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HANDBOOK ON BIODIVERSITY LAWS, ACCESS AND BENEFIT SHARING

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PREFACE

CEERA, NLSIU has been involved in multiple environment related projects since its inception in 1997. It has contributed to not only research in these areas but also been active in consultancy and advocacy work in environment related issues. The Centre is currently the lead technical agency for the UNDP-GEF (Global ABS Project) and in the execution of the project has developed specific capacity in the area of Biological Diversity laws and Access and Benefit Sharing. This Handbook is a reflection of the research and expertise that the members of this Centre have gained from the Global ABS Project.

The Handbook on Biological Diversity and Access and Benefit Sharing is an attempt to contribute to the legal jurisprudence on the biodiversity law. We hope that all stake holders and persons interested will benefit from the reading of this book.

The handbook is not only going to help in the understanding, interpretation and analysis of the law and policy in the area of biodiversity conservation and sustainable use, but will also endeavour to clarify certain applications of the law which is pertinent considering the fact that the legal framework on biological diversity is still evolving.

This work deals with the practical implication of the Biological Diversity (BD) Act, 2002 on the industries making use of biological resources and the society at large. It discusses the process of adjudication, wherein further light is thrown upon the remedies and penalties under the Biological Diversity law. Monopolising the gifts of nature (biodiversity) which are available for use of all mankind in general is an area of concern and therefore it is important to reflect upon the relationship between biodiversity and intellectual property rights.

Access and Benefit Sharing is one of the three objectives under the Convention of Biological Diversity and India has been at the forefront in implementing the same. In relation to this, some of the success stories on access and benefit sharing have also been discussed in the Handbook.

The Handbook also deals with some of the ambiguous terms within the BD Act such as Value Added Products and scope of the term Commercial Utilisation, and tries to bring better clarity with respect to the same.

With the implementation of the BD Act, several questions have cropped up with regard to the ambit of the law and as to which industries should be regulated under its provisions? The next part of the handbook tries to address the above issues.

The following section deals with the perspective of industries on the application of the BD Act and tries to bring forth their views, grievances and suggestions for better implementation of the Act.

The BD Act consists of regulators and the regulated. The regulators are the State Biodiversity Boards and the National Biodiversity Authority while the regulated are the users of biological resources. Therefore the subsequent part shares the views of the regulator and the issues faced by them while implementing the BD Act.

Since the BD Act came into existence in 2002 one of the major issues was whether the regulations pertaining to Access and Benefit Sharing are applicable to body corporates, associations or organisations which do not have any non-Indian participation in its share capital or management. The Divya Pharmacy judgement has finally made it clear that even those entities which do not have any non-Indian participation in its share capital or management must share benefits on use of biological resources. This judgment along with its implications has been discussed in the next part.

The last part of the Handbook provides a Stakeholder's guide to the BD Act which will be helpful for the readers to get a better understanding of the law under the BD Act.

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This Handbook on Biodiversity Laws, Access and Benefit Sharing is a result of the of the research conducted by the Centre for Environmental Law, Education, Research and Advocacy (CEERA), NLSIU, Bengaluru. This work focuses more on the practical implications of the biological diversity law and concept and function of Access and Benefit Sharing in India.

The law on biodiversity is still in its infant stage and is therefore rapidly evolving. A number of issues remain to be settled and this handbook addresses a few of those issues.

We would like to express our sincere gratitude to Prof. (Dr.) R. Venkata Rao, Vice Chancellor, National Law School of India University, Bengaluru, for his continuous support and supervision in our research and also for motivating us in our efforts.

This handbook is a compilation of several chapters contributed by authors from academia, industry, and regulatory bodies. We are immensely grateful for their efforts and inputs for enriching the content in the handbook. Specifically we would like to acknowledge Dr. Shaber Ali, Associate Professor, V.M. Salgaocar College of Law, Goa, Dr. Suhas Nimbalkar, Partner, Eitimo Ventures LLP, Bengaluru, and Mrs. Veena P.G, Consultant-ABS, Karnataka Biodiversity Board for their contribution and expert opinions on the theory and practice of the Biological Diversity law, without which this Handbook would not have been possible.

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LIST OF ABBREVIATIONS

ABS	Access and Benefit Sharing
BD	Biological Diversity
BD Act	Biological Diversity Act, 2002
BHS	Biodiversity Heritage Sites
BMC	Biodiversity Management Committees
BRs	Biological Resources
CBD	Convention on Biological Diversity
CROs	Contract Research Organisations
DNA	Deoxyribo Nucleic Acid
ECs	Expert Committees
FDI	Foreign Direct Investment
FEBS	Fair and Equitable Benefit Sharing
GI	Geographical Indication
GMCL	Gram Mooligai Company Limited
GMOs	Genetically Modified Organisms
GP	Gram Panchayat
GRs	Genetic Resources
GST	Goods and Services Tax
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
NBA	National Biodiversity Authority
NGOs	Non-Governmental Organizations
NGT	National Green Tribunal

NRI	Non Resident Indians
NTAC	Normally Traded as Commodities
NUN	Novelty, Utility and Non-obviousness
PBRs	People's Biodiversity Register
PRI	Panchayati Raj Institutions
PPVFRA	Protection of Plant Varieties and Farmer's Rights Act
SBB	State Biodiversity Board
TBGRI	Tropical Botanical Garden and Research Institute
TK	Traditional Knowledge
TRIPS	Trade Related Aspects of Intellectual Property Rights
UBB	Uttarakhand Biodiversity Board
UNCED	United Nations Conference on Environment and Development
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

CONTENTS

INTERNATIONAL LAW FOR THE CONSERVATION OF BIOLOGICAL DIVERSITY : OVERVIEW

1

The concept of conservation of wildlife, flora and fauna in the early 20th Century International Legal regime can be found in many international legal instruments such as the International Convention for the Protection of Birds of 1950, Convention on International Plant Protection, 1951, Agreed Measures for the Conservation of Antarctic Fauna and Flora, 1964 etc. This phase marked the beginning of a growing awareness of environmental concerns. With the end of World War II and the unprecedented progress of science and technology, a parallel issue that drew the concern of the international community was that of the exploitation of the nature and its resources that seemed to be accompanying the technological progress.

The first International legal instruments to have noted the importance of environmental conservation and which are still widely regarded as the beginning of the international environmental jurisprudence were the United Nations Conference on Human Environment held in 1972 and the Ramsar Convention on Wetlands adopted in 1971.

1.1 International Legal Instruments on Biological Diversity and ABS

1.1.1 The Convention on Wetlands, 1971 (Ramsar Convention)

The Ramsar Convention on Wetlands is a major International Treaty with regard to environmental conservation. The Convention took place in the city of Ramsar, Iran in the year 1971. This Convention provides a framework for national and international cooperation for the conservation and wise use of wetlands and their resources.[1] The Convention came into force in the year 1975 and since then 169 countries i.e. almost 90% of the United Nations Member States have become contracting parties to the Convention.[2]

1 (Dec. 09, 2017), https://www.ramsar.org.

2 *Id.*

Under this Convention, the term Wetlands is applied to a various human made and natural habitats which range from lakes, coral reefs, swamps, peat bogs, marshes, bodies of waste (natural, artificial, temporary, and permanent). This instrument encourages the designation of sites that contain rare or unique wetlands, or wetlands that are important for conserving biological diversity.[3] These sites, once designated are added to the Convention's List of Wetlands of International Importance and become Ramsar Sites. The Contracting Parties to this Convention have a duty to protect and promote the conservation of such wetlands. India is one of the contracting parties to the Convention and the convention entered into force in India on 1st February 1982. India currently has 26 sites designated as Wetlands of International Importance (Ramsar Sites), with a total surface area of 689,131 hectares.[4]

Ramsar Sites in India[5]

No.	Name	Date of Declaration	State
1	Ashtamudi Wetland	19 Aug 2002	Kerala
2	Bitarkanika Mangroves	19 Aug 2002	Orissa
3	Bhoj Wetland	19 Aug 2002	Madhya Pradesh
4	Chandra Taal Wetland	08 Nov 2005	Himachal Pradesh
5	Chilika Lake	01 Oct 1981	Orissa
6	Deepor Beel	19 Aug 2002	Assam
7	East Calcutta Wetlands	19 Aug 2002	West Bengal
8	Harike Lake	23 March 1990	Punjab
9	Hokera Wetland	8 November 2005	Jammu and Kashmir
10	Kanjli Wetland	22 January 2002	Punjab
11	Keoladeo National Park	1 October 1981	Rajasthan
12	Kolleru Lake	19 August 2002	Andhra Pradesh
13	Loktak Lake	23 March 1990	Manipur
14	Nalsarovar Bird Sanctuary	24 September 2012	Gujarat
15	Point Calimere Wildlife and Bird Sanctuary	19 August 2002	Tamil Nadu
16	Pong Dam Lake	19 August 2002	Himachal Pradesh
17	Renuka Lake	8 November 2005	Himachal Pradesh
18	Ropar Wetland	22 January 2002	Punjab

3 *Id.*

4 (Dec. 09, 2017), https://www.ramsar.org/wetland/india.

5 (Dec. 09, 2017), https://rsis.ramsar.org/ris-search/?f[0]=regionCountry_en_ss%3AIndia&pagetab=1.

19	Rudrasagar Lake	8 November 2005	Tripura
20	Sambhar Lake	23 March 1990	Rajasthan
21	Sasthamkotta Lake	19 August 2002	Kerala
22	Surinsar-Mansar Lakes	8 November 2005	Jammu and Kashmir
23	Tsomoriri	19 August 2002	Jammu and Kashmir
24	Upper Ganga River (Brijghat to Narora Stretch)	8 November 2005	Uttar Pradesh
25	Vembanad-Kol Wetland	19 August 2002	Kerala
26	Wular Lake	23 March 1990	Jammu and Kashmir

Source: Ramsar Sites Information Service

1.1.2 United Nations Conference on Human Environment, 1972

The United Nations Conference on Human Environment also known as the Stockholm Conference was held in Stockholm, Sweden in June 1972. This conference was the 1st major conference on environmental matters by the United Nations. 114 Governments were represented by their delegates in this Conference and the resultant document was the Declaration of the United Nations Conference on the Human Environment which contained 26 principle regarding development and the environment such as safeguarding wildlife and natural resources, prevention of oceanic pollution and promotion of environmental education and human rights.

Most importantly, emphasis was placed on viewing development and preservation of environment as parallel objectives, not in opposition to each other. One of the Principles of the Declaration even states that Development was needed to improve the environment.[6]It even stressed the need for assisting developing countries in this aspect.[7]

Another document that came forward as a result of the Conference was the Framework for Environmental Action. This document was an Action Plan that consisted of a total of 109 recommendations related to the implementation of the Principles of the Declaration.

