



LAW  
ENVIRONMENT AND  
DEVELOPMENT  
JOURNAL

# LEAD

BEYOND THE THUMBRULE APPROACH: REGULATORY  
INNOVATIONS FOR BIOPROSPECTING IN INDIA

Kabir Sanjay Bavikatte and Morten Walløe Tvedt

ARTICLE

FORTHCOMING IN VOLUME 11/1



VOLUME  
11/1

*LEAD Journal (Law, Environment and Development Journal)*  
*is a peer-reviewed academic publication based in New Delhi and London and jointly managed by the*  
*School of Law, School of Oriental and African Studies (SOAS) - University of London*  
*and the International Environmental Law Research Centre (IELRC).*

*LEAD is published at [www.lead-journal.org](http://www.lead-journal.org)*

*ISSN 1746-5893*

*The Managing Editor, LEAD Journal, c/o International Environmental Law Research Centre (IELRC), International Environment  
House II, 1F, 7 Chemin de Balexert, 1219 Châtelaine-Geneva, Switzerland, Tel/fax: + 41 (0)22 79 72 623, [info@lead-journal.org](mailto:info@lead-journal.org)*

## ARTICLE

# BEYOND THE THUMBRULE APPROACH: REGULATORY INNOVATIONS FOR BIOPROSPECTING IN INDIA

Kabir Sanjay Bavikatte\* and Morten Walløe Tvedt\*\*

This document can be cited as  
Kabir Sanjay Bavikatte and Morten Walløe Tvedt, 'Beyond the Thumbrule Approach: Regulatory Innovations for Bioprospecting in India',  
11/1 *Law, Environment and Development Journal* (2015),  
available at <http://www.lead-journal.org>

Kabir Sanjay Bavikatte, JSPS-UNU Postdoctoral Fellow, United Nations University- Institute for the Advanced Study of Sustainability, Tokyo, Japan, Email: [kabir@naturaljustice.org](mailto:kabir@naturaljustice.org)

Morten Walløe Tvedt, Senior Research Fellow, Fridtjof Nansen Institute (FNI), Oslo, Norway, P.O. Box 326, 1326 Lysaker, Norway, Email: [mwt@fni.no](mailto:mwt@fni.no)

Published under a Creative Commons Attribution-NonCommercial-NoDerivs 2.0 License

\* Kabir Sanjay Bavikatte is a JSPS-UNU Postdoctoral Fellow in the Biodiplomacy Initiative of UNU-IAS. Kabir has practiced as an environmental lawyer for over a decade focusing on the rights of indigenous and local communities to their territories and cultures. He is the co-founder of Natural Justice an international collective of environmental lawyers providing legal assistance to communities and advising governments in Asia, Latin America, Africa and the Pacific. Kabir has been the legal advisor to the African Group of countries through their negotiations towards the Nagoya Protocol on Access and Benefit Sharing and within the Working Group on Article 8j. He has also advised the governments of India, South Africa, Namibia, Bhutan and Micronesia in developing Access and Benefit Sharing (ABS) law and policy.

\*\* Morten Walløe Tvedt is a Senior Research Fellow at the Fridtjof Nansen Institute. He has published extensively in the area of biological resources law and intellectual property. He has co-authored an important monograph regarding genetic resources (M.W. Tvedt and T. R. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, IUCN Environmental Policy and Law Paper No. 67/1). Tvedt is currently working on a monograph on patent law and the sui generis options in the plant sector for developing countries.

## TABLE OF CONTENTS

---

1. Background	3
2. Bioprospecting and the Convention on Biological Diversity	4
3. Bioprospecting in India	6
4. The Nagoya Protocol on Access and Benefit Sharing	7
5. Private Contracts in Public International Law	8
6. ABS Agreements/Mutually Agreed Terms as Private Contracts	8
7. The Indian Situation on ABS Agreements	9
8. Bioprospecting Approval Process in India	11
9. Challenges in the Indian Bioprospecting Approval Process	13
10. Examples of the Thumb-Rule Approach	15
11. Possible Solution	16
12. Using Scoping and Actualization Agreements under the BD Act and Rules	17
13. Conclusion	19

# 1

## BACKGROUND

The Nagoya Protocol on Access and Benefit Sharing (ABS)<sup>1</sup> and other emerging environmental regulatory frameworks like Reducing Emissions from Deforestation and Forest Degradation (REDD+)<sup>2</sup> and Payments for Ecosystem Services

(PES),<sup>3</sup> belong to a menu of innovative financing mechanisms designed to incentivize conservation and sustainable use of biodiversity under the rubric of the Green Economy paradigm. The Green Economy paradigm takes a two-pronged approach to the conservation of common pool resources. It does so by affirming rights of countries and communities stewarding local ecosystems to determine the access and use of such ecosystems and by ensuring that they are incentivized. The incentivizing occurs through facilitating a flow back of monetary and non-monetary benefits arising from the commercial and research utilization of the resources from the ecosystems to these rights holders, be it in the form of genes or carbon stocks.

While a vast amount of policy and regulatory efforts have been directed towards setting up these incentivizing mechanisms, there has been insufficient legislative and implementation experience on ways to effectively secure the rights of the countries and communities who have stewarded the local ecosystems that are the basis of the 'natural capital' traded in the Green Economy. This is a result of an unstated assumption that in the Green Economy, the market will be able to best devolve rights. However, a close scrutiny of the

---

1 The Nagoya Protocol is an international treaty that was adopted in October 2010 by the 193 Parties to the Convention on Biological Diversity (CBD). The Protocol was intensely negotiated over six years under the framework of the CBD. The aim of the Nagoya Protocol on Access and Benefit Sharing is to give effect to the fair and equitable benefit sharing provisions of the CBD. Specifically Article 15 of the CBD that recognizes the rights of States to their genetic resources and Article 8(j) that recognizes the rights of communities to their traditional knowledge. The Nagoya Protocol seeks to ensure that commercial and research utilization of genetic resources and associated traditional knowledge shares the benefits of such utilization with the governments and communities that have conserved such resources and knowledge. See 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 (adopted 29 October 2010, entered into force 12 October 2014) <<http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>> (Nagoya Protocol).

2 In 1992, the United Nations Framework Convention on Climate Change (UNFCCC) was adopted as the basis for a global response to the problem of climate change. With 194 Parties, the ultimate objective of the Convention is to stabilise greenhouse gas concentrations in the atmosphere at a level that will prevent dangerous human interference with the climate system. The Convention is complemented by the 1997 Kyoto Protocol, which has 192 Parties. Under this treaty, 37 industrialised countries and the European Community have committed to reducing their emissions by an average of 5 percent by 2012 against 1990 levels. Industrialized countries must first and foremost take domestic action against climate change. But the Protocol also allows them to meet their emission reduction commitments abroad through so-called "market-based mechanisms". See, *An Introduction to the United Nations Framework Convention on Climate Change (UNFCCC) and its Kyoto Protocol*, Fact Sheet (UNFCCC, February 2011).

---

3 A definition for payment for ecosystem services (PES) that has become fairly well accepted has been put forward by Sven Wunder, in which he explains, "A payment for environmental services scheme" is a voluntary transaction in which a well defined environmental service (ES), or a form of land use likely to secure that service is bought by at least one ES buyer from a minimum of one ES provider if and only if the provider continues to supply that service (conditionality)." Wunder, Sven 2005, quoted on CIFOR website: [http://www.cifor.cgiar.org/pes/\\_ref/about/index.htm](http://www.cifor.cgiar.org/pes/_ref/about/index.htm) accessed 14 September 2014. The key characteristic of PES deals is that the focus is on maintaining a flow of a specified ecosystem "service" — such as clean water, biodiversity habitat, or carbon sequestration capabilities — in exchange for something of economic value. The critical, defining factor of what constitutes a PES transaction, however, is not just that money changes hands and an environmental service is either delivered or maintained. Rather, the key is that the payment causes the benefit to occur where it would not have otherwise. That is, the service is "additional" to "business as usual", or at the very least, the service can be quantified and tied to the payment. See, *Payment for Ecosystem Services- Getting Started: A Primer* (UNEP, Forest Trends and the Katoomba Group 2008) 3.

different Green Economy models has shown that without a well thought out and experienced based strategy to ensure corresponding Green Governance, the Green Economy will neither secure rights nor facilitate incentives to those directly involved in biodiversity conservation. We consciously use the term Green Governance to mean a system of governance that not only concerns itself with governance that is efficient, fair and transparent but also ensures the conservation and the sustainable use of the environment and upholds the rights of communities and countries stewarding it.

