <http://www.d-sector.com/article-det.asp?id=1374>

Otherwise, however, the sharing of benefits with local communities had not yet taken place as of 2010. According to the NBA, “Efforts are being made to form Biodiversity Management Committees by State Biodiversity Board of Tamil Nadu in coastal villages to distribute the benefits accrued thus far with 754 benefit claimers spread across 4 districts in Tamil Nadu.”¹⁴ Further difficulties arose with ensuring consultations with local communities at the time, and the BMCs were not formed as of 2007. In reply to a Right to Information application, in July 2010 the NBA admitted that the money received from Pepsi was “yet to be ploughed back to the benefit claimers.” (Bhutani and Kohli 2010) There are claims that the company has transferred certain benefits in the form of training to the local communities, but this has been criticized as being inadequate.

The PepsiCo case shows that, even when revenue is collected from companies, the distribution of benefits can be difficult. In addition to the problem of distributing benefits over a large group of people located in various areas, there is lack of clarity about how community development is to be assisted. The fact that training was given to women self-help groups was held up as an important benefit from this agreement. However, it is not clear if this was training that provides the women with skills for sustainability, or was just to facilitate exports. Moreover, is this specific type of commodity to be focused on in terms of benefit sharing? The export of seaweed provides neither technology transfer nor sustainable practice to support the local communities. The NBA has as of 2014 reportedly stopped providing access permits due to claims that this seaweed is becoming an invasive species (Dhar et al., 2014). This illustrates the inadvisability of relying on raw materials as a source of revenue and development for local communities. In addition, the international agreements dealing with benefit sharing focus on *genetic* resources, whereas India's law points to *biological* resources. In this case, the agreement relates to a commodity that is accessed and used for exports, rather than a genetic resource. India needs to consider whether commodities used for exports should also be categorized under this type of ABS arrangement, or should require different policies. It may lead to difficulties for India if commodities and genetic resources are dealt with in the same manner, and this is not what the global agreements envision.

5.1.3 Bio India Biologicals¹⁵

In another case, the NBA collected Rs. 55,035.00 (about US \$924) from Bio India Biologicals for the export of 2000 kg of neem (*Azadirachta indica*) to Japan. According to the NBA, members of the local community of Amarchinta village in Andhra Pradesh collected and dried the leaves “by undertaking a few special operations” before handing it over to the company for export.¹⁶

¹⁴ http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf

¹⁵ This section draws on Dhar, Biswajit, T.C. James, and Pandey Vinayak (2014) *National Study on ABS Implementation in India*, Research and Information Systems for Developing Countries, New Delhi: India Habitat Centre, April

¹⁶ http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf?

The NBA states that it has transferred a “part of the royalty amount” to the local biodiversity body in Amarchinta for “planting neem saplings and creation of awareness about biodiversity conservation”—approximately INR 20,000 (Dhar et al., 2014).

Neem was in fact central in one of the initial cases of ABS concerning bio-piracy, in India and abroad. It was pointed out at the time that a country’s natural resources should not be utilized by foreigners without compensation, and that the traditional knowledge base should be recognized and developed. The sale of neem abroad for a small amount of money seems counter to the very principles on which the issue of biopiracy has been raised. Simply transferring a small amount of money to the local community to plant neem saplings is little concession. Criticism of this approach with regard to benefit sharing is being voiced in India, questioning the reasons why local communities have not been consulted and why benefits have not yet reached the communities (Bhutani and Kohli, 2010) . In this case, as in the PepsiCo example, the focus has been on a commodity rather than genetic resources. This gives rise to questions about the implications of dealing with commodities under ABS laws, rather than purely genetic resources as envisaged under the CBD.