6 Principle 8, Declaration of the United Nations Conference on the Human Environment, 1972.
7 Principle 9, 10, Declaration of the United Nations Conference on the Human Environment, 1972.

1.1.3 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) was adopted with the objective of regulating the commercial trade in wild plants and animals that was happening worldwide. It was adopted in 1973 and entered into force in 1975 with the goal of ensuring that the existence and survival of any species was not threatened by international trade. From 1973 to present, the number of countries that are a party to the Convention has been steadily growing. The Convention was a result of a resolution adopted in a 1963 meeting of member countries of the International Union for Conservation of Nature. The parties to the Convention are obligated under this instrument to adopt their own domestic legislations to implement its objectives.

There are three classification made under CITES for threatened plants and species based on the level of threat they face.

Categories	Species Covered
Appendix I	• Species that are in danger of extinction. • Prohibits outright the commercial trade of these plants and animals. • Some may be transported internationally in extraordinary situations for scientific or educational reasons.
Appendix II	• Species that are not threatened with extinction but that might suffer a serious decline in number if trade is not restricted. • Their trade is regulated by permit.
Appendix III	• Species that are protected in at least one country that is a CITES member. • And the CITES member has petitioned others for help in controlling international trade in that species.

CITES has in the past many years held the distinction of being one of the largest international conservation agreements with about 183 Parties currently serving as members to the Convention. The Convention currently accords various degrees of protection to more than 35,000 species of animals and plants.[8]

1.1.4 Bonn Convention on Migratory Species (CMS)

The Convention on Migratory species (CMS) or the Convention on the Conservation of Migratory Species of Wild Animals or also popularly known as the Bonn Convention

8 (Dec. 09, 2017), Convention on International Trade in Endangered Species of Flora and Fauna, https://www. cites.org/eng/disc/what.php.

was signed in the year in 1979 in Bonn, Germany and entered into force in 1983 with the objective of garnering international cooperation in the conservation and sustainable use of migratory animals and their habitats.[9] The CMS is an environment treaty formed under the aegis of the United Nations Environment Programme that looks into conservation of migratory species, their habitats and migration routes and aims for cooperation and coordination with various stakeholders such as NGO's, media, international organizations etc. to achieve those objectives.

There are 2 classification made under CMS for Migratory species:

Categories	Species Covered
Appendix I	• Migratory species threatened with extinction • Parties to the CMS strive towards: i. strictly protecting these animals, ii. mitigating obstacles to migration iii. conserving or restoring the places where they live iv. controlling other factors that might endanger them
Appendix II	• List of Migratory species that need or would significantly benefit from international co-operation • Conclude Agreements covering the conservation and management of migratory species in Range States (any nation that exercises jurisdiction over any part of a range which a particular species inhabits, crosses or overflies at any time on its normal migration route.)

Source: http://www.cms.int/en/node/3916

As of 1 December 2017 the Convention on Migratory Species has 126 Parties and it provides an overarching framework for all efforts to conserve migratory species. CMS and the agreements formed under it provide policy guidance on various issues regarding conservation measures through resolutions, action plans, decisions etc.[10]

1.1.5 Convention on Biological Diversity (CBD)

The international legal instrument that is probably the most crucial with regard to Biological Diversity is the Convention on Biological Diversity, which is a multilateral treaty that aims at achieving the three main goals[11]of:

9 (Dec. 09, 2017), http://www.cms.int/en/legalinstrument/cms.
10 (Dec. 09, 2017), http://www.cms.int/en/parties-range-states.
11 (Dec. 09, 2017), https://www.cbd.int/intro/default.shtml.

- conservation of biological diversity
- sustainable use of biological diversity
- fair and equitable sharing of the benefits arising from the use of genetic resources

The CBD was opened for signature in Rio De Janeiro during the Earth Summit in 1992. It was in 1988, that the United Nations Environment Programme convened an Ad Hoc Working Group of Experts on Biological Diversity where the idea of an international convention on Biological Diversity was conceived and soon after that in 1989 an Ad Hoc Working Group of Technical and Legal Experts was convened to prepare an international legal instrument for the conservation and sustainable use of biological diversity.[12] It was for the first time with the coming into force of this convention, that conservation of Biological Diversity was recognized as a "common concern of humankind" in international law.[13]

The CBD's governing body is the Conference of the Parties (CoP), which includes all the countries that have ratified the treaty. The CoP which includes the representatives of all the Parties to the Convention meet every two years to review progress, set priorities and commit to work plans.[14] 196 parties till date have ratified the Convention. India signed the treaty in 1992 and ratified the Convention in 1994.[15]

CBD is considered to be the key international instrument on sustainable development and also reaffirms the sovereign rights of nations over their biological resources. With regard to the duties of the States parties to the convention, Article 6 of the CBD enjoins certain obligations on them which require each contracting party to:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

12 (Dec. 09, 2017), https://www.cbd.int/history/default.shtml.
13 *Id.*
14 (Dec. 09, 2017), http://www.un.org/en/events/Biological Diversityday/convention.shtml.
15 (Dec. 09, 2017), https://www.cbd.int/information/parties.shtml.

The two relevant supplementary agreements to the Convention on Biological Diversity are:

1.1.5.1 The Cartagena Protocol on Biosafety

The CBD is the main international instrument for addressing Biological Diversity issues in a holistic and comprehensive way. Under the CBD, Biosafety is one of the issues that has been especially focused on. The concept of Biosafety refers to the need to protect human health and the environment from any possible adverse effects of the products of modern biotechnology.

At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care.[16] The Convention recognizes these twin aspects of modern biotechnology. The Protocol on the one hand provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity[17] and on the other hand also seeks to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health.[18]

It was in 1995 at the second meeting of the Conference of the Parties to the Convention, that an Open-ended Ad Hoc Working Group on Biosafety was established to develop a draft protocol on biosafety. This draft was to specifically focus on the transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.[19]

16 Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal: Secretariat of the Convention on Biological Diversity. (Dec. 16,2017), https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

17 Article 16 and Article 19, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity. (Dec. 16, 2017), https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

18 Article 8(g) and Article 19, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Secretariat of the Convention on Biological Diversity, (Dec. 16, 2017), https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

19 *Supra at* 16.

In January 2000, after several years of negotiation, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was finalized and adopted in Montreal. The Cartagena Protocol is considered to be a major step forward in the matter of Biosafety and the enabling of an environment for environmentally sound application of biotechnology while minimizing the possible risks to human health and environment. Currently the Protocol has 171 countries as Parties with the latest ratification being that of Kuwait on June 1st 2017.[20]

1.1.5.2 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 was adopted at the tenth meeting of the CoP to the CBD held in Nagoya in October 2010. This Protocol was adopted with the aim to further advance the implementation of the third objective and relevant articles[21] of the CBD. The said third objective and relevant articles called for negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources.[22]The CoP in its 10th meeting mandated its Ad Hoc Open-ended Working Group on Access and Benefit sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing.

The Nagoya Protocol was finally adopted in 2010 in Japan after 6 years of negotiations.[23] The Protocol aims to deliver greater legal certainty and transparency for both providers and users of genetic resources. The Protocol encapsulates specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing

20 (Dec. 16, 2017), https://bch.cbd.int/protocol.

21 Articles 15 (Access to Genetic Resources) and Article 8(j) (Traditional Knowledge), 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, Secretariat of the Convention on Biological Diversity (Dec. 13, 2017), https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

22 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, Secretariat of the Convention on Biological Diversity (Dec. 13, 2017), https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

23 Convention On Biological Diversities, Parties To Nagoya Protocol, (Dec. 13, 2017), https://www.cbd.int/abs/nagoya-protocol/signatories/.

genetic resources and contractual obligations reflected in mutually agreed terms. These are done with the objective of ensuring the sharing of benefits when genetic resources leave a Party nation that is providing the resource.[24] The Protocol also looks into the access to traditional knowledge held by indigenous and local communities when it is associated with genetic resources and the strengthening of the ability of these communities to benefit from the use of their knowledge. India ratified the Protocol in 2012 and there are currently 101 Parties to the Agreement.[25]

1.1.6 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

In 1983, the Commission on Genetic Resources for Food and Agriculture was established, and the voluntary International Undertaking on Plant Genetic Resources was adopted. This was done taking into account the importance of the need to conserve and sustainably use plant genetic resources for food and agriculture, which the Treaty states is key to ensuring that the world will produce enough food to feed its growing population in the future.[26]

In 1996, another major step was taken at the Leipzig International Technical Conference on Plant Genetic Resources where a Global Plan of Action was adopted. All this work culminated in 2001 with the historic adoption of the legally binding International Treaty on Plant Genetic Resources for Food and Agriculture which entered into force in 2004.[27]

This Treaty was adopted by the Thirty-First Session of the Conference of the Food and Agriculture Organization of the United Nations on 3 November 2001 and as of 2017 has 144 contracting Parties.[28]

24 *Supra at* 22.

25 Convention On Biological Diversities, Parties To Nagoya Protocol, (Dec. 13, 2017), https://www.cbd.int/abs/nagoya-protocol/signatories/.

26 Food and Agricultural Organisation of the United Nations, (Dec. 15, 2017), http://www.fao. org/plant-treaty/overview/en/.

27 *Id.*

28 Food and Agricultural Organisation of the United Nations, (Dec. 15, 2017), http://www.fao. org/fileadmin/user_upload/legal/docs/033s-e.pdf.

The Treaty aims at:[29]

- recognizing the enormous contribution of farmers to the diversity of crops that feed the world;
- establishing a global system to provide farmers, plant breeders and scientists with access to plant genetic materials;
- ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.