It is therefore important to begin to facilitate the transition into a Green Economy by firmly grounding the principles of Green Governance both internationally and domestically. Of particular concern is the need to figure out how the private sector and research can invest in a Green Economy while at the same time ensuring robust Green Governance. Ironically while the Green Economy is being hailed as the economy of the future, this enthusiasm is not matched by an implementation of the principles of Green Governance. This is not a result of any lack of frameworks for Green Governance in law and policy. In the context of genetic resources and associated traditional knowledge there has been a lot of progress in international law and domestic law establish rules to ensure that research, development and commercial utilization of genetic resources and associated traditional knowledge (referred to hereon as bioprospecting) 'give back' to the countries and communities involved in biodiversity conservation.

In this article we will undertake to do the following:

- i) Analyse international and domestic law relating to bioprospecting with a special focus on the Indian experience in Green Governance;
- ii) Identify the challenges faced by Indian regulators in ensuring effective Green Governance;
- iii) Highlight experiences from Bhutan, South Africa and Australia that could aid in overcoming these challenges;
- iv) Elaborate practical lessons for India based on the experiences of the aforementioned countries that could be easily implemented within the existing parameters of the Indian ABS framework.

## 2 BIOPROSPECTING AND THE CONVENTION ON BIOLOGICAL DIVERSITY

The concept of 'bioprospecting' is based on recognition of the importance of natural product discovery for the development of new crops and medicines, often based on traditional knowledge. For example in many developing countries, a large part of the population depends upon traditional medicines for their primary health care needs. In India, 65% of the population only has access to traditional systems of medicine, and in Africa 80% of the population uses traditional medicines.<sup>4</sup>

Much of this knowledge has not been examined using the most advanced scientific methods, however this is rapidly changing. As Laird and Wynberg<sup>5</sup> note, natural products continue to play a dominant role in the discovery of new leads for the development of drugs. They contribute significantly to the bottom lines of large pharmaceutical companies. Between January 1981 and June 2006, for example, 47 per cent of cancer drugs and 34 per cent of all small molecule new chemical entities for the treatment of all disease categories were either natural products or directly derived therefrom.<sup>6</sup> Research into specific natural products is usually

4 WHO *Traditional Medicine Strategy 2002-2005* (WHO, 2002); K Timmermans, 'Intellectual Property Rights and Traditional Medicine: Policy Dilemmas at the Interface' (2003) 57/4 *Social Science and Medicine* 745.

5 Sarah Laird and Rachel Wynberg (eds), *Access and Benefit Sharing in Practice: Trends in Partnerships Across Sectors* (Technical Series, No. 38, CBD Secretariat, 2008) 12.

6 D.J. Newman and G.M. Cragg, 'Natural Products as Sources of New Drugs over the Last 25 Years' (2007) 70/3 *Journal of Natural Products* 461.

directed by existing knowledge, often directly from indigenous or local communities, but now in many cases as transferred through the 'public domain'.<sup>7</sup>

The *Biodiversity Prospecting* by Reid et al.<sup>8</sup> describes bioprospecting as: 'the exploration of biodiversity for commercially valuable genetic and biochemical resources'. They also suggest the need for appropriate policies and institutions 'to ensure that the commercial value obtained from genetic and biochemical resources is a positive force for development and conservation'.<sup>9</sup>

The need to incentivize the conservation of biodiversity through fair and equitable benefit sharing saw the CBD text include elements on 'access and benefit-sharing' (ABS). Article 1 of the CBD lists its three objectives as: i) the conservation of biological diversity; ii) the sustainable use of its components; and iii) the fair and equitable sharing of benefits arising from such use. The CBD recognizes the sovereign rights of states over genetic resources found in *in situ* conditions within their territories.

This is unprecedented in international law to the extent that it requires parties to the CBD to uphold within their jurisdictions, the rights of other parties to the CBD over their (the latter's) genetic resources.<sup>10</sup> Specifically, the CBD, through its Article 15,<sup>11</sup>

requires access to genetic resources to be subject to the prior informed consent of the party providing such resources and a fair and equitable sharing with that party of the benefits that arise from the commercial and other utilization of those resources.

In many ways, Article 15 was a reaction by developing countries against the increasing number of patents taken out by research and commercial sectors from the developed world over pharmaceutical, agricultural and other biotechnological innovations based on genetic resources freely accessed from developing countries.<sup>12</sup> Many developing countries saw the CBD as an effective vehicle to reclaim the political ground that had been lost under the World Trade Organization (WTO).<sup>13</sup>

With respect to traditional knowledge, Article 8(j) of the CBD makes a critical link between the knowledge, innovations and practices (traditional knowledge) of indigenous peoples and local communities<sup>14</sup> and conservation of biological diversity. It requires states to protect and promote such traditional knowledge by securing the rights of communities to consent to any non-traditional uses of their knowledge and the right to share in any benefits that may arise from the research or

7 Daniel F. Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Earthscan 2010) 11.

8 W.V. Reid et al., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* (World Resources Institute 1993) 1.

9 *ibid* 2, 3.

10 Doris Schroeder et al., 'Justice and the Convention on Biological Diversity' (2009) 23/3 *Ethics and International Affairs* 267.

11 Article 15.5 of the CBD: Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. Article 15.6 of the CBD: Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 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.

12 See generally, Gurdial Singh Nijar, *In Defence of Local Community Knowledge and Biodiversity: A Conceptual Framework and the Essential Elements of a Rights Regime* (Third World Network 1996); P.R. Mooney, *Seeds of the Earth: A Private or Public Resource?* (International Coalition for Development Action 1979); Tewolde Egziabher, 'The Convention on Biological Diversity, Intellectual Property Rights and the Interests of the South' in Vandana Shiva (ed), *Biodiversity Conservation: Whose Resources? Whose Knowledge?* (Indian National Trust for Art and Cultural Heritage 1994) 198–215; J. Rifkin, *The Biotech Century: Harnessing the Gene and Remaking the World* (Tarcher 1998) 43.

13 Based on informal conversations between one of the author and the delegates from developing countries at the 9<sup>th</sup> Conference of Parties to the CBD. See generally, Susan Bragdon et al, 'Safeguarding Biodiversity: the Convention on Biological Diversity (CBD)' in Geoff Tansey and Tasmin Rajotte (eds), *The Future Control of Food* (Earthscan 2008) 82.

14 The phrase that Article 8(j) uses is 'indigenous and local communities'. Here when we use the term 'communities' it should be understood as referring to indigenous and local communities.

commercial uses of that knowledge.<sup>15</sup> In sum, the CBD in Articles 15 and 8(j) recognizes the rights of both states and communities to their genetic resources and traditional knowledge, respectively, and emphasizes the duty to share benefits arising from commercial and research use.

### 3 BIOPROSPECTING IN INDIA

India's ratification of the CBD in 1994 resulted in its first national law regulating bioprospecting. The Biodiversity Act of 2002 and the Biodiversity Rules of 2004 regulate bioprospecting of Indian biological resources and associated traditional knowledge. India is a significant source country for bioprospecting as evidenced by the report of the Traditional Knowledge Task Force established by the World Intellectual Property Organization (WIPO) in 2001. The Task Force carried out a search on international patent databases on patents relating to traditional knowledge systems. The search uncovered in excess of 5000 patent references relating to 90 medicinal plants in the US Patent and Trademark Office alone. 80 percent of the patents relating to these 90 medicinal plants came from seven plants, all seven of which were of Indian origin.<sup>16</sup>

To further underscore the extensive bioprospecting of Indian plants in drug discovery, 50 percent of the drugs reported in the British Pharmacopoeia have their origins in medicinal plants from the Western

Himalayan region alone. This is not surprising considering that the genetic diversity of the Western Himalayas informs 80 per cent of *Ayurvedic*, 46 per cent of *Unani* and 33 per cent of allopathic system of medicines.