5.1.4 Intellectual Property Rights¹⁷

We should also note a case of benefit sharing in India involving intellectual property rights (IPR). When an applicant utilizes biological resources in claiming a patent, the NBA can impose benefit-sharing fees. Dr. Geeta Pandurang Pawar, an Ayurvedic doctor from Pune, was granted a patent for an Ayurvedic anti-snake venom made from four medicinal plants. The tablet, “Pinak,” provides immediate temporary relief until the victim can be taken to the hospital. The NBA fixed the fee as 2% of the gross sales or gross revenue of the product. After commercialization of the patented product, the applicant paid INR 3,940 in benefit-sharing fees to the NBA. It is surprising that more cases relating to IPRs, particularly traditional knowledge and biological resources in foreign patent applications, have not been part of benefit sharing under the NBA.

5.1.5 Natural Remedies

Natural Remedies Pvt. Ltd, Bengaluru, purchased *kalmegh* (*Andrographis paniculata*), a bitter medicinal herb, from BMC of Malajkhand in the Balaghat district of Madhya Pradesh State, paying Rs. 21,000 directly to the BMC. That is the only case where benefit sharing has been shared by the NBA with the BMC (Dhar et al., 2014).

¹⁷ This sub-section builds on material presented in “Access and Benefit Sharing in India,” http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf

5.2 State and Local Level

Practices at the state and local levels indicate interpretations of benefit sharing different from those at the national and international levels. Here we examine activities in two Indian states, under the Madhya Pradesh State Biodiversity Board and the Uttarakhand Biodiversity Board.

5.2.1 *Madhya Pradesh State Biodiversity Board*¹⁸

The Madhya Pradesh State Biodiversity Board has been very active in promoting benefit sharing and has been able to collect fees from companies for accessing resources. In addition to the national framework, the Madhya Pradesh State Biodiversity Board (MPSBB) has adopted an interesting interpretation of benefit sharing, using a broad definition of the term “biological resources” and issuing notices to several companies involved in pharmaceuticals, *coal mining*, food and other industries known for utilizing biological resources. The MPSBB has highlighted that each of the industries, as per the Biodiversity Act, needs to inform the MPSBB and pay Rs 1,000 as they are carrying out “commercial utilization” of biological resources. The industries to which notices have been issued are asked to deposit 2% of their gross sales or gross revenue towards benefit sharing in the State's Biodiversity Fund. The logic, as stated in a letter from the MPSBB to the NBA in April 2013, is that “coal is a plant fossil and it has the genetic material of a plant,” and should therefore be treated as a biological resource under the Biodiversity Act. Similarly, “limestone is a genetic material of marine organisms and is made after calcification of marine organisms.” Further, the MPSBB argues, not only coal mining but also thermal and other industrial operations that use coal should come under the purview of the ABS.

These actions of the MPSBB have been met with strong reactions from industry and have been widely criticized. The Environment Ministry, the NBA, environmentalists and legal experts have stated that the interpretations were wrong. Companies became so angry that some filed a case with the National Green Tribunal (NGT), terming the action illegal. The MP state government leaders asserted that ABS can be a big source of revenue for the government. As Kohli and Bhutani (2013; 16), point out, “The argument against the MPSBB's position on this issue can be that aspects of ABS in the BD Act are applicable only to genetic material and not biological resources in general.” Such disputes are likely to continue, unless the terms can be clearly defined, in India and in international agreements (see section 6.5) Madhya Pradesh's initiative led SBBs in Karnataka, Andhra Pradesh and Uttarakhand to start functioning as well.

¹⁸ This sub-section builds on material presented in Kohli & Bhutani, 2013.

5.2.2 *Uttarakhand State Biodiversity Board*

The Uttarakhand Biodiversity State Board has been active in promoting benefit sharing. It has issued notices to over 300 industries.¹⁹ The State Board has also been active in preparing also Biocultural Community Protocols and People's Biodiversity Registers.

6 Analysis

India has established an elaborate structure with legal principles to realize the goal of benefit sharing. However, actual cases reveal the limitations in practice. Not only have there been very few instances of benefit sharing with local communities — the revenues collected have also been insignificant. There have been difficulties in transferring the agreed amounts to the local communities in almost all the cases. Due to a complex interplay of various issues, implementation of benefit sharing on the ground has not matched the high expectations outlined in the policy framework. Here we focus on major domestic factors and how these may link up with international regime complexity.