The Treaty, popularly known as the Seeds Treaty is considered to be an International agreement in consonance with the CBD, aimed at the sustainable use of Plant genetic resources, conservation of such resources for food and agriculture, and fair and equitable benefits arising from its use. The Treaty in order to find a solution to the issues of access and benefit sharing of plant genetic resources employs a Multilateral System wherein 64 of the most important crops (these crops together account for 80 percent of the food we derive from plants) are put into an easily accessible global pool of genetic resources, which is freely available to potential users in the Treaty's ratifying nations for some uses.[30]

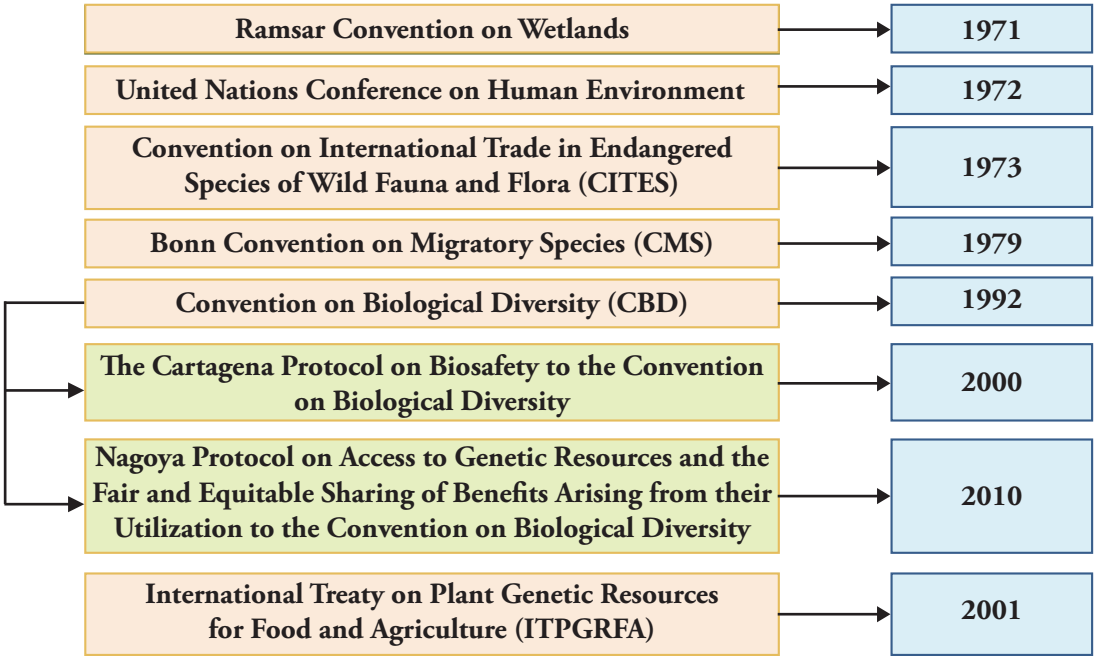
Through this Treaty, access to the genetic materials of the said 64 crops is facilitated for training, food and agriculture, breeding and research. The persons accessing the above mentioned resources are required to be from the ratifying nations to the Treaty and share benefits according to the Benefit Sharing arrangements laid out in the Treaty. Another important aspect of the Treaty is that it prevents the recipients of genetic resources under the Treaty from claiming intellectual property rights over those resources in the form in which they were as well as the mandate of protection of Farmers Rights.[31]

29 *Id.*

30 *Id.*

31 Food and Agricultural Organisation of the United Nations, (Dec. 15, 2017), http://www.fao. org/3/a-i0510e.pdf.

Conventions and International Legal Instruments on Biological Diversity and ABS



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INTRODUCTION TO BIOLOGICAL DIVERSITY ACT, 2002: LAW, POLICY AND PRACTICE

2

In 2002, the Government of India enacted the Biological Diversity (BD) Act in order to achieve the obligations prescribed under the Convention on Biological Diversity (CBD), an internationally legally binding agreement that was adopted in 1992. India became a party to the CBD in 1994 and enacted the BD Act and subsequent Rules in 2004 to adopt the goals of the CBD nationally, which is to conserve biological diversity, ensure sustainable use of its components and to have fair and equitable sharing of the benefits arising from genetic resources.[1]

There are two relevant protocols that have been adopted under the CBD.

a. The Cartagena Protocol on Biosafety in 2000 and
b. the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2010.

Before the CBD came into being, biological resources were considered common heritage of mankind and were exchanged freely. The country providing raw material for developing useful products rarely ever got any benefits from commercialisation of those products. This situation was perceived to be inequitable, especially by the biodiversity rich countries and that is why the concept of Access and Benefit Sharing was introduced in CBD.

The first protocol of CBD is the Cartagena Protocol on Biosafety for regulating the movement of living modified organisms between countries. After several years of negotiation, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was finalized and adopted in Montreal in 2000. This Protocol is considered to be a major step forward in the matter of Biosafety and has helped enable a situation for the environmentally sound application of biotechnology and the use of living modified organisms while minimizing the possible risks to human health and environment.

1 *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 Convention on Biological Diversity, United Nations (2011), https:// www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

The second protocol of CBD is the Nagoya Protocol which focuses on Access and Benefit Sharing (ABS). India along with other megadiverse countries played an important role in shaping the Protocol. ABS refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).[2]

The benefits to be shared can be monetary, such as sharing royalties when the resources are used to create a commercial product, or non-monetary, such as the development of research skills and knowledge.[3]

In order to implement the provisions of the Biological Diversity Act, the National Biodiversity Authority, the State Biodiversity Boards (SBBs) and local level Biodiversity Management Committees (BMCs) were established under the BD Act in 2002. With respect to ABS, the NBA deals with requests for access to bio resources and granting approvals for access subject to the mutually agreed terms and conditions set forth in the ABS Agreement. This is done in order to ensure equitable sharing of benefits from the use of biological resources and associated knowledge.

The structural and procedural framework for accessing biological resources and sharing the benefits of that access has been extensively dealt under the Biological Diversity Act, 2002.

2.1 Existing and the Historical Development of Policies on ABS and BD

Prior to the enactment of the Biological Diversity Act in 2002, there was no formal legal regime regarding conservation of biodiversity, access to and sharing of benefits from the access to bio resources and traditional knowledge. Article 6 of the Convention on Biological Diversity of which India became a signatory in 1992, states that the Parties to the Convention must prepare their own strategies, plans and policies to ensure conservation and the sustainable use of bio resources. Post the CBD, a National Policy and Macro level Action Strategy on Biological Diversity was developed and submitted to the CBD secretariat.

2 Evason Chege Kamau & Gerd Winter & Peter-Tobias Stool, Research and Development on Genetic Resources: Public Domain Approaches In Implementing The Nagoya Protocol Routledge (2015).

3 *Id.*

This was done after an extensive consultative process with the relevant stakeholders and after getting approval of the Committee of Secretaries in 1999.[4]

The Ministry of Environment and Forests, in 2002, finally implemented the National Biological Diversity Strategy and Action Plan (NBSAP). Under this Plan multiple action plans were made for the conservation of biological diversity. On the basis of these action plans, a final technical report of NBSAP project was prepared. This report, though accepted, could not be adopted until a National Environment Policy (NEP) existed. So after the Cabinet approval of the NEP in 2006, the National Biodiversity Action Plan (NBAP) was prepared by utilizing and revising the two reports (the National Policy and Macro level Action Strategy and the technical report: National Biodiversity Strategy and Action Plan) while also taking into account congruence of the said reports with the National Environmental Policy. The NBAP was approved by the Cabinet in 2008.[5]

Along with the preparation of the National Biodiversity Strategy and Action Plan (Article 6), the CBD enjoins another mandatory unqualified obligation on its Parties. Article 26 of the Convention on Biological Diversity requires the parties to present continuous National Reports to the Conference of the Parties (CoP) regarding the measures taken by the member Nations for the implementation of the Convention and the effectiveness of those measures. Currently five National Reports have been presented by India. The fifth Report was presented in March 2014 and the sixth was submitted in December 2018.[6]

Before the Convention on Biological Diversity came into being, it was considered that bio resources were the common heritage of mankind and were free for exchange.[7] But as instances of bio piracy and other countries extracting the resources of biodiverse rich nations for commercial gains rose, it was perceived that steps need to be taken to counter the inequity that the bio diverse countries, which were also not very economically well to do, were facing. Due to such instances, the concept of Access and Benefit Sharing was

4 Ministry of Environment and Forests GOI, National Biological Diversity Action Plan (NBAP), The Ministry of Environment And Forests, GoI (Nov. 11, 2017), http://envfor.nic.in/division/nationalBiological Diversity-action-plan-nbap.

5 *Id.*

6 Press Information Bureau, GOI, Ministry of Environment Forest and Climate Change, (Jan 11, 2019) http: pib.nic.in/newsite/PrintRelease.aspx?relid=186916.

7 The Convention on Biological Diversity, United Nations Environment Programme, (Nov. 12, 2017), https:// www.cbd.int/gbo1/chap-02.shtml.

introduced in the CBD. The Convention reaffirmed the sovereign Rights of the States over their genetic resources and gave authority to National Governments to legislate the manner in which such resources could be accessed and benefits could be shared.[8]

The Nagoya Protocol, which is a supplementary agreement to the CBD entered into force on the 12 Oct 2014 and aimed to further develop the Access and Benefit sharing framework that was provided by the CBD.[9] India has designated the Ministry of Environment Forests and Climate Change as its national focal point and the National Biodiversity Authority as the competent national authority for the Nagoya Protocol.[10]

The Indian Constitution encompasses the protection of Environment and this sentiment is enshrined in Article 48A[11] and 51A ((g))[12] which states that "the State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country and that it shall be the duty of every citizen of India to protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures."

In efforts to realise the Constitutional mandate of environmental protection, India has planned and executed multiple policies, programs and laws. One of the important laws in relation to biodiversity access, utilization and conservation and bringing into effect the Convention on Biological Diversity (CBD) is the Biological Diversity Act 2002. There are about 36 Acts and Rules related to Biological Diversity in India such as the Indian Forests Act, 1927, the Air (Prevention and control of Pollution) Act 1981, Protection of Plant varieties and Farmer's Rights (PPVFR) Act, 2001 etc.[13] India was one of the first few countries to bring about a comprehensive legislation on Biological Diversity conservation

8 COP 10 Decision X/1, UNITED NATIONS ENVIRONMENT PROGRAMME (Nov. 12, 2017), https://www.cbd.int/ decision/cop/?id=12267.