Despite being an early entrant among countries developing bioprospecting legislation, bioprospecting in India continues to proceed unregulated. Large amounts of medicinal plants are exported from unregulated local markets in Mumbai, Delhi, Chennai and Tuticorin that function through supply chains that are indifferent to regulatory requirements. Furthermore there is a lack of sufficient data and trained personnel to monitor this trade. The reasons for this include a lack of inventories on Indian medicinal plants, unavailability of reliable systems matching trade names to botanical names and the fact that the medicinal plant trade occurred in dried form making these plants difficult to identify.<sup>17</sup> While the inventorying gaps are gradually being overcome the greater challenge of distinguishing between bioprospecting and commodity trade and developing practical ways of regulating the different stages of bioprospecting still remain.

Besides the pharmaceutical and the cosmetics sector, Indian plant genetic resources for food and agriculture is widely used by agribusinesses including for the development of genetically modified varieties and other proprietary lines. Many of these agribusinesses have Indian germplasm in their collections, which they use to develop new proprietary varieties. However despite the existence of the Biodiversity Act since 2002, none of these companies have disclosed any information regarding their use of Indian germplasm nor have they made any concrete offers to share any benefits arising from such use.<sup>18</sup> While

---

15 While Article 8j of the CBD does not specifically use the terms prior informed consent, the Article has been interpreted to mean so through subsequent CBD COP decisions including most explicitly in the report of the Ad-hoc Technical Expert Group on Traditional Knowledge Associated with Genetic Resources commissioned by the CBD COP to provide inputs to the Working Group on ABS. See Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regime on Access and Benefit-Sharing, 15 July 2009, UNEP/CBD/WG-ABS/8/2.

16 Council of Scientific & Industrial Research (CSIR). 2001. *CSIR News* 51 (5&6: 1-3).

---

17 Harbir Singh, 'Prospects and Challenges for Harnessing Opportunities in Medicinal Plants Sector in India' (2006) 2/2 *Law, Environment and Development Journal* 196, 202,203.

18 Based on conversations conducted in the first quarter of 2013 between the author and the Indian Seed Association, a confederacy of seed companies registered in India. Despite several requests from the National Biodiversity Authority (the Indian national competent authority tasked with implementing the Biodiversity Act), none of the seed companies have disclosed the full extent of their ongoing use of Indian germplasm in their proprietary lines.



some of the recalcitrance amongst agribusinesses has to do with ignorance or wilful violation of the law, discussions between regulatory authorities and agribusinesses representatives reveal a lack of clarity and consensus on both sides regarding at the different stages of bioprospecting and when benefits are to be shared.

## 4 THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING

Nearly 11 years after the CBD came into force in 1993, India was one of the leading developing countries to push for a supplementing international regime on access and benefit sharing to counteract the non-implementation of their CBD obligations by developed states. The trigger for this was a growing concern regarding the lack of compliance with the Indian bioprospecting laws by users of India's biological resources and associated traditional knowledge in jurisdictions outside India.

The continued inability to secure compliance of the Indian Biodiversity Act and Rules by bioprospectors led India to play a key role as a part of the Like Minded Mega Diverse Countries (LMMC) in the negotiations towards an international regime on access and benefit sharing (which later took the form of the Nagoya Protocol). The negotiations were driven by an imperative of 'justice in exchange'<sup>19</sup> that underscored that conservation and sustainable use of biological resources would not be achieved unless benefits arising from the use of such resources were equitably shared with countries and communities conserving them.

The success of the LMMCs (and therefore India's) lobbying for a binding international regime on ABS was exemplified by the decision by the 7<sup>th</sup> COP to

the CBD in 2004 in Kuala Lumpur that kicked off the negotiations of the regime.<sup>20</sup> The intensity of the negotiations towards the Nagoya Protocol picked up from the 9<sup>th</sup> COP to the CBD<sup>21</sup> and culminated in the adoption of the Nagoya Protocol on Access and Benefit Sharing at the 10<sup>th</sup> COP in Nagoya Japan. The Nagoya Protocol sought to elaborate a legal framework in international law to implement the ABS provisions of the CBD namely Articles 15 and 8(j).

Fleshing out the CBD, the Nagoya Protocol details the rights and obligations of countries of origin of genetic resources and associated traditional knowledge (hereafter referred to as provider countries) and countries in whose jurisdiction these genetic resources and associated traditional knowledge are used (hereafter referred to as user countries). The Nagoya Protocol also recognizes the rights of indigenous and local communities over genetic resources and associated traditional knowledge in accordance with domestic laws of countries where these communities are located.

The Nagoya Protocol therefore heralds an unprecedented step in public international law. It makes it obligatory for parties to ensure that users of genetic resources and associated traditional knowledge (bioprospectors) within their jurisdiction comply with the domestic ABS regulatory requirements of the provider countries. This national obligation on bioprospectors requires them to not only comply with domestic ABS frameworks of provider countries but where required by such laws enter into ABS agreements with legitimate providers of such resources and knowledge.

<sup>19</sup> See generally, Doris Schroeder and Balakrishna Pisupati, *Ethics, Justice and the Convention on Biological Diversity* (UNEP 2010).

<sup>20</sup> COP Decision VII/19 (Global Taxonomy Initiative), 13 April 2004, UNEP/CBD/COP/DEC/VII/9, <<http://www.cbd.int/decision/cop/?id=7756>> accessed 13 December 2013.

<sup>21</sup> COP Decision IX/12 (Access and Benefit-Sharing), 9 October 2008, UNEP/CBD/COP/DEC/IX/12 <<http://www.cbd.int/doc/decisions/cop-09/cop-09-dec-12-en.pdf>> accessed 13 December 2013.

## 5

### PRIVATE CONTRACTS IN PUBLIC INTERNATIONAL LAW

The Nagoya Protocol is a treaty in public international law that ultimately makes it incumbent on bioprospectors to enter into private access and benefit sharing agreements with the legitimate providers of such resources and knowledge. While such bioprospectors would be required to comply with the domestic ABS regulatory frameworks of provider countries, these frameworks additionally make the utilization of genetic resources and associated traditional knowledge conditional on mutually agreed terms between the bioprospectors and the domestic providers.

According to the Protocol, the mutually agreed terms would be predicated on the prior informed consent of the providers of the resources and knowledge- meaning that the providers must be willing to provide access to their resources and knowledge. Furthermore the mutually agreed terms could include the fair and equitable sharing of benefits arising from the commercial or research use of the resources and knowledge.

It is important to note that the terms of access to genetic resources and associated traditional knowledge and the nature and extent of sharing of benefits arising from their utilization would all have to be detailed out in a private contract between the bioprospectors and providers. What the Nagoya Protocol does is to require user countries to ensure that private users in their jurisdiction enter into such ABS agreements before utilizing genetic resources and associated traditional knowledge from other countries.

The effective implementation of the Nagoya Protocol then requires three steps:

- 1) Provider countries have to have a regulatory framework on ABS detailing the obligations of users of genetic resources and associated traditional knowledge and the

rights of the providers of such resources and knowledge;<sup>22</sup>

- 2) User countries have to have a regulatory framework that requires users of genetic resources and associated traditional knowledge in their jurisdiction to comply with the ABS regulatory framework of the countries from where they access such resources and knowledge;<sup>23</sup>
- 3) Users of genetic resources and associated traditional knowledge (bioprospectors), where required by the provider country ABS framework, have to enter into ABS agreements with legitimate providers of such resources and knowledge.<sup>24</sup>

## 6

### ABS AGREEMENTS/MUTUALLY AGREED TERMS AS PRIVATE CONTRACTS

Provider and user country legal frameworks are ways of ensuring compliance from bioprospectors. These frameworks could require bioprospectors using genetic resources and associated traditional knowledge to enter into ABS agreements and penalize those bioprospectors who don't. The Nagoya Protocol is therefore public international law that requires Parties to the Protocol to ensure that users in their jurisdictions will comply with domestic ABS frameworks of provider countries and enter into private contracts when bioprospecting if such contracts are required by such frameworks.