6.1 Lack of a Clear Objective

The lack of a clearly defined objective with regard to benefit sharing makes implementation problematic. Authors such as Kohli and Bhutani (2013) have noted the difficulty of trying to solve too many problems at once. It is impossible for one single mechanism (like benefit sharing) to ensure conservation, sustainable use, community development, and prevent bio-piracy. What is needed is a strategy that embeds benefit sharing as part of a wider development plan.

Lack of a clearly defined objective and the focus on multiple goals are also problematic at the international level. Benefit sharing has been debated in various international forums, leading to different objectives based on the underlying premise of that particular agreement. Historically also we find the regime-shifting strategies of developing countries have contributed to multiple interpretations of the real purpose of benefit sharing. In India, the demand for benefit sharing arose as a reaction to the increasing focus on IPRs promoted by countries of the North in forums such as TRIPs of the WTO. Patents based on traditional knowledge and resources, particularly on products such as neem and basmati rice, created a huge backlash against IPRs and led to the call for recognizing and rewarding biological resources. As the WTO was not a favorable forum for developing countries to raise this issue, it was taken to the Convention on Biological Diversity (CBD), where the main goal is conservation—so benefit sharing had to then be linked to this objective.

¹⁹ <http://www.tribuneindia.com/news/uttarakhand/community/biodiversity-board-asks-firms-to-deposit-5-of-profit-as-per-act/83672.html>

Ambiguity on benefit sharing internationally has further fueled the lack of clarity at the domestic level. Different international agreements under which benefit sharing is upheld have varying objectives. According to Article 1 of the CBD,

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and 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.

And Nagoya Protocol Article 1:

The objective of this Protocol is the fair and equitable sharing of the benefits arising from 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, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Further, according to Article 1.1 of the ITPGRFA:

The objectives of this Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.

Benefit sharing is thus intertwined with diverse objectives including: conservation, sustainable use, fair and equitable sharing, and transfer of technology. In addition, the goals of local community development, poverty alleviation, and farmers' rights are mentioned in these agreements. The capacity of one mechanism to ensure these multiple, broad and highly complex objectives is itself questionable. Moreover, in practice some of the objectives themselves may lead to conflict, due to the interests of different stakeholders.

6.2 Regulating Access over Benefit Sharing

As noted, India's policy focuses more on regulating access to resources than on benefit sharing. The aim of the regime is tilted towards preventing bio-piracy and collecting revenue from biological resources. India's Act focuses on creating a bureaucratic structure for approving various types of applications with regard to biological resources. It sets up a national level authority with little scope for involving other stakeholders in decision-making, leading to a top-down approach. The Act is designed as a structure to prevent exploitation of biological resources, particularly from non-Indians. This goes back to the fact that India's initial reason for proposing benefit sharing was to prevent bio-piracy, so that India could make profits from its own biological resources. However, the objectives of community rights and benefit sharing with local people become marginalized when the focus is on revenue collection. The coal case in Madhya Pradesh (see section 5.2.1) illustrates

this. Monetary rewards rather than conservation take on more importance. However as pointed out by Dhar et al (2014; 4):

tangible benefits from the implementation of BDA have come in the form of financial payments accruing from the ABS agreements. These amounts have been small and have, therefore, made no significant contribution towards conservation and sustainable use of BRs in the country..... A major problem is that even the paltry monetary benefits accruing from commercial use of BR have not reached the local communities who are the preservers and conservers of BR and associated TK.

Political economy factors, where the interests of stronger actors are promoted over weaker ones, can provide some explanation for this focus on access rather than benefit sharing. But we can also see the impact of *regime complexity* here, where formal rules framed at the global level become re-defined and re-interpreted at the implementation stage. Regime complexity affects domestic implementation when the politics shifts to the implementation stage as interpretations and application of rules are worked out by national actors.