9 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, Convention on Biological Diversity United Nations,(2011), https://www. cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

10 COP 10 Decision *Supra at 8.*

11 INDIA CONST. art. 48, cl. A.

12 INDIA CONST. art. 51, cl. A. sub cl. g.

13 Ministry of Environment, Forest and Climate Change, Convention on Biological Diversity, Biological Diversity Act and Related Issues, The Ministry Of Environment And Forests, GOI, (Nov. 12, 2017), http://www.moef.gov.in/sites/default/files/Biological%20Diversity.pdf.

and the BD Act and Rules notified in 2004 give effect to the various objectives of the CBD along with the provisions relating to Access and Benefit sharing.[14]

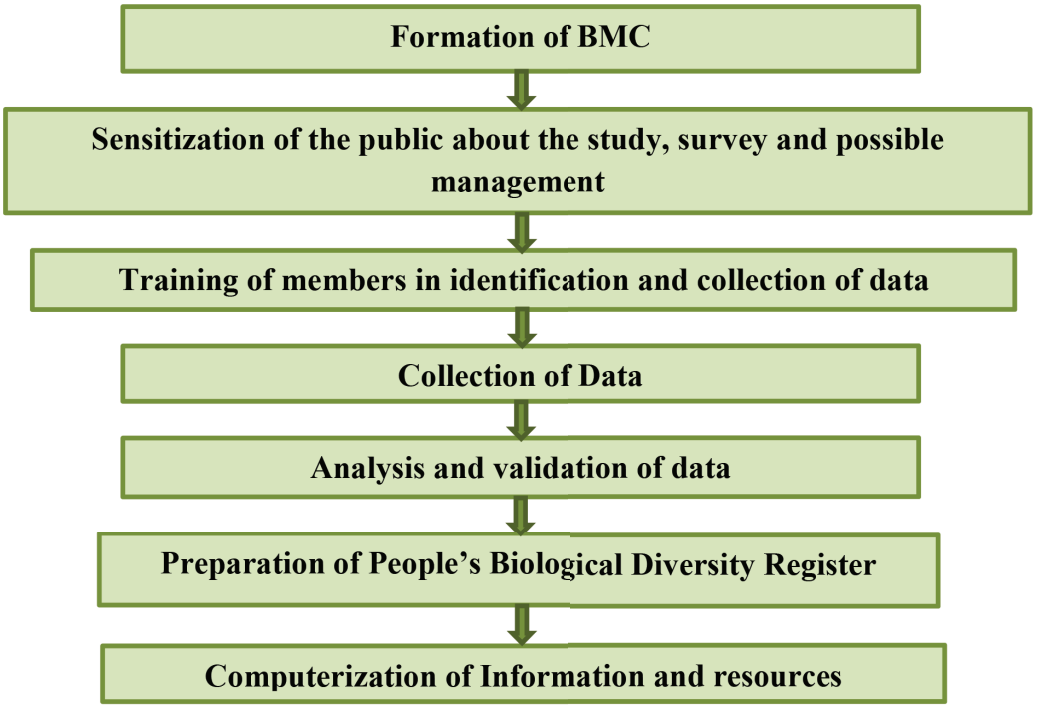
2.2 The Biological Diversity Act Discussed with Focus on the Procedural Aspects as well as the Functions of the Authorities Under the Act

The Access and Benefit Sharing mechanism, which is set out in the Nagoya Protocol is implemented in India through the domestic legislation, Biological Diversity Act 2002 and is done so through a three tiered mechanism: the National Biodiversity Authority (NBA), State Biodiversity Boards (SBBs) and local level Biodiversity Management Committees (BMCs). The Biodiversity Management Committees which are at the local level are required to prepare People's Biodiversity Registers (PBRs). These registers are maintained to contain all the information on local biological resources and associated knowledge. The State Biodiversity Boards (SBBs) are constituted by the State Government and are required to deal with applications and matters related to access to biological resources and traditional knowledge that are made by Indians.[15]

Matters relating to requests for access to biological resources and associated knowledge (AK) by "non-Indian individuals or entities (body corporates/associations/organizations) having non-Indian participation (in its share capital/management)"for research and/or commercial utilization; for transfer of results of research by any person (Indians/non-Indian individuals/entities) to non-Indian individuals or entities with non-Indian participation is dealt with by NBA. Also, applications from any person seeking approval before applying for an Intellectual Property Right (IPR) based on research/information on biological resources obtained from India is dealt by NBA. Further, NBA also deals with applications for transfer of the approved biological resources and/or AK to a third party, the approval from NBA is mandatory. NBA grants approvals subject to mutually agreed terms and conditions on the access to biological resources and/or AK which is set forth in the ABS Agreement so as to make the sharing of the benefits more equitable.[16]

14 Section 41 (1), the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
15 Section 23 (b), the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
16 Section 19, 20, 21, the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

People's Biodiversity Registers Preparation Process



The BD Act exempts certain persons from the obligation of taking approval or permission from the authorities for access to biological resources and associated knowledge. These persons include local people and communities that have free access to such resources, cultivators, growers, vaids and hakims or practitioners of traditional medicinal systems. The exemptions also include a list of biological resources referred to as Normally Traded Commodities (NTC) that have been notified by the Central Government in exercise of the powers conferred by Section 40 of the Biological Diversity Act 2002.[17] The list includes commodities such as Barley, Common Millet, Bengal Gram, Ground Nut, Rice bean etc. and consists of 385 commodities in total with subcategories of certain items. Since these

17 Ministry Of Environment, Forest and Climate, 2016, Change, No., S.O. 1352(E), Acts Of Parliament, 2016. (India).

are food crops and forages, they are exempted from Section 3[18] & Section 4[19] of Biological Diversity Act 2002.

Sections 3 and 4 are also not applicable to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government sponsored institutions of India, and such institutions in other countries.[20] The collaborative research projects shall have to conform to the policy guidelines issued by the Central Government and have approval by the Central Government.[21]

The provisions of the Act also states that all collaborative research projects that were based on agreements concluded before the commencement of the Act and in force, will, to the extent the provisions of agreement are inconsistent with the provisions of this Act or any guidelines stated in the Act, be void.[22] This provision applies to collaborative research projects other than the projects that are mentioned in Section 5(1) of the Act.

18 Section 3(2), National Biological Diversity Authority, 2002, No. 18 of 2003, Acts of Parliament, (India).

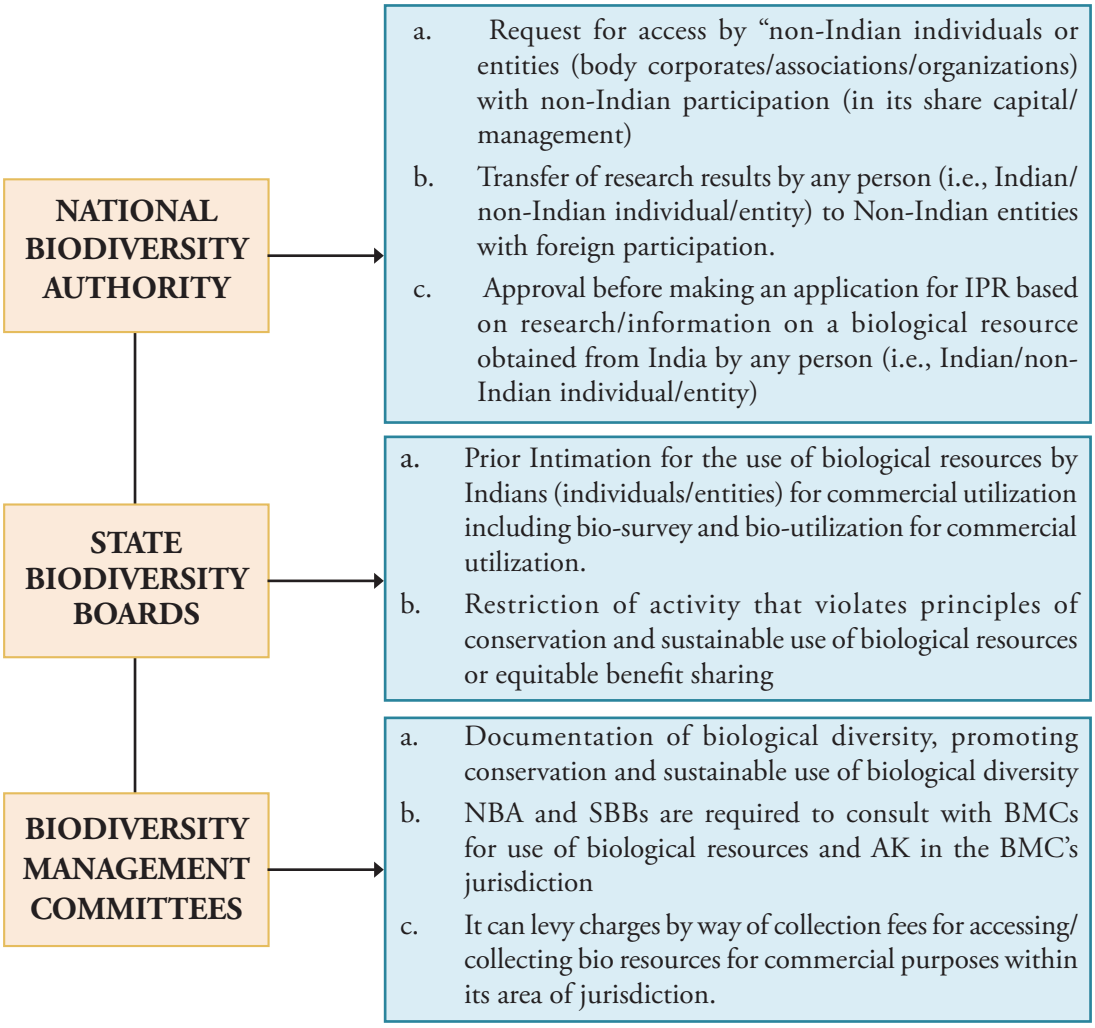
19 Section 4, National Biological Diversity Authority, 2002, No. 18 of 2003, Acts of Parliament, (India). "No person shall, without the previous approval of the National Biological Diversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961 or a body corporate or organization which Is not registered or incorporated in India or which has any non-Indian participation in its share capital or management".

20 Section 5(1), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

21 Section 5(3), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

22 Section 5(2), the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

Authorities, jurisdiction and responsibility for Access and Benefit Sharing in India



2.3 Regulation of Access to Biological Diversity

Chapter II of the BD Act of 2002 deals with the Regulation of Access to biological diversity. Section 3 of the said Act deals with persons who are not to undertake biological diversity

related activities without approval of NBA. Section 3(1) of the Act is applicable to the persons mentioned in sub section (2) of Section 3 which includes (a) a person who is not a citizen of India; (b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961; (c) a body corporate, association or organization which is not registered in India or incorporated or in India under any law for the time being in force or which has any non-Indian participation in its share capital or management.

Section 3(1), which is probably the most important provision of the BD Act states that "no persons mentioned in Section 3(2) as stated above shall obtain any biological resources occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization without the approval of NBA."

Definitions of terms present in Section 3(1) in the Biological Diversity Act 2002

Biological Resources [Section 2(c)]	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;
Value added products [Section 2 (p)]	Products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form.
Research [Section 2 (m)]	Study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use.
Commercial Utilization [Section 2(f)]	End uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.
Bio-Survey And Bio-Utilization [Section 2 (d)]	Survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterization, inventorisation and bioassay.

Another important provision of the BD Act with respect to regulation of Access is Section 4. This Section deals with the transfer of results of research to certain persons without the approval of NBA. The provision states that "No person shall, without the previous approval of the National Biodiversity Authority, transfer the results of any research relating to any biological resources occurring in, or obtained from, India for monetary consideration or otherwise to any person who is not a citizen of India or citizen of India who is non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961 (43 of 1961) or a body corporate or organisation which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management."

The explanation to this particular section elucidates that the term 'transfer' is not to include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government. This explanation of the term transfer is applicable only for the purpose of this section. I.e. Section 4.

The next Section i.e. Section 5(1) lays down the instances where Sections 3 and 4 regulating access would not apply. Section 5(1) talks about certain collaborative research projects and the non-applicability of Sections 3 and 4 to such projects. The Section states that "The provisions of sections 3 and 4 shall not apply to collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions, including Government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions specified in sub-section (3)."