An ABS agreement then is a contract providing a bioprospector with the right to use genetic resources and associated traditional knowledge in exchange for a share of the benefits derived from such use. The

<sup>22</sup> Nagoya Protocol (n 1) Article 6.

<sup>23</sup> *ibid* Article 15.

<sup>24</sup> *ibid* Article 5.

CBD and the Nagoya Protocol are international treaties that make such agreements possible by a process that requires all Parties to the CBD to ensure that the bioprospectors in their jurisdictions respect the rights of provider countries and communities over genetic resources and associated traditional knowledge. It isn't that prior to the CBD or the Nagoya Protocol, countries could not assert their sovereign rights over their resources. However, the crucial difference is that because of the CBD and the Nagoya Protocol, user countries will have to recognize the resource rights of provider countries in the former's jurisdictions- and this is unprecedented.

The assignment of resource rights in provider countries and recognition of such rights in user countries creates owners or holders of such resources across national boundaries. These owners or holders can through ABS agreements set the specific terms for the use of their resources and knowledge in exchange for a share of the benefits generated from such use. The benefits are usually determined through the assignment of prices by market forces (however imperfectly) to research and products based on such resources and knowledge that were previously shielded from market exchange or for various reasons unpriced.<sup>25</sup>

Even without the Nagoya Protocol, ABS agreements can technically be entered into with users of genetic resources or associated traditional knowledge if a provider of such resources and knowledge has the right to do so in domestic law. This is because ABS agreements are fundamentally private contracts that involve an offer by one party, its acceptance by another party and a transfer of consideration between them. The advantage of an ABS agreement is that even if a user country (the country where the bioprospector operates) has no laws requiring an ABS agreement, the agreement would still be enforceable since the bioprospector has voluntarily

agreed to its terms and conditions. Nevertheless, as per the Nagoya Protocol, an ideal situation would be functioning ABS legal frameworks in both user and provider countries and an ABS agreement in place between the bioprospector and the provider of genetic resources and associated traditional knowledge.

However, a large number of countries still do not have "provider legislation" to regulate access to genetic resources of their countries, and even fewer countries regulate their users by requiring bioprospectors in their jurisdictions to comply with the laws of provider countries.<sup>26</sup>

## 7 THE INDIAN SITUATION ON ABS AGREEMENTS

The Biological Diversity Act 2002 (BD Act) and the Biological Diversity Rules 2004 (BD Rules) regulate access to Indian biological resources<sup>27</sup> and associated knowledge.<sup>28</sup> The central regulatory authority permitting access to the resources and knowledge is

25 Castree cites N. Brenner & N. Theodore, 'Cities and the Geographies of "Actually Existing Neoliberalism' (2002) 34 *Antipode* 349; J. Peck & A. Tickell, 'Neoliberalizing Space' (2002) 34 *Antipode* 380; J. McCarthy & S. Prudham 'Neoliberal Nature and the Nature of Neoliberalism' (2004) 35 *Geoforum* 276.

26 See Morten Walloe Tvedt & Tomme Young, *Beyond Access: Exploring the Implementation of the Fair and Equitable Sharing Commitment in the CBD* (IUCN Environmental Policy and Law Paper No.67/2, IUCN 2007); See also Morten Walloe Tvedt & Ole Kristian Fauchald, 'Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway' (2011) 14/5 *The Journal of World Intellectual Property* 383.

27 The BD Act uses the term biological resources instead of genetic resources but specifies the kinds of uses of biological resources that are regulated under the BD Act in the definition section of the Act. This specification of the kinds of uses of biological resources falling under the scope of the BD Act can broadly be equated to the Nagoya Protocol's understanding of what constitutes 'utilization of genetic resources' in Article 2(d).

28 The BD Act does not use the term 'traditional knowledge' but instead uses 'associated knowledge' to mean knowledge associated with biological resources. Therefore the term 'associated knowledge' will be used hereon when referring to the BD Act and Rules.

the National Biodiversity Authority (NBA). The BD Act also devolves certain powers of oversight to the State Biodiversity Boards at the state level and the Biodiversity Management Committees at the local level.

The BD Act and Rules bring the following activities in relation to Indian biological resources and associated knowledge under the purview of ABS:

- a) Commercial utilization of Indian biological resources to develop products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention. However this commercial utilization does not include conventional or traditional practices that are used in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping;<sup>29</sup>
- b) Research which means any study or investigation or technological application of biological resources or their derivatives to develop products or processes;
- c) Biosurvey or bioutilization which means survey or collection of biological resources for any purpose;<sup>30</sup>
- d) Application for any intellectual property rights based on Indian biological resources and associated knowledge.<sup>31</sup>

Any other uses of biological resources for e.g. direct consumption, trading, as commodities etc. do not attract the provisions of the BD Act and Rules.

The BD Act and Rules require non-Indians to get the prior approval of the NBA when engaging in the aforementioned activities. However, there are certain situations where Indians are also required to

get the approval of the NBA. Non-Indians as per the BD Act are individuals who are not citizens of India, non-resident Indians (as per Section 2(30) of the Income Tax Act) and body corporates, associations or organizations not incorporated or registered in India or having non-Indian participation in its share capital or management.<sup>32</sup> Nevertheless, both Indians and non-Indians are required to get the previous approval of the NBA when they apply for intellectual property rights or transfer for monetary consideration research relating to Indian biological resources and associated knowledge.<sup>33</sup>

The reasoning behind the distinction between Indians and non-Indians in the BD Act has to do with incentivising domestic industry by giving them a free pass at least to the point where they secure proprietary rights over innovations based on Indian biological resources and associated knowledge. This distinction however has been increasingly harder to maintain since a large number of Indian companies have non-Indian participation in its share capital and management.

Moreover differences between the NBA and the State Biodiversity Boards (SBBs) regarding the interpretation of the BD Act and Rules regarding benefit-sharing obligations of Indian companies are becoming increasingly public and frequent. This is exemplified by actions of insufficiently funded SBBs interpreting the BD Act as providing them with the discretion to require Indian companies to engage in benefit sharing where they use Indian biological resources from the jurisdiction of the SBBs.<sup>34</sup>

---

32 *ibid* s 3.

33 *ibid* ss 4 & 6.

34 The most recent example of this is the Madhya Pradesh SBB issuing notices to Indian coal mining companies in its jurisdiction to engage in benefit sharing arguing that coal is a biological resource and that the requirement under the BD Act for Indian companies to inform the SBB's of their activities relating to Indian biological resources implies that the SBB's have a right to require benefit sharing. See Sudheer Pal Singh, 'More Trouble Likely for Captive Coal Miners in Madhya Pradesh' *Business Standard* (12 June 2013) <[http://www.business-standard.com/article/companies/more-trouble-likely-for-captive-coal-miners-in-madhya-pradesh-113061100849\\_1.html](http://www.business-standard.com/article/companies/more-trouble-likely-for-captive-coal-miners-in-madhya-pradesh-113061100849_1.html)> accessed 20 December 2013.

---

29 Biological Diversity Act 2002, s 2(f).

30 *ibid* s 2(d).

31 *ibid* s 6.