6.3 State-led Structure

The fact that benefit sharing in India is framed by the state can mean that the interests of the state are prioritized over community interests. This may lead to certain state-led actors appropriating resources in the name of communities. Differences within various bodies also affect implementation. Differences in how benefit sharing should be implemented can be seen between the national and local levels as well as in turf wars between various ministries. Regime complexity can be used by powerful actors at the domestic level to promote their interests. The existence of a regime complex can lead to competition among actors for resources. It can lead to the selection of certain aspects of international regimes over others. India chose to focus on bilateral contractual mechanisms for monetary rewards rather than on multilateral systems that focus on sharing of resources. India's approach is more aligned with CBD/NP approach rather than ITPGRFA approach. While this may not directly lead to weak implementation, it does show that the preference for a contractual approach may not be well-suited for local communities.

6.4 Administrative Difficulties

Administrative difficulties are a major reason for the lack of implementation — indeed, India's policy-makers would say it is the main issue. Determining the amounts to be levied has itself been problematic. As Tvedt and Kabir (2015) point out, Indian regulators use a “rule of thumb” approach where the amount of benefit sharing is pre-set rather than emerging from a process of negotiation. This, they go on to say, takes place because of the lack of time and expertise available to examine the applications. Identifying the communities/individuals who should receive rewards from benefit sharing is a major stumbling block. In addition come the problems of how to distribute the rewards in practice and in what form. Moreover, India has not been able to keep a check on patents filed related to genetic resources. Although it has argued strongly

for a legal mechanism for ensuring disclosure on patent applications, this has not been accepted internationally. The existence of interrelated international agreements prescribing different, imprecise or even contradictory policy prescriptions further contributes to difficulties in domestic implementation.

6.5 Definitions and Use of Terminology

The international agreements relating to benefit sharing emphasize “genetic resources,” whereas India’s National Biodiversity Act (2002) focuses on “biological resources.” According to this Act, “biological resources” means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material.” The CBD states that “‘Biological resources’ includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.” “‘Genetic material’ means any material of plant, animal, microbial or other origin containing functional units of heredity. ‘Genetic resources’ means genetic material of actual or potential value.”

India’s use of the term “biological resources” has resulted in extending benefit sharing to include commodities and even attempts to push its definition to include natural resources. The main cases concluded to date have dealt with commodities as opposed to genetic resources. According to the Dhar et al (2014, 4), India’s Act “exempts normally traded commodities from the purview of the Act. While a list of 190 such commodities has been notified thus far, there is no consensus yet on an agreed definition of what constitutes a ‘commodity’ for the purposes of the Act, and, therefore, stakeholder groups have varied interpretations of this term.” At the global level, the lack of clarity as to the term “genetic resources” itself is problematic, and affects the domestic sphere as well. As Schei and Tvedt (2010, 2) point out, the term “genetic resources” “has been used with various differently expressed or implied meanings. Lack of consistency creates legal uncertainty in ABS transactions, and this will have to be resolved for an international regime to be functional.”

7 Conclusions

The lack of efficient mechanisms to implement benefit sharing in India stems from domestic as well as international sources. While the structure of the country’s political economy has enabled powerful actors to exercise their interests over weaker ones in determining benefit sharing, international regime complexity has brought ambiguity regarding the real objective of benefit sharing. It is not possible to trace the origin of the problem to solely the global or the national level, because of the dynamic interplay with each structure influencing and shaping the other.

India will need to reframe its benefit-sharing objectives and define clearly what it aims to achieve. Regulatory changes and quick fixes cannot deal with the underlying problems — they can only achieve minor administrative changes. To truly align the ideals of benefit sharing with

practice on the ground, India must identify one main objective and focus on it. Perhaps community development could be the first objective; later, additional goals might be included. Moreover, it has become clear that benefit sharing cannot be relied upon to provide a major source of monetary gain. More viable would be a shared focus on monetary *and* non-monetary rewards for communities, designed through a process such as community protocols. Furthermore, India needs to move away from a state-led structure for benefit sharing, to one that can enable a more inclusive policy. And finally, India must aim to match the global targets of benefit sharing with domestic frameworks.

As this study has shown, both international and domestic factors have combined to create weak implementation in India. In order to ensure effective implementation, a comprehensive approach that can align both the national and global strategy is required.

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