Subsection 3 of Section 5 states what collaborative research projects are included for the purpose of Section 5(1). Projects that (a) conform to the policy guidelines issued by the Central Government in this behalf; (b) are approved by the Central Government would be considered as collaborative research projects for the purpose of Section 5(1).

Section 5(2) further talks about collaborative research projects which are based on agreements that were concluded before the commencement of the BD Act. It states that "All collaborative research projects, other than those referred to in sub-section (1) which are based on agreements concluded before the commencement of this Act and in force

shall, to the extent the provisions of agreement are inconsistent with the provisions of this Act or any guidelines issued under clause (a) of sub-section (3), be void."

Section 6 of the BD Act, 2002 talks about prior approval from the NBA before an application for Intellectual Property Rights is made. Section 6(1) states that "No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application".

The provisos to Section 6(1) state that "if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned" and "that the National Biodiversity Authority shall dispose of the application for permission made to it within a period of ninety days from the date of receipt thereof."

The subsections to Section 6 cover other aspects related to Intellectual property rights in relation to the BD Act.

Important Sections of the Biological Diversity Act, 2002

Sections of BD Act 2002	Activity Covered	Purpose
Section 3	Obtainment of any biological resource occurring in India or knowledge associated thereto.	Research, Commercial Utilization, Bio-survey and Bio-utilization.
Section 4	Transfer of results of any research relating to any biological resource occurring in, or obtained from India, to any person covered under Section 3.	Transfer of research results for monetary consideration or otherwise.
Section 6	Application of any IPR in or outside India for any invention based on any research or information on a biological resource obtained from India	Obtaining IPR, by whatever name called, in or outside India.

Section 5(exemption from S. 3 & 4)	The collaborative research project must be between institutions including government sponsored institutions and such institutions in other countries. • The collaborative research project must be approved by the Central Government. • The collaborative research project must conform with the Central Government guidelines	Transfer or exchange of biological resources or information relating thereto between the collaborating institutions. No IPR exemption is provided.
Section 19	Submission of application to NBA for prior approvals under Sections 3, 4 and 6. • All application to be accompanied by fee prescribed. • NBA to make enquiries as it may deem fit. • NBA to consult an Expert Committee if necessary. • Approve or reject the application.	Rule 14, 17 and 18 of the Biological Diversity Rules, 2004, read with Form I, II and Form III thereto are the applicable provisions for applications under Sections 3, 4 and 6 respectively.
Section 20	***Procedural Provisions:*** Submission of application to NBA for prior approvals for transfer of biological resources already accessed as per Section 19, to third parties. All application to be accompanied by fee prescribed. NBA to make enquiries as it may deem fit. NBA to consult an Expert Committee if necessary. Approve or reject the application.	Rule 19 of the Biological Diversity Rules, 2004, read with Form IV thereto are the applicable provisions for applications under Section 20.

2.4 Procedures for Access and Benefit Sharing

The Act lays out a fairly straightforward procedure for access for the purposes of research, commercial utilization, obtaining approval before applying for an IPR or for transfer to a third party within or outside India. The procedure includes submission of an application to the NBA for non-Indian entities with foreign participation and intimation to SBBs

when it comes to Indian entities. In both instances a final agreement cannot be signed unless there is consultation with the concerned BMCs at the village or urban ward level.

The request for access to biological resources or AK is required to be made to the NBA in the prescribed Forms listed at the end of the BD Rules, 2004. Once the request is accepted, agreements in the prescribed format are signed between the NBA and the applicant. Today, agreements between the NBA and the applicant require payment of royalty fees which changes on a case to case basis and are regulated by the ABS Guidelines 2014. When NBA grants approval for research for commercial utilization, for transfer of results of research, for Intellectual Property Rights or for third party transfer, a charge equivalent to 5% of accrued benefits is applied, out of which half of the amount is retained by the NBA and the other half may be passed on to the concerned SBB for administrative charges.[23] 95% of the accrued benefits are supposed to go to the concerned BMCs and/ or benefit claimers.[24]

Types of Access Applications to the NBA and the Application Fees

TYPE	FEE
Application for Access to Biological Resources and/or AK(Form I)	**Rs. 10,000**
Application seeking approval for transferring results of research (Form II)	**Rs. 5000**
Application for seeking prior approval of NBA for applying for Intellectual Property Right (Form III)	**Rs. 500**
Application for 3rd party Transfer (Form IV)	**Rs.10,000**

Currently, there is one Expert Committee (EC) that looks into the matter of ABS out of the 5 total expert committees that are presently appointed under the NBA. This committee is called the Expert Committee on Access and Benefit Sharing for Processing the Applications (EC-ABS). In 2009, it was decided that the Expert Committee on Access, Patent, Transfer of Research Results and Third Party Transfer and the Expert Committee on Determination of Benefit Sharing would be merged into one. So EC-ABS is a merger of both the above

23 Section 15(a), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014.

24 Section 15(b), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014.

mentioned committees. It is considered as a standing committee and its function is to provide guidance to the Authority in the matter of processing applications that are received and deciding on the benefit sharing component.[25]

2.4.1 Procedures for Access

The main function of the NBA is to deal with requests for access to biological resources and/or associated knowledge by "non-Indian individuals or entities (body corporates/associations/ organizations) with non-Indian participation (in its share capital/management)"and also deal with applications from any persons (both Indians/non-Indian individuals/entities) with respect to transfer of research results to a non-Indian individual/entity with foreign participation or for applying for an IPR or transfer to a third party.

NBA can grant approval subject to any regulations or conditions as it deems fit including the imposition of charges by way of royalty.[26] Any persons mentioned above making an application for access to biological resources and/or associated knowledge for the purpose of research and/or commercial utilization or bio-survey and bio-utilization must make the application under the form and payment prescribed.[27]

The NBA on the receipt of the application can make enquires as it deems fit and if necessary consults an expert committee constituted for this purpose. After doing the above, it can grant approval subject to certain conditions and regulations as discussed above. In cases where the application is rejected by the NBA, it must record the reason for the same in writing.[28] It is mandatory that the NBA provide an opportunity of being heard to the person affected in cases where an order for rejection has been passed[29] and also give public notice in cases where approval has been granted.[30]

25 *Supra at 2.*
26 Section 19(3), the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
27 Section 19(1) and (2), the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
28 *Supra at 2.*
29 *Id.*
30 Section 19(4) The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

2.4.1.1 Procedure for granting approvals for Access under the BD Act and ABS Guidelines

Access to biological resources and/ or associated knowledge for research or bio-survey and bio-utilization for *research*

Persons who intend to obtain access to biological resources and/or associated knowledge for research or bio-survey and bio utilization for research would need to apply to the National Biodiversity Authority (NBA) in Form I of the Biological Diversity Rules, 2004 accompanied with a fee of ten thousand rupees in the form of a cheque or demand draft drawn in favour of the Authority.[31]After being satisfied with the application, the NBA can enter into a Benefit Sharing Agreement with the applicant that would be deemed as a grant of approval.[32] In cases where the application is for a biological resource having high value, the Benefit Sharing Agreement may contain a clause to the effect that the benefit sharing shall include an upfront payment by the applicant, of an amount as agreed between the NBA and the applicant.[33]

Procedure for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization

Persons intending to obtain access to biological resources including access to biological resources harvested by Joint Forest Management Committee (JFMC)/ Forest dweller/s Tribal cultivator/ Gram Sabha, would need to apply to the NBA in Form-I of the Biological Diversity Rules, 2004 accompanied with a fee of ten thousand rupees in the form of a cheque or demand draft drawn in favour of the Authority or to the State Biodiversity Board (SBB), in such form as may be prescribed by the SBB, as the case may be, along with Form 'A' annexed to these regulations.[34]

31 Section 1(1), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Ministry of Environment, Forests and Climate Change (National Biological Diversity Authority), No G.S.R 827, Acts of Parliament, Nov. 21, 2014, (India).

32 Section 1(2), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Ministry of Environment, Forests and Climate Change (National Biological Diversity Authority), No G.S.R 827, Acts of Parliament, Nov. 21, 2014, (India).

33 Section 1(2) Proviso, Ministry of Environment, Forests and Climate Change (National Biological Diversity Authority), No. G.S.R 827, Acts of Parliament, Nov. 21, 2014, (India).

34 Section 2(1), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing. Regulations 2014, Ministry of Environment, Forests And Climate Change (National Biological Diversity Authority), Nov. 21, 2014, No G.S.R 827, Acts Of Parliament, 2014, (India).

After the application is submitted to the NBA or SBB, they can enter into a Benefit Sharing Agreement with the applicant if they are satisfied with the application. In such instances, entering into the Benefit Sharing Agreement by the NBA or SBB with the applicant would be deemed to be the grant of approval for the access to the biological resource. This access is in relation to commercial utilization, bio-survey and bio-utilization for commercial utilization.[35]

Procedure for transfer of results of research relating to biological resources

If a person intends to transfer the results of research relating to biological resources that occur in or is obtained from India to persons who are not citizens of India, are non-residents or a body corporate/association/organization not incorporated or registered in India or which is incorporated but has any non-Indian participation in its share capital or management, has to apply to the NBA. The application has to be made in Form II of the Biological Diversity Rules, 2004 accompanied by a fee of five thousand rupees in the form of a Bank draft or Cheque drawn in favour of the Authority. The evidence has to be provided to the NBA by the applicant for access to the bio resource and AK involved in research.[36] Every application received by the NBA should be decided upon by the Authority as far as possible within a period of three months from the receipt of the same.[37]

If the NBA is satisfied with the application, it can enter into a Benefit Sharing Agreement with the applicant which would be deemed as the grant of approval.[38] If the Authority does not approve an application, it has to record the reasons for it in writing.[39]

Procedure for obtaining Intellectual Property Rights (IPR)

Persons who intend to obtain any IPR in or outside India for any invention that is based on any research or information on any biological resource that is obtained in India will

35 Section 2(2), Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Ministry of Environment, Forests And Climate Change (National Biological Diversity Authority), No G.S.R 827, Act Of Parliament, Nov. 21, 2014.