The growing frequency of SBB's interpreting the BD Act and Rules in a manner that would generate a revenue stream for them is a key challenge for the NBA. Companies aggrieved by these actions of the SBBs have approached the NBA for redress and have also filed petitions in courts to challenge the actions of the SBBs. The opportunistic interpretations of the BD Act and Rules by the SBBs despite direct instructions by the NBA to the contrary are a sign of the times in India where increasing administrative and judicial battles will be fought around the meaning of the BD Act and Rules in the context of India's ratification of the Nagoya Protocol.

It is clear that the time has come for the Government of India to review the BD Act and Rules with the experience of hindsight and against the backdrop of the Nagoya Protocol. In the meantime efforts such as this article are being made to suggest innovative ways of interpreting the BD Act and Rules to ensure the optimal implementation of India's ABS framework.

Despite the interpretation challenges regarding the benefit sharing obligations of Indians and non-Indians, the BD Rules are clear about the process of securing the prior approval of the NBA for the use of Indian biological resources and associated knowledge. The users of the resources and knowledge (bioprospectors) depending on the nature of use would have to make an application to the NBA in accordance with one of the relevant forms included in the BD Rules.<sup>35</sup>

## 8

### **BIOPROSPECTING APPROVAL PROCESS IN INDIA**

The BD Act and Rules are unique to the extent that the approval of the NBA for bioprospecting is in the form of a written agreement or contract between

the NBA and the bioprospector.<sup>36</sup> The NBA is required by the BD Rules to provide its approval in the form of an ABS agreement between itself and the bioprospector that includes the terms of utilization of the biological resources and associated knowledge and also the quantum of benefits arising from such utilization to be shared.<sup>37</sup> However the benefits are supposed to be mutually agreed between the user of the resources and knowledge and NBA with the latter having to consult with the local bodies<sup>38</sup> and benefit claimers<sup>39</sup> when determining such benefits. Therefore in law, the rights over genetic resources and associated traditional knowledge do not rest with the NBA but with the benefit claimers providing access to the resources and knowledge. However the NBA is tasked with the role of entering into the ABS agreements and concluding them in accordance with the mutually agreed terms as negotiated by the benefit claimers.

The BD Act and Rules therefore vest the powers of negotiating and entering into ABS agreements relating to Indian biological resources and associated knowledge with the NBA. The rights of the local custodians of the resources and knowledge is assured through the requirement that the NBA consult with the Biodiversity Management Committees (BMC) at the village level if the subject matter of the ABS agreement has to do with the resources or knowledge from the jurisdiction of the BMC. However the NBA effectively remains the only party on the Indian side to all ABS agreements relating to Indian resources and knowledge. As per the requirement in the BD Rules the NBA uses a standard set of ABS agreements depending on the nature of the resource or knowledge utilization that will constitute an ABS approval.<sup>40</sup>

Since 2003 the NBA has received nearly 844 bioprospecting applications with the numbers

<sup>35</sup> Biological Diversity Rules 2004, Forms 1, 2, 3 and 4 read with Rules 14, 17, 18 and 19 respectively.

<sup>36</sup> *ibid* Rules 14.5, 17.5, 18.5 and 19.5.

<sup>37</sup> *ibid* Rule 14.6.

<sup>38</sup> Biological Diversity Act 2002, s 2(h) (defines local bodies as panchayats, municipalities and other local institutions of self-government).

<sup>39</sup> *ibid* s 2(a) (defines benefit claimers as conservers of biological resources and holders of knowledge relating to such biological resources).

<sup>40</sup> These standard agreements can be accessed on the NBA website at <<http://nbaindia.org/content/104/38/1/download.html>> accessed 20 December 2013.

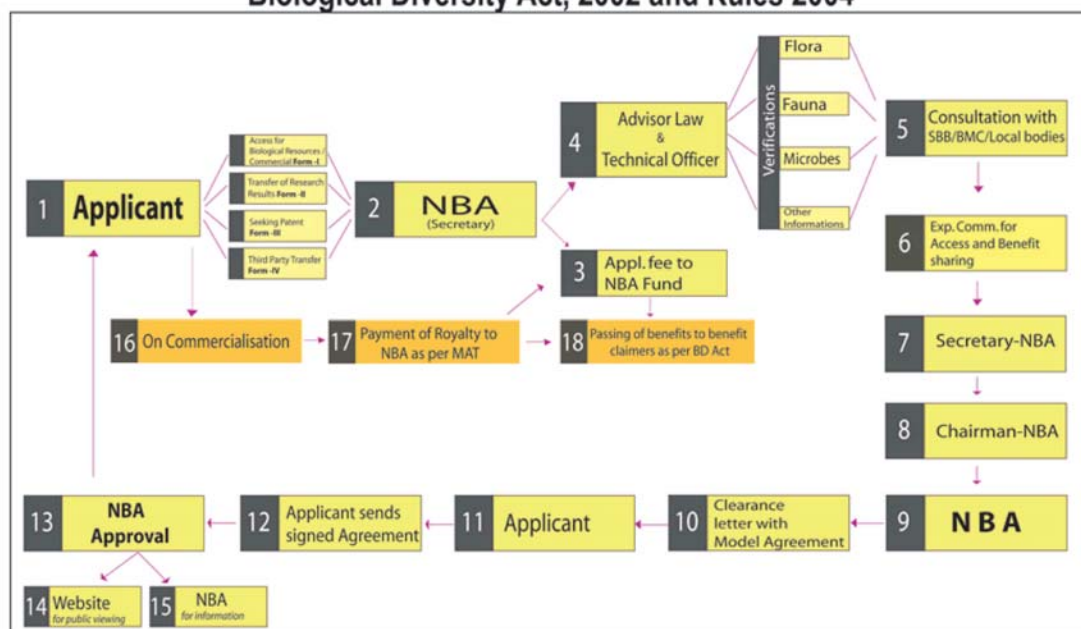
having increased drastically from 2006 onwards. The NBA has since processed 477 applications, closed 99 applications, entered into 117 ABS agreements and is currently still processing 282 applications.<sup>41</sup> The NBA therefore receives an average of around 84 bioprospecting applications a year or about 7 every month.

The processing of ABS applications involves various steps as laid down by the NBA in the decision making map below.<sup>42</sup> There are 13 steps that need to be undertaken with each of these steps being time consuming for various reasons ranging from incomplete applications submitted by the bioprospector to time taken to consult the BMCs or to organize meetings of the Expert Committee or the NBA to approve or reject the applications.

In reality, the critical step where decisions regarding terms of access and benefit sharing are made is step 6 in the decision chart where the Expert Committee on ABS applies its mind regarding a bioprospecting application. Prior to submitting a bioprospecting application for the consideration of the Expert Committee, the legal and technical advisors (step 4) are expected to have completed all enquiries regarding the application, ensured that the application is complete in terms of the necessary documentation and facilitated the consultation with the relevant bodies such as the BMCs and the SBBs (step 5).

It is only after these processes have been completed by the legal and technical advisors within the NBA will a bioprospecting application be placed before

### 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

41 See <<http://nbaindia.org/content/333/25/1/approval.html>> accessed 20 December 2013.

42 See <<http://nbaindia.org/uploaded/images/application-process-with-benefit-sharing-component-14-07-11.jpg>> accessed 20 December 2013.

the Expert Committee. Once the Expert Committee makes its decision, this decision is placed before the Secretary and Chairman of the NBA, who in turn place it for final approval before a full meeting of the NBA which consists of a Chairperson, 10 official representatives of the different relevant ministries and 6 non-official experts.<sup>43</sup> It is however rare that the full meeting of the NBA would disagree with the recommendations of the Expert Committee.<sup>44</sup>

## 9

### **CHALLENGES IN THE INDIAN BIOPROSPECTING APPROVAL PROCESS**

One of the key challenges we will focus on here is the requirement to enter into a full-fledged ABS agreement between the NBA and the bioprospector including benefit sharing as a condition of utilizing biological resources and associated knowledge.

The manner in which the quantum of benefits is determined is usually through a meeting of the Expert Committee on ABS.<sup>45</sup> The Expert Committee meets once every few months for about two days and usually makes recommendations on anywhere between 14- 25 ABS applications per meeting along with discussing various other related matters.<sup>46</sup> The Expert Committee therefore

effectively spends an inadequate 15-20 minutes per ABS application within which time it would have to not only comprehend the subject of the application and the nature of the industry or research sector that seeks to bioprospect but also determine what would constitute fair and equitable sharing of benefits.

ABS negotiations are unique due to the high levels of uncertainty involved. The cases before the Expert Committee are usually ones where neither the bioprospector nor the members of the Committee are able to specify the quantum of benefits likely to accrue at the early stages of research and development. Moreover the paradox in the approval process is that step 5 (the local consultation process) precedes step 6 (deliberation by the Expert Committee). The legal and technical staff of the NBA and the SBBs and BMCs (step 5) all rely on the Expert Committee to assist them in understanding the nature of the bioprospecting application, the potential benefits and the terms they should negotiate. However the Expert Committee ironically requires the completion of consultations with the SBBs and BMCs before deliberating on the application in question.

This situation is experienced time and again in the meetings of the Expert Committee. It's members find it difficult to assist the legal and technical staff of the NBA to ensure effective local consultations while at the same time determining value of a resource for a particular industry based on the exploratory phase of the research and insufficient information regarding market potential and various other imponderables. There are instances where bioprospecting applicants and industry bodies were asked to appear before the Expert Committee to clarify the nature and goals of the bioprospecting though in the author's experience, there have been no instances where the benefit claimers have appeared before the Expert Committee to discuss their preferred terms for the ABS agreement. While discussions with applicants and industry bodies clearly assisted the Expert Committee in its decision making, it also made it obvious to the experts that early stage bioprospecting in most cases involve several uncertainties making it very difficult to have a fair approximation of the benefits that are likely to be generated.

---

<sup>43</sup> Biological Diversity Act 2002, s 8.

<sup>44</sup> This view is based on the author's (Bavikatte) experience that during the nearly two years where he worked as a legal consultant to the NBA, a recommendation by the Expert Committee regarding benefit sharing was never rejected by a full meeting of the NBA.

<sup>45</sup> A committee of experts from various fields including law, science, economics, business, development etc. who are tasked with reviewing an ABS application and then determining what would constitute fair and equitable benefit sharing.

<sup>46</sup> From 2012-2014 the author worked as a legal consultant to the NBA and sat in on the Expert Committee meetings as a legal advisor to the process. The information presented here is based on the first hand experience of the author from these meetings.

At the same time the BD Act and Rules requires an ABS agreement as a pre-condition for any approval for the utilization of resources and knowledge from India. Given the limited amount of time that the Expert Committee has to apply its mind regarding a bioprospecting application and the fact that oftentimes the members of the Expert Committee don't have the domain expertise in the particular area relating to the application, it is unlikely that determination of benefit-sharing can be done with any degree of accuracy or deliberation. The members of the Committee are appointed by the full meeting of the NBA and the Chairman of the NBA usually provides the NBA with a list of suggested appointees. While the Chairman tries to ensure a wide range of expertise on the Expert Committee and includes some scientists and economists, it is still extremely difficult to ensure the distribution and depth of expertise in one committee of the varied and dynamic aspects of bioprospecting.

Due to the high volumes of bioprospecting applications for prior approval and the need to enter into an ABS agreement as a way of providing an approval for bioprospecting, the Expert Committee works on a standardized thumb-rule for determining benefits. The thumb-rule pre-sets the share of benefits in any ABS agreement and it is rare that there is any negotiation between the bioprospector and the NBA regarding benefit sharing. The bioprospector is essentially informed that this is the percentage or amount of benefits that is required by the NBA and this would be included in the model ABS agreement (step 10 of the decision chart) that the bioprospector would then be expected to sign. The lack of negotiation between the Expert Committee and the bioprospector regarding the quantum of benefit sharing tends to violate the letter of the BD Act which requires benefit sharing to be in accordance with 'mutually agreed terms' between the bioprospector, the local bodies from whose jurisdiction the resource was accessed and benefit claimers (local stewards of the biological resources and associated knowledge).<sup>47</sup> Moreover while the efficiency motives behind the thumb-rule approach is understandable, it clearly goes against the grain of BD Act which seeks to ensure that the local holders

of biodiversity (BMCs and benefit claimers) have a say in terms of access to their resources and the nature and share of benefits accrued therein.

The thumb-rule of the Expert Committee is usually an up-front payment for access to biological resources and associated knowledge for research, biosurvey or bioutilization or commercial use. Where the bioprospector seeks an approval for applying for an intellectual property right the Expert Committee will require the bioprospector to pay a royalty of 2.0-5.0% of the ex-factory sale price of the product sold or used for captive consumption. In situations where the bioprospector intends to license the process/product/innovation based on an Indian biological resource or associated knowledge for commercialization, the Expert Committee would require the bioprospector to pay 5% of the fee (in any form including the license /assignee fee) and an additional 5% of royalty amount received annually from the assignee/licensee as benefit sharing throughout the term of agreement. On the other hand, the Expert Committee may also require the assignee/licensee to enter into a tripartite agreement with the bioprospector and the NBA and agree to pay royalty 4% of the ex-factory sale price of the product sold and also used for captive consumption annually. Moreover the bioprospector shall also be required to pay 5% of the license fee (if any) received from licensee to NBA.<sup>48</sup>

The thumb-rule approach to benefit sharing by the Expert Committee has three reasons. First, the BD Act and Rules require approval for bioprospecting to be in the form of an ABS agreement which details not only terms of access and use but also benefit sharing; Second, the NBA has a limited amount of time and human resources to research the realistic commercial potential of every bioprospecting application especially considering the volume of applications it receives, and it needs to dispose each application within a period of six months; and finally, the decisions regarding bioprospecting applications

<sup>47</sup> Biological Diversity Act 2002, s 21.1.

<sup>48</sup> This information is based on the draft template on Benefit Sharing Guidelines. These Guidelines have not been formally issued by the NBA and are still under discussion. However the percentages of benefit sharing provided here are based on the standard practice of the Expert Committee.



are not made by the Secretariat of the NBA (the technical and legal officers, the Secretary or Chairman) but rather through two large committees (the Expert Committee and the full meeting of the NBA), with only periodic time bound meetings to conclude on large numbers of applications.

Hence a thumb-rule approach seeks to be an easy and standardized fix to challenges that arise from rules and decision-making arrangements developed more than a decade ago when the numbers of bioprospecting applications were few and far between. While concerns have been raised within the Secretariat of the NBA for a review of the Biodiversity Act and Rules and a simplifying of the bioprospecting approval process, there is still a long way to go before any changes will be put into effect. In the meantime, it seems like the thumb-rule approach is here to stay. In fact the thumb-rule approach is symbolic of the significant gap between law making and its implementation. In the context of Green Governance it highlights the chasm between the lofty aims of ABS law and policy and the reality of its implementation when the rubber meets the road where the first casualty tends to be the rights of the local stewards of biodiversity.

The thumb-rule approach to benefit sharing has caused a fair amount of concern amongst researchers and the private sector seeking bioprospecting permits from the NBA. Their main grievance is that the need to enter into full-fledged ABS agreements including upfront payments and pre-set percentages are premature at early stages of bioprospecting. Oftentimes it is nearly impossible to predict the likely benefits that are to accrue to the bioprospector at early stages of bioprospecting and a thumb rule approach in all fairness prevents them from actually 'negotiating' mutually agreed terms as required by the BD Act.<sup>49</sup> Moreover questions regarding the logic behind the thumb-rule and the pre-set percentages abound from both bioprospectors and NGOs. While the thumb-rule arises from the efforts of one of the earlier Expert Committees in consultation with a legal consultant to the NBA to establish Access Guidelines, it is clear that not only

is the thumb-rule highly dated, but also a result of insufficient discussions with the different sectors engaging in bioprospecting and BMCs on the ground.

The Expert Committee on the other hand is well aware of these problems but is of the view that this is the best possible approach considering the specificities of India's ABS legal framework.