36 Rule 17(1) & 17(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

37 Rule 17(3), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

38 Rule 17(4) & 17(5), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

39 Rule 17(6), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

have to make an application to the NBA in Form III of the BD Rules, 2004 accompanied by a fee of five hundred rupees.[40] Persons who are not citizens, are non-residents or body corporates that are not incorporated /registered in India or are having any non-Indian participation have to provide evidence of approval from the NBA for access of the bio resource or AK used in the research leading to the invention.[41]The NBA after appraising the application and collecting any additional information that may be required would grant the approval on the basis of merit within a period of 3 months as far as possible from the receipt of the application.[42] The Authority must record the reasons in case of rejection of the application and must give an opportunity of hearing to the applicant before passing the order for rejection.[43]

But persons applying for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (53 of 2001) shall be exempted for making an application to the NBA.[44]

Procedure for transfer of accessed biological resource and/ or associated knowledge to third party for research/ commercial utilization

If a person intends to transfer the bio resources and/or AK which has earlier been given access to by the NBA to a third party for commercial utilization or for research would have to apply to the NBA in Form IV of the BD Rules 2004 accompanied by a fee of ten thousand rupees in the form of Bank draft or cheque drawn in favour of the Authority.[45]The Authority shall after collecting any additional information, decide upon the application as far as possible within a period of six months of receipt of the same.[46]The approval to access shall be in the form of a written agreement duly signed by the authorized officer of the Authority and the applicant.[47]

40 Rule 18(1) & Rule 18(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

41 Section 8, Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, No. 612, Acts Of Parliament, Nov. 21, 2014, (India).

42 Rule 18(3), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

43 Rule18(6), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

44 Section 8, Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, No. 612, Acts Of Parliament, Nov. 21, 2014, (India).

45 Rule 19(1) & 19(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

46 Rule 19(3), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

47 Rule 19(5), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

2.4.1.2 Revocation of access or approval

The NBA[48]or SBBs[49] may either on the basis of any complaint or suo moto withdraw the approval granted for access and revoke the written agreement due to certain conditions, such as when the person who has been granted approval fails to comply with the terms of the agreement or conditions of access granted.

The approval can be revoked also on account of public interest or for protection of environment and conservation of biological diversity.[50] The Authority, under the BD Rules is required to send a copy of every order of revocation issued by it to the concerned State Biodiversity Board and the Biodiversity Management Committees for prohibiting the access and also for assessing the damage, if any caused and in order to take steps to recover the damage.[51]

2.4.1.3 Appeals by the persons aggrieved by any determination of benefit sharing

Any person who is aggrieved by the determination of benefit sharing or order made, on or after the commencement of the National Green Tribunal Act, 2010, by the National Biodiversity Authority or a State Biodiversity Board under the provisions of the Biological Diversity Act, 2002, may, within a period of thirty days from the date on which the order or decision or direction or determination is communicated to him, prefer an appeal to the National Green Tribunal. The Tribunal may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the said period, allow it to be filed within a further period not exceeding sixty days.[52]

2.4.1.4 Penalties

According to the Biological Diversity Act, 2002, a person who contravenes or abets the contravention of provisions that deals with the undertaking of Biological Diversity related

48 Section 11, 12, Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, No. 612, Acts of Parliament, Nov. 21, 2014, (India).

49 Section 16, Karnataka Biological Diversity Rules, 2005, No. 151 ENV, Acts of Parliament, 2005, (India).

50 Rule 15(1), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

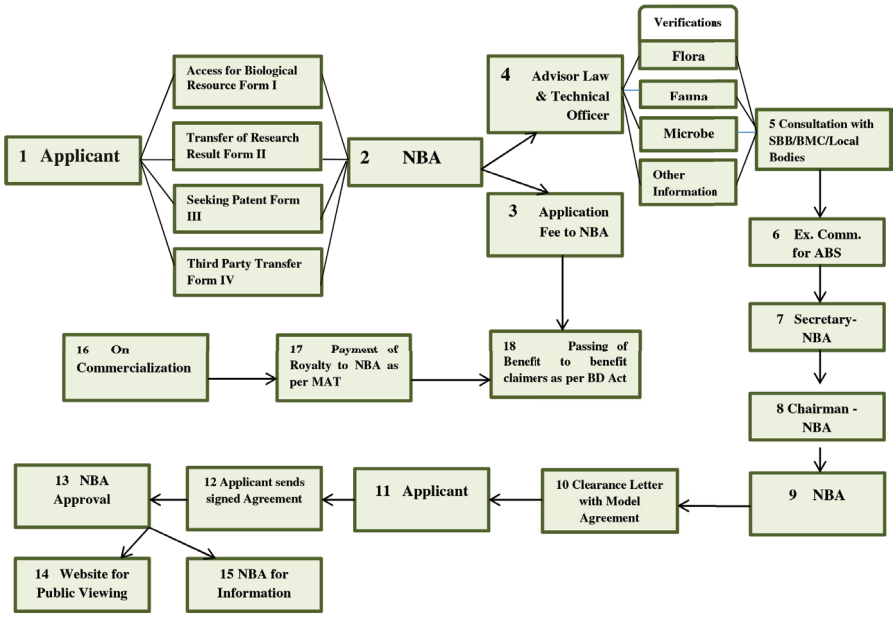
51 Rule 15(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

52 Section 16(j), The National Green Tribunal Act, 2010, No. 19, Acts of Parliament, 2010, (India).

activities[53], transfer of results of research[54] and applying for intellectual property rights[55] without approval of National Biodiversity Authority, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten lakh rupees.[56] In cases where the damage caused exceeds 10, 00,000 rupees, the fine may be commensurate with the damage caused, or with both.[57]

Persons who contravene or abets the contravention of provisions that deals with prior intimation to be given to the State Biodiversity Board for obtaining biological resource for certain purposes[58]or any orders passed by the State Biodiversity Board under Section 24(1) of the BD Act, 2002 are punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both.[59]

The ABS Process in India



53 Section 3, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
54 Section 4, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
55 Section 6, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
56 Section 55(1), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
57 *Id.*
58 Section 7, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
59 Section 55(2), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

2.5 ABS and Biological Diversity in Practice

The National Biodiversity Authority was established under Chapter III of the BD Act, 2002 by the Central Government in 2003 to implement India's BD Act (2002). The NBA is a Statutory Body and it performs facilitative, regulatory and advisory functions for the Government of India on issues of conservation, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of biological resources.

India ratified the Nagoya Protocol in 2014. However, the domestic legislation containing provisions for Access to Biological and Genetic Resources and sharing the equitable benefits which arise therefrom was already present in 2002.

The role of the NBA as established under the BD Act is to regulate access of biological resources and/or associated knowledge occurring in or obtained from India and to provide for conservation, sustainable use of biological diversity by ensuring equitable sharing of benefits arising from its access/utilization/transfer.

Receipt of Applications under different categories

Form	Category	Applications Received since 2004
Form I	Access to biological resources and /or associated knowledge for research/commercial utilization	**395**
Form II	Transferring results of research for monetary consideration or otherwise	**51**
Form III	Seeking no objection to obtain Intellectual Property Rights	**1575**
Form IV	Third Party Transfer of accessed biological resources and/or associated knowledge	**82**
Form B	Conducting non-commercial research for emergency purpose outside India by Indian researchers/ government institutions using biological resources	**67**
	Not applied in prescribed form and fee	**13**
Total		**2183**

Source: NBA, Total Applications Received as of 31-03-2018

As of 31 March 2016, all 29 States in India have established SBBs but BMCs which have been facilitated to protect the loss of genetic and biological resources have been inactive or non-functional in quite a few States. The NBA's website[60] as of 2018 listed 62,502 BMCs across all states and union territories in India. But neither the NBA nor SBB officials deny the huge challenges that they face in trying to operationalise BMCs as per the law. They admit that the numbers on paper do not imply that all BMCs are desirably functional or adequately empowered.[61] Since its inception, NBA has received 1758 applications from different stakeholders. Even though the number of applications received in the past few years has been steadily increasing, the number of Applications still appears to be quite low for 15 years of the Authority functioning; therefore it is possible that a substantial chunk of access is still taking place without approvals.[62]

Recently there have been cases in the Bombay High Court[63] and the Uttrakhand High Court[64] where loss of Biological Diversity and the hasty management of the State and Central authorities have been highlighted. Such issues and challenges in the functioning of the various Authorities under the BD Act would be brought forth in the case studies in the next chapters. Appropriate suggestions must be found in order to construct a strengthened Biological Diversity regime which would ensure better conservation of biological resources and make the ABS mechanism more efficacious.

Authorities Under The Biological Diversity Act: NBA, SBBs AND BMCs

2.6 The National Biodiversity Authority

The NBA, established under Chapter III of the Biological Diversity Act, 2002 is the authority responsible chiefly for the regulation of access to biological and genetic resources

60 (Jan ,28.2018), http://nbaindia. org.

61 Biological Diversity Management Committees, Lost in Numbers Kanchi Kohli, Shalini Bhutani, Economic & Political Weekly, April 19, 2014 Vol XlIX no 16. (Dec,09,2017), http://www.kalpavriksh.org/images/CCCBD/BMC%20Lost%20in%20Numbers_EPW_16%20April_2014.pdf.

62 Kohli, K. & Bhutani, S (2013). THE BALANCING ACT: Experiences with Access and Benefit Sharing under India's Biological Diversity Regime. Kalpavrikha and Swissaid, India.

63 Central India Ayush Drugs Manufacturers Association & Ors. v. State of Maharashtra, W.P No. 6360/2015.

64 M/s Vishwanath & Ors. v. State of Uttarakhand, Writ Petition No.1425 of 2016.

in India. To regulate access to such resources and to ensure there is no exploitation of any kind, NBA has been given certain powers and privileges to roll out conditions and procedures wherever required. The NBA also has the power to provide for penalties in case of any violation of the orders of the NBA or of the SBBs, and/or violation of any provision under the Act.

2.7 State Biodiversity Boards

The functions of the SBB, a body corporate[65] established by the State Governments under and for the purpose of the BD Act,[66] include advising the State Government on matters relating to biological diversity conservation, sustainable use of its components, and equitable sharing of the benefits.[67] The SBB is responsible for regulating the grant of approvals and requests for bio-survey, bio-utilization or commercial utilization of biological resources by Indians. It also has to perform any such function that is deemed necessary to carry out the BD Act or as is prescribed by the State Government.[68]

Under the BD Act, any citizen of India, organization, body corporate or association that is registered in the country who is intending to obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization can do so only after giving prior intimation to the concerned SBB.[69] The SBB, on receipt of intimation for the above purposes can prohibit or restrict any such activity after consulting with the concerned local bodies. It can do so if in its opinion the activity is detrimental to the objective of conservation and sustainable use of biological diversity or equitable sharing of benefits.[70]

Such orders can be made by the SBB only after the opportunity of being heard is given to the affected persons. The information given by the applicant in the prescribed form to the SBB would have to be kept confidential and undisclosed by the Board.[71]

65 Section 22(3), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
66 Section 22(1), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
67 Section 23(a), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
68 Section 23(b) & (c), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
69 Section 24(1), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
70 Section 24(2), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
71 Section 24(2) proviso & Section 24(3), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).