## 10 EXAMPLES OF THE THUMB-RULE APPROACH

Some of the key examples of the thumb-rule approach have been highlighted in the briefing papers of the NBA. While some of these examples may not cleanly fit within a Nagoya Protocol approach of 'utilization of genetic resources,' they are nevertheless how the NBA interprets its mandate under the BD Act and Rules and its obligations under the Nagoya Protocol.

An interesting example to consider here is the one involving the seaweed (*Kappaphycus alvarezii*/ *Eucheimia cottonii*), 2000 tons of which has been exported by Pepsico India to countries like Malaysia, Philippines and Indonesia. As per the ABS agreement, the exporter paid the NBA 5% of FoB (Free on Board) costs of the seaweed amounting to around 3.9 million rupees.

Another case involves the export of around 2000 kilograms of neem leaves (*Azadirachta indica*) to Japan by the Bio India Biologicals Company. According to the ABS agreement, here too the 5% of FOB rule was applied and the NBA was paid a sum of 55,035 rupees as benefit sharing.

The thumb rule approach goes beyond bulk exports of Indian biological resources and extends to approvals by the NBA for patent applications. A much-publicized example by the NBA refers to an ABS agreement relating to the patenting of an anti-venom tablet by an Indian doctor. The benefits to

<sup>49</sup> Based on conversations conducted in the first quarter of 2013 between the author and legal advisors representing the bioprospectors.

be shared with the NBA as per this agreement were 2% of the gross sales of the final product.<sup>50</sup>

From the examples here, it seems that for better or worse, the thumb rule approach ensures that bioprospecting applications are cleared within a reasonable period given the challenges mentioned above. Nevertheless, this still leaves open the question of whether there are other possible approaches that could address the concerns of the Expert Committee within the limited regulatory and bureaucratic parameters in which it operates.

In the authors considered opinion, there could be a better solution to speedily process the high volumes of ABS applications while at the same time moving away from a thumb rule approach that is arbitrary and unpopular amongst not only bioprospectors but also communities on the ground who are keen on being actively involved in negotiating benefits arising from the use of their resources. It is this solution that we will elaborate upon here.

## 11 POSSIBLE SOLUTION

An approach adopted by countries such as South Africa<sup>51</sup>, Bhutan<sup>52</sup> and Australia<sup>53</sup> on processing bioprospecting applications could offer a possible solution to the NBA. In both these countries, like in India, situations abound where bioprospectors

seek access to genetic resources and/or associated traditional knowledge and are at a stage of research and development where they are unable to realistically quantify the benefits likely to accrue. However the regulatory frameworks in South Africa, Bhutan and Australia as we shall see below have been developed on the premise that situations like this are less an exception and more the rule. The national competent authorities in these countries regulating bioprospecting are uniquely empowered to provide bioprospectors access to the genetic resources and/or associated traditional knowledge without concluding a benefit sharing agreement.

In Bhutan and South Africa they are able to do so by virtue of being able to enter into what is called a 'scoping agreement.' A scoping agreement enables a bioprospector to conduct research on the genetic resource and/or associated traditional knowledge within an agreed period of time without benefit sharing. The bioprospector is authorized by the agreement to undertake only specified kinds of research activities and prohibited from any steps towards commercialization including market testing, product development, advertising, manufacturing and applying for intellectual property rights.

In Bhutan's case for example, the possible risks of a bioprospector being provided access to resources without a full-fledged benefit sharing agreement is countered by the bioprospector having to deposit an agreed sum of money in the national competent authority's trust account as a security deposit. The security deposit would be returned to the bioprospector at conclusion of the scoping agreement. If the research results are positive and the bioprospector intends to commercialize its findings, then it would then enter into a benefit sharing agreement with the national competent authority. The authority can also require the bioprospector in the scoping agreement to provide support to Bhutan's research sector through technology transfer and training.

In South Africa on the other hand, no such deposit is required, but rather clear conditions are laid down in the scoping agreement (or what they refer as the discovery phase of bioprospecting). These conditions include prohibitions on various kinds of activities that

50 National Biodiversity Authority, Access and Benefit Sharing Experiences from India <[http://nbaindia.org/uploaded/pdf/ABS\\_Factsheets\\_1.pdf](http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf)> accessed 12 December 2014.

51 See the South African National Environment Management: Biodiversity Act 2004.

52 The approach here is a part of Bhutan's draft ABS policy currently before the Bhutanese parliament for adoption. However the National Biodiversity Center in Bhutan, which is charged with regulating access to Bhutan's genetic resources and associated traditional knowledge, has already begun using this approach when dealing with bioprospecting applications.

53 See Christian Prip et al, 'The Australian ABS Framework: A Model Case for Bioprospecting?' (*Fridtjof Nansen Institute Report 1 2014*).

would be deemed as moving beyond the discovery phase into the commercialization phase. Furthermore, the scoping agreement prevents the bioprospector from transferring any of the acquired resources to third parties and is required to report back to the national competent authority at pre-agreed intervals to ensure effective checks and balances.

The system in the Australian federal legislation to distinguish between the discovery and the commercialization phase of bioprospecting does not involve scoping agreements. Instead it builds on two types of bioprospecting permits provided by the national competent authority. These are permits for commercial or potentially commercial purposes or non-commercial purposes. Permits for commercial or potentially commercial purposes require a benefit sharing agreement with the provider of the resource. Permits for non-commercial purposes do not require benefit-sharing agreements. However, applicants are required to provide a statutory declaration stating that they will not conduct, or allow others to conduct commercial research without entering into a benefit sharing agreement. The statutory declaration in Australia is a general means of declaring that the signatory undertakes responsibility for the statement. It includes a reference that the signatory understands the nature of the statement, and that s/he explicitly accepts criminal sanctions in cases of non-compliance.

The ABS regulatory frameworks of Bhutan, South Africa and Australia are built on an understanding that bioprospecting involves high levels of uncertainty and that many bioprospectors would be unable to specify the quantum of benefits likely to accrue at the early stages of research and development. An initial research or a scoping agreement for the discovery period with certain guarantees is intended take care of the interests of the bioprospector in identifying commercial viability and that of the governments for security. If the bioprospecting proves viable with an indication of a profit-generating outcome, then the ABS frameworks of these countries require a subsequent actualization or commercialization agreement that is based on a realistic estimate of benefits and a fair and equitable sharing of the same. Besides clarity regarding benefits, the added advantage of such an approach is that it fosters a

long-term partnership between the parties by ensuring collaborative problem solving with the common aim of maximizing benefits from bioprospecting, not to mention offering innovative options for non-monetary benefit sharing.

The breaking down of bioprospecting processes with scoping/research and actualization agreements allows for the much needed flexibility amidst the uncertainties of bioprospecting and facilitates faster agreements at the early stages while saving the difficult benefit sharing negotiations to a later stage when there is more clarity regarding research and development outcomes. Some companies and research institutions continue to raise concerns regarding the risks of investing large amounts of financial and human resources in research and development at the scoping phase without the guarantees of an actualization agreement should they discover something of value. Be that as it may, this two step approach is more advantageous for the bioprospector especially if the alternative is, as in the Indian context, being forced to enter into a full-fledged benefit sharing agreement based on pre-set percentages at a scoping stage where there is little or no clarity as to the outcomes of the bioprospecting.

We believe that the two-step approach could be adapted for the Indian context as it fits neatly into the framework of the BD Act and Rules as we show below. Its merit is that it does not require any amendments to the BD Act and Rules nor a restructuring of the bioprospecting approval process. Moreover it has the added advantage of effectively resolving the challenge of time-bound processing of the high volumes of bioprospecting applications the NBA receives.