2.7.1 Constitution of the National Biodiversity Authority and State Biodiversity Board

The National Biodiversity Authority according to the Act is required to have a Chairperson with the requisite qualifications who is to be appointed by the Central Government, 3 ex officio members, two of whom are representing the Ministry dealing with Environment and Forests (one of whom should be an Additional Director General of Forests or the Director General of Forests) and the other one member representing the Ministry dealing with Tribal Affairs, all of whom would be appointed by the Central Government.[72]

Seven other ex officio members are to be chosen by the Central Government representing the Ministries of Agricultural Research and Education, Biotechnology, Ocean Development, Agriculture and Cooperation, Indian Systems of Medicine and Homoeopathy, Science & Technology and Scientific and Industrial Research.[73] Five non- official members would be appointed from amongst specialists and scientists who have special knowledge of or experience in matters related to biological diversity and conservation.[74]

The State Biodiversity Boards under the BD Act, 2000 are required to consist of a Chairperson an eminent person having adequate knowledge and experience in the conservation and sustainable use of biological diversity and in matters relating to equitable sharing of benefits.[75] The Chairperson is to be appointed by the State Government.[76]

The Act states that not more than five ex officio members are to be appointed by the State Government to represent the concerned Departments of the State Government[77] and not more than five members to be appointed from amongst experts in matters relating to conservation of biological diversity, sustainable use of biological resources and equitable sharing of benefits arising out of the use of biological resources.[78]

72 Section 8(4) (a) & (b), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
73 Section 8(4) (c), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
74 Section 8(4)(d), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
75 Section 22 (4) (a), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
76 *Id.*
77 Section 22 (4) (b), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
78 Section 22 (4) (c), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

2.7.2 Annual Reports and Budgets

The NBA[79] and the SBBs[80] are required to prepare an annual report in a prescribed form each financial year, which gives an account of its activities during the previous financial year and the Authorities are required to furnish the reports to the Central Government and State Government respectively each year before the prescribed dates and also furnish the audited copy of its accounts together with the auditor's report to the respective Governments. The NBA has to prepare a budget, maintain proper accounts and other relevant records and is also required to prepare an annual statement of account in such form as prescribed by the Central Government in consultation with the Comptroller and Auditor General of India.[81]

The Account of the NBA is audited by the Comptroller and Auditor-General of India at the intervals specified by him[82] and the SBBs[83] accounts are audited and maintained in a particular manner in consultation with the Accountant-General of the State. The accounts of NBA certified by the CAG along with the audit report are forwarded annually to the Central Government and the report is laid out before the Parliament.[84] Similarly the SBB are also required to furnish the audited copy of accounts together with auditor's report to the State Government before the prescribed date. The State Government will then lay out the annual report and auditor's report before the House of State Legislature as soon as it is received.[85]

79 Section 28, Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
80 Section 33, Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
81 Section 29(1), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
82 Section 29(2), Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India)
83 Section 34, Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
84 Section 30, Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).
85 Section 34 & 35, Biological Diversity Act 2002, No. 18, Acts of Parliament, 2003, (India).

States that have enacted and notified their State Biological Diversity Rules (As of 2016)

Sl. No.	Name of the State	Notification No.	Date of Notification
1	Andhra Pradesh	G.O.MS.No.70	21.08.2009
2	Arunachal Pradesh	G.O.No. SFRI/APBB/3/10	01.07.2011
3	Assam	G.O.No.FRN/57/2005/187	24.02.2010
4	Chhattisgarh	08-04/2011/10-02	01.06.2015
5	Gujarat	WLP/2003/1777/2009(45)/W(Part-II)	18.02.2010
6	Jharkhand	Vanyaprani-03/2005/5014	30.08.2007
7	Jammu and Kashmir	SRO-200	29.06.2015
8	Karnataka	FEE 151 ENV 2005	03.05.2006
9	Kerala	G.O.(P)No.1/2008/Envt	10.06.2008
10	Madhya Pradesh	F-1-2-2002-L VII	17.12.2004
11	Maharashtra	WLP.1004/C.R.226/F-1	10.12.2004
12	Manipur	428	05.03.2009
13	Meghalaya	FOR/57/2002/244	30.08.2010
14	Mizoram	11015/26/2010-FST	25.04.2012
15	Nagaland	FOR/WORKS-11/2004	22.09.2012
16	Odisha	10-F(TR)52/2012/22461/F&E	03.12.2012
17	Punjab	G.S.R.78/C.A.18/2003/S.63/2016	11.11.2016
18	Rajasthan	G.S.R.99	02.03.2009
19	Sikkim	504/F	14.09.2006
20	Tripura	F.8(31)A/for-WL/98/Part-ll/6919-7308	16.06.2008
21	Telangana	G.O.MS.No23	14.05.2015
22	Uttar Pradesh	570/XIV-5-2010-57/2006	09.04.2010
23	West Bengal	En/136/T-ll-7/005/2004	27.01.2006

Source: Compendium of State Biological Diversity Rules (National Biological Diversity Authority)

2.7.3 Appeals for Settlement of Disputes among the Biodiversity Authorities

For disputes arising between one or more State Biodiversity Boards and the National Biodiversity Authority with regard to a policy decision or the implementation of an order or direction, the parties can prefer an appeal to the Central Government, Secretary MoEF.[86]

86 Rule 23(1), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).

In the instance of a dispute between one or more State Biodiversity Boards, the aggrieved parties can prefer the points of dispute to the Central Government, which then will refer the same to the National Biodiversity Authority.[87]

The appellant is required to submit a Memorandum of appeal to the Central Government mentioning the facts of the case, the grounds relied upon by the appellant for preferring the appeal and the relief sought for along with the authenticated copy of the order, direction or policy decision that the appellant is aggrieved by.[88]

The Central Government after hearing the parties may dispose the appeal and may modify, vary or cancel the impugned order, direction or policy.[89] The NBA in adjudicating disputes among State Biodiversity Board is required to follow the principles of natural justice and should follow the same procedure adopted by the Central Government in adjudicating disputes as far as possible.[90]

2.7.4 Meetings of the Authority

The National Biodiversity Authority is required to meet at least four times in a year at the headquarters of the Authority or at any such place which is decided by the Chairperson of the Authority.[91] In instances where a written request is made to the Chairperson of the Authority by not less than five members of the NBA or when a direction of the Central Government is given to do so, the Chairperson is required to call a special meeting.[92]

A notice of at least fifteen days is required to be given to the members if an ordinary meeting is being held. In case of a special meeting, a notice of at least three days along with the specifications regarding the purpose, the time and place where the meeting is to be held has to be given.[93] The meeting of the Authority is to be presided over by the Chairperson and in his absence a presiding officers has to be elected by the present members.[94]

87 Rule 23(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).
88 Rule 23(3) and (4), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).
89 Rule 23(7) and (8), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).
90 Rule 23(9), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament, 2004, (India).
91 Rule 23(7) and (8), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
92 Rule 23(9), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
93 Rule 10(1), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
94 Rule 10(2), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

The quorum at every meeting of the Authority would be five members and each member has one vote.[95] A decision at a meeting can be taken by a simple majority of the members present and voting and the Chairperson or the member presiding (in the Chairpersons absence).[96]The vote of the member presiding would be a second or casting vote.[97]

The Rules require that no member should bring forward any matter for consideration in the meeting without a notice of that matter being brought up, at least ten days prior to the meeting.[98] An exception to this would be if the Chairperson in his discretion would allow a member to do so.[99]

2.7.5 Removal of Members

The Central Government has the authority to remove any member from the National Biodiversity Authority who in its opinion has been adjudged as insolvent, been convicted of an offence which involves moral turpitude, has become mentally or physically incapable of acting as a member, has abused his position as to render his continuance in office detrimental to public interest or has acquired such financial or other interest as is likely to affect prejudicially his functions as a member.

2.8 Biodiversity Management Committees (BMCs)

Section 41 of the Biological Diversity Act talks about the constitution of Biodiversity Management Committees and states that every local body is required to constitute a BMC within its area of jurisdiction for the purpose of promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals, microorganisms and chronicling of knowledge relating to biological diversity.[100] The constitution of the BMC must be done in accordance with Rule 22(1) of the Biological Diversity Rules, 2004. The composition of the BMC consists of a Chairperson with a

95 Rule 10(3), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
96 Rule 10(4), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
97 Rule 10(7) and (6), Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
98 Rule 10(8) Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
99 *Id.*
100 Section 41, Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

tenure of 3 years and six persons nominated by the local body, of which one-third are women and 18% are Scheduled Castes / Tribes.[101]

2.8.1 Functions of BMC

Under the BD Act, 2002 wide powers are given to the BMC to promote conservation, sustainable use and documentation of biological diversity which includes the preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms. It is also required to document biological resources and chronicle knowledge related to those resources.[102]

But the BD Rules of 2004 limits the role of BMCs and make the function of preparation, maintenance and validation of People's Biological Diversity Register (PBR) in consultation with the local people, as its main function. The SBBs are to guide them in carrying out this particular function.[103] The PBRs are required to contain comprehensive information on availability and knowledge of local biological resources, their medicinal use, other use or any other traditional knowledge associated with them.[104]

BMCs are to maintain a Register giving information about the details of access to biological resources and traditional knowledge granted, details of the collection fee imposed and details of the benefits derived and the mode of their sharing. It is required to maintain data about the local vaids and practitioners using the biological resources.[105] According to the Rules, the other main function of the BMCs is to advise on any matter referred to it by the State Biodiversity Board or National Biodiversity Authority for granting approval.

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101 Rule 22(2) Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
102 *Supra* at 98.
103 Section 22 (6) Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).
104 *Id.*
105 Section 22 (7) Biological Diversity Rules, 2004, No. G.S.R. 261(E), Acts of Parliament,2004, (India).

CASE STUDIES ON BIOLOGICAL DIVERSITY: JUSTIFICATION FOR THE BIOLOGICAL DIVERSITY LAW IN INDIA

3

3.1 Biological Diversity Conservation: The Initial years

Before the enactment of the BD Act in India in 2002, cases related to biological diversity mostly involved issues relating to the destruction and disregard of biodiversity in our Country. For example, in the case of *Vellore Citizens Welfare Forum v. Union of India*[1] the Court reiterated the need for all stakeholders to be mindful towards biological diversity and further conservation efforts. It stated that there should be a commitment of all citizens and the State towards the objectives of the CBD, to which India was a party. The focus of the judgment, while considering biological diversity and biological resources was on the conservation and furtherance of the principles of sustainable development.

Similarly, in another important case of *S. Jagannath v. Union of India*[2], emphasis was given to the conservation of all biological and genetic resources which the Court stated must be protected at all times. Since this judgment came prior to the Biological Diversity Act being enacted in 2002, the Court focused on the stated violations of the provisions of the Environment Protection Act, 1986 and Rules[3] as well as other environmental legislations such as the Water Act, 1974.[4] This case was regarding the ecological and social implications of commercial shrimp farming in India. It was noticed that the traditional shrimp culture system used by Indian fishermen had begun to give way to more intensive methods of shrimp culture which could produce thousands of kilograms per hectare. A large number of private companies and multi-national corporations had started to invest in shrimp farms and the issue in this case was regarding the implications of such intensive shrimp farming systems on the ecology and biological diversity of areas where it was being practiced.