## 12 USING SCOPING AND ACTUALIZATION AGREEMENTS UNDER THE BD ACT AND RULES

The BD Rules require that any approval for access to Indian biological resources and associated

knowledge shall be in the form of an agreement between the NBA and the bioprospector. The BD Rules even provide the elements of such an agreement including a requirement that lists the quantum of monetary and other incidental benefits and if required a commitment to enter into a fresh agreement particularly in case the biological material is taken for research purposes and later on sought to be used for commercial purposes or in case of any other change in use.<sup>54</sup>

It is therefore possible to read the BD Rules as providing the space for scoping and actualization agreements as a way for the NBA to provide approvals for different stages of bioprospecting. Section 3 of the BD Act requires the previous approval of the NBA to embark on any research, bio-survey and bio-utilization and commercial utilization of Indian biological resources and associated knowledge. Rule 14 of the BD Rules requires such an approval to be in the form of a contract between the NBA and the bioprospector. Section 3 of the BD Act read with Rule 14 of the BD Rules therefore allows for the NBA to enter into scoping agreements with bioprospectors. These scoping agreements can be used to provide speedy approvals for bioprospecting and can include specific restrictions as to what will not be allowed during the scoping phase of bioprospecting.

The scoping phase involving Indian biological resources and associated knowledge would be the initial exploratory phase of research and development with the aim of establishing market or research potential. This would be the phase where the Expert Committee, the benefit claimers and the bioprospector would find it hard to predict the nature and extent of benefits that could be derived from the resources and knowledge. The scoping phase can require a 'scoping agreement' with the NBA. The NBA, if satisfied with the information received from a bioprospector intending to engage in the scoping phase can issue the bioprospector with a scoping permit. This scoping permit shall be in the form of an agreement between the NBA and the bioprospector and will contain a set of conditions

for utilization, including the condition to secure a full-fledged benefit sharing agreement prior to entering into the actualization phase of bioprospecting. The scoping permit can be made conditional on the payment of a processing fee and a cash guarantee deposit returnable on the conclusion of the scoping phase (See Annex 1 for a Model Scoping Agreement).

The scoping agreement does not have to be devoid of all benefit sharing. It could along with guarantee deposits, also require technology transfer, collaboration with domestic research institutes, training, fellowships etc. In our opinion an innovative scoping agreement could lay the foundations of a long-term relationship between the NBA and the bioprospector and involve the sharing of different kinds of benefits depending on whether the research is at the discovery stage or the commercialization stage.

The actualization phase would then be the phase when specific steps are undertaken to commercialize or engage in focused research on Indian biological resources and associated knowledge. The actualization phase would include, but not be limited to applications for intellectual property rights, product testing and marketing. The actualization phase can only begin with an actualization permit issued by the NBA, which will be in the form of an ABS agreement between the bioprospector, and the NBA.

The reality of bioprospecting in India is however that only a fraction of the bioprospecting at the scoping phase) actually will lead to the actualization phase.<sup>55</sup> This is a situation similar to other countries with extensive bioprospecting. Under the federal Australian ABS legislation with two types of permits described above, all permits but one have been for non-commercial purposes and none of the non-commercial permit holders have so far come back to national competent authority to declare that their activity has developed into a commercial intent thus requiring a benefit sharing agreement. A large amount of time and energy of the Expert Committee

<sup>54</sup> Biological Diversity Rules 2004, Rule 14.6.

<sup>55</sup> See <<http://nbaindia.org/content/333/25/1/approval.html>> accessed 20 December 2013.

and the NBA is consumed because of the need to enter into full-fledged ABS agreements with details of the nature of benefits and how they will be shared when neither the Committee, the NBA nor the bioprospector can realistically estimate the quantum and likelihood of benefits.

By dividing bioprospecting in India under the BD Act and Rules into a scoping and an actualization phase the NBA can speedily process a large number of applications by requiring the bioprospectors to agree to scoping agreements that do not require determining benefits or any negotiations. Since only a fraction of those with scoping permits are likely to engage in actualization, the Expert Committee and the NBA can then effectively use its time and resources to effectively consult with the BMCs and benefit claimers and thereafter negotiate ABS agreements at the actualization phase when there is greater clarity regarding the benefits that will accrue.

Such an approach acts like a funneling system where a large number of initial applications are quickly disposed off through scoping contracts and the smaller number of ABS agreements can get the attention they deserve. Moreover this funneling system also foregrounds good Green Governance by ensuring that the rights of the BMCs and benefit claimers are effectively upheld by freeing up the time and resources required for effective consultations as required by the BD Act. Clearly there are risks involved in scoping agreements and this is because bioprospectors have rapid access to resources without entering into full-fledged benefit sharing agreements. But such a risk exists even without the two-step process. In fact the NBA currently faces huge challenges of monitoring and tracking the development of existing ABS agreements due to limited human resources and because a large amount of the efforts of the Secretariat is spent in processing the high volume of bioprospecting. All things considered, we believe that the adoption of the two-step approach to processing bioprospecting applications might ensure that the finite resources of the NBA are focused on negotiating and monitoring high quality ABS agreements with a clear understanding of the benefits that are likely to ensue.

## 13 CONCLUSION

Bioprospecting works with high levels of unpredictability. Bioprospectors embark on the research and development of genetic resources or associated traditional knowledge with varied levels of certainty regarding the ultimate product. The value chain beginning with the identification of genetic resources and/or associated traditional knowledge of potential value and culminating in the final commercial or research success is on many occasions a long and uncertain one. Furthermore ABS as an innovative financing mechanism for biodiversity conservation can only work if real benefits from bioprospecting can be generated and local rights to biodiversity are respected. This implies that both provider countries, communities and bioprospectors would have to engage in not only later stage benefit sharing but also early stage 'risk sharing'.

The risk incurred by the bioprospector is investing in the research and development of genetic resources and associated traditional knowledge with the possibility of failure. The risk that a provider country or a community would incur is providing access to its resources and knowledge with the chance that the bioprospector could default on obligations to share benefits. However this situation should not have to be dealt with by making it mandatory to enter into a full-fledged ABS agreement at the outset. Doing so results in negotiating in the blind escalating transaction costs and leading to perverse incentives.

Instead standard scoping agreements could be entered into resulting in simplified access by saving time and resources. The scoping agreements will bind the bioprospectors to specific uses of the genetic resources and associated traditional knowledge and require them to come back and negotiate ABS agreements if they intend to enter into the actualization or commercialization phase. Such an

approach has the dual benefit of incentivizing compliance by bioprospectors by radically reducing transaction costs and early-stage benefit-sharing burdens while at the same time reducing the workload of the competent national authorities tasked with approving bioprospecting. However, it is not necessary to enter into scoping agreements in every situation of bioprospecting and a final ABS agreement can be entered into at the outset. For certain kinds of new products, for e.g. specific fragrances or moisturizers,<sup>56</sup> the final output is clear at the beginning along with a fair understanding of market potential and possible revenues.

The scoping and actualization approach has been used with some success in Australia, Bhutan and South Africa, where ABS administrative structures that are much smaller than India's. India would do well to consider using a similar model. In the long run, the measurement of success of ABS as a financing model should depend on whether the benefits/revenues it generates outweigh the capital outlay in regulating it. If the costs of regulating ABS are far more than the benefits derived from it, then it is perhaps best that a country's investment into ABS is re-routed directly into conservation. In the Indian case, since 2002, its investment into the ABS regulatory system with the NBA, SBBs and BMCs has been far more than the benefits earned since the inception of the BD Act and Rules.<sup>57</sup> We hope that the solutions offered here would be a useful contribution in lessening the gap between India's investment into ABS and the benefits it derives from it.

---

<sup>56</sup> Based on information provided to the author by cosmetic manufacturers in South Africa negotiating an ABS agreement with the Bushbuckridge Traditional Healers Association.

<sup>57</sup> Based on conversations between the author and some of the staff at the Secretariat of the NBA.

*LEAD Journal (Law, Environment and Development Journal) is jointly managed by the  
School of Law, School of Oriental and African Studies (SOAS) - University of London  
<http://www.soas.ac.uk/law>  
and the International Environmental Law Research Centre (IELRC)  
<http://www.ielrc.org>*