1 Vellore Citizens Welfare Forum vs. Union of India & Ors, (1996) 5. SCC 647 (India).
2 S. Jagannath vs. Union of India (1997) 2 SCC 87: AIR 1997 SCC 811 (India).
3 Rule 5 (3)(d), Environment (Protection) Rules, 1986, No. S.O. 844 (E), Acts of Parliament, 1986, (India).
4 Section 25, the Water (Prevention & Control of Pollution) Act, 1974, No. 6, Acts of Parliament, 1974, (India).

The Court in this case cited various reports including the Justice Suresh Committee Report[5] and commenting on Shrimp Culture the judgment reiterated the necessity to conserve the habitat of shrimps so as to protect the particular genetic resource. It focused on aspects such as environmental impact assessments needing to take into account the social impact of the industry on different populations in the area before permission was granted to install commercial shrimp farms. The Courts using the "Precautionary Principle" and "the Polluter Pays" principles directed that no shrimp culture pond, as defined in the Coastal Zone Regulation Notification[6] could be constructed or set up within the coastal regulation zone. It also directed that an authority was required to be constituted under the Central Government according to the provisions of the Environment Protection Act, 1986[7] for ensuring the regulation of such activities in the coastal regulation zone.

3.2 Access and Benefit Sharing Case Studies

A case study that inevitably comes into picture while discussing the origins of Access and Benefit Sharing in India is that of the Kani Tribe, which is a case from the late 1980s. This case was considered to be one of the flagship cases in the arena of Access and Benefit Sharing and took place even before the mandate of the BD Act or the CBD existed. This case is a good example of how access to indigenous biological resources was handled equitably and the profits arising were shared in a bonafide manner with the tribal community, who possessed the traditional knowledge related to the particular biological resource. But there were also various criticisms with regard to the agreement that took place in this case, which went on to inform subsequent decisions on the matter of ABS in India.

3.2.1 The Kani Case of Arogyapaccha: Brief Background

The Kani Tribe of the Agasthyamalai Hills in Kerala are one of the oldest tribal communities, who have traditionally lived in the forests of the Agastya Koodam ranges. In 1987, a research team from the All India Coordinated Research Project on Ethnobiology (AICPRE) arrived in the area inhabited by the particular tribe and sought permission from the Chief

5 The Water (Prevention & Control of Pollution) Act, 1974, No. 6, Acts of Parliament, 1974, (India), "Expert Committee Report on Impact of Shrimp Farms Along the Coast of Tamil Nadu and Pondicherry".

6 The Coastal Regulation Zone Notification, 1991, No. S.O. 944 (E), Act of Parliament, Dec. 15, 1990, (India).

7 Section 8(3), the Environment Protection Act, 1986, No. 29, Acts of Parliament, May. 23, 1986, (India).

Tribesman to launch a small expedition in their territory for certain research purposes.[8] The permission was granted to the scientists and some local Kani tribals were sent on this expedition along with the research team as guides. It was during this expedition that the team discovered the unique fruit of the Arogyapacha plant (Trichopus zeylanicus) that the native tribes consumed and of the fruits medicinal qualities of improving fatigue and providing energy.

The tribal physicians of Kani called Plathi were considered to be the exclusive holders of the traditional medical knowledge of the tribe, which itself had a long tradition of using the plants found in the forests of the region for health purposes. The Kani tribe had a custom wherein only the Plathi had the right to transfer and disseminate their traditional knowledge on the medicinal plants. Initially, during the expedition, the Kani guides were reluctant to share the source of the fruit and with some persistence of the AICPRE team led them to the Arogyapacha plant.[9]

The term Arogya pacha in Malayalam translates into "healthful green". Samples of plant were taken back to their laboratory and after conducting phytochemical and pharmacological studies on the samples, the scientists came to the conclusion that the plant possessed certain immunity-enhancing and anti-fatigue properties.[10]

After seven years of the research on the plant, around 12 active chemical compounds were isolated and combined with certain other plants and the end result of this research project was the development of a drug called Jeevani. Jeevani which translates to "giver of life" was prepared using the leaves of the plant, and not the fruit, as was the case with the Kani tribe and their usage. The first patent with regard to this case was awarded to the Regional Research Laboratory, Jammu team in 1994[11] on the process for isolation of glycolipid in the Arogyapacha plant.[12] After that by TBGRI, four patents were applied for. Among

8 (Dec. 17,2017), http://www.wipo.int/ipadvantage/en/details.jsp?id=2599, "Using Traditional Knowledge to Revive the Body and a Community."

9 *Id.*

10 Chaturvedi, Sachin (2007) Kani Case. A Report for GenBenefit, available at:www.uclan.ac.uk/genbenefit.

11 A process for the isolation of glycilipid fraction from Trichopus zeylanicus possessing adaptogenic activity File No: 88/Del/1994, (Joint patent obtained by RRL, CSIR Jammu and TBGRI).

12 Anitha Ramanna-Pathak, Benefit Sharing: Reframing India's Policy, Fridtjof Nansen Institute, (Oct. 11, 2017), https://www.fni.no/getfile.php/134134/Filer/Publikasjoner/FNI-R0117.pdf.

them one was on the process for the herbal drug Jeevani.[13] A patent was also granted on an anti-diabetic herbal drug developed at the TBGRI in 1996.[14] Similarly, herbal sports medicine was developed called 'Vaji' for which a patent was granted.[15] The TBGRI also received a patent for herbal medicinal components for cancer treatment from the Janakia arayalpathra root and Trichopus zeylanicus leaf.[16]

But TGBRI, though being responsible for the invention of Jeevani could not commercialize it, since it was a research institution and did not have the capacity to do so.[17]In 1996, the technology for making this drug was transferred to Arya Vaidya Pharmacy Ltd (AVP) in Coimbatore, which was one of the largest herbal pharmacies in India. The technology was transferred for a licensing fee of US$50,000 and 2 per cent royalties at ex-factory sale.[18]

The TBGRI proposed to share the benefits at a 1:1 ratio with the Kani Community, which amounted to fifty percent of the licensing fee and royalties. For this purpose, a separate trust for the Kanis, The Kerala Kani Community (Samudaya) Welfare (Kshema) Trust was registered in November 1997. This was done to regulate and direct the inflow of money received by the Kanis as benefits.[19]

There were a number of legal and mostly ethical issues which were raised in this case. Some of them being:

- Whether the community was adequately represented in the Kani Trust and whether it received appropriate benefits from the commercialization of the Arogyapacha Plant and their AK.

13 Rajasekhran S. and George V., (1996), Patent application number 959/MAS/96 dated June 4, 1996, (India), "'A process for the preparation of a novel immune-enhancing, anti-fatigue, anti-stress and hepatoprotective herbal drug (Jeevani)' (Pushpangadan P)."

14 A process for the preparation of a Glycolipid fraction from Trichopus zelyanicus possessing adpatogenic activity, (Butani, D. K., Taggi B. S., Anand K. K., Kapil R. S., Pushpangadan P., and Rajsekhran S., 1994, Patent application number 88/Del/94).

15 958/MAS/96 dated June 4, 1996.

16 A process for the preparation of a novel herbal medicinal composition for cancer treatment from Janakia arayalpatra and Trichopus zeylanicus leaf. Awarded patent No. 193609 dated 22.09.2006.

17 *Id.*

18 (Dec. 17, 2017), http://web.worldbank.org/archive/website00297C/WEB/IMAGES/KANI.PDF.

19 New York: UNDP. Equator Initiative (2002), 'The Innovative Partnership Awards for Sustainable Development in Tropical Ecosystems'.

- Whether the people for the Kani community as a whole had acquiesced to the commercialisation of their traditional knowledge, considering the fact that the community was initially reluctant to share its indigenous knowledge with the AICPRE research team.

This case arose much before India signed or ratified the CBD and is still noted for creating a model for access and benefit sharing which tried to take into regard the rights and the benefit sharing privileges of the indigenous community.

Legal and Ethical Issues Involved[20]

This case occurred quite some time before any Biological Diversity laws had come into force in India. Therefore, in the pre-CBD/BDA context, the issues which were raised were few. They were:

First Issue: Fears were raised by the Kerala Legislative Assembly on the amount being given to the Kanis as benefits being very low, considering the huge economic potential of the manufactured drug Jeevani.

Second Issue: It was contended that the licensing of the indigenous know-how and traditional knowledge relating to the Arogyapacha plant must not have been given to the privately owned and run Arya Vaidya Pharmacy Ltd. It was proposed that it would have been better to give it to a Government Company or a Public Sector Undertaking.

Third Issue: Objections were raised by the Kerala Institute for Research, Training and Development of Scheduled Caste and Scheduled Tribes, which stated that the Kanis had in overall received an unfair deal. The Institute specified that the Kani's were no longer a unified community that stayed together. Their population was dispersed, therefore the agreement with the tribe had been done only with those who were found available at that time and those few tribes' people did not represent the whole community. The Panchayat Head of the village, which consisted of a number of Kani people wrote to the Chief Minister of Kerala stating the same. He also expressed his concern regarding the area where the plant was cultivated and that it may be affected due to its commercialization.

20 Chaturvedi, Sachin (2007) Kani Case, Report for GenBenefit, (Oct. 11, 2017), https://www.uclan.ac.uk/research/explore/projects/assets/cpe_genbe neift_kani_case.pdf.

But despite this letter being sent in October 1995, the TBGRI, under the Chairmanship of Kerala's Chief Minister, struck an agreement of Transfer of Technology with Arya Vaidya Pharmacy Ltd. and decided to transfer the technology of manufacturing Jeevani for a consolidated sum of US$50,000 and amount made on 2 percent of the future drug sales.

Fourth Issue: The drug company ran into manufacturing issues due to lack of raw material since the Forest Department (FD) in Kerala refused to permit the collection of leaves for the drug's manufacture. It stated that the area where the Trichopus zeylanicus plants were naturally found was within the Core area of the Reserved Forest and cited concerns of excessive leaf-plucking that may cause the plant to become rare. TBGRI in response to the FD's action proposed an Integrated Tribal Development Program which would aim at aiding the cultivation of the plant and stated that only the leaves of the plant would be purchased without destroying the plant itself. They proposed that this was a sustainable solution to the issues posed by the FD regarding the plant becoming rare and also stated that additional benefit that would be received by the Kani community from the sale of the plant.[21]

Core Outcomes[22]

The Kani case is an example illustrating the complexities of a benefit sharing agreement. This case came into existence before a legal mandate on such issues existed and also earned the criticism of various stakeholders in the process. The criticism regarding the transfer of technical and technological know-how to a private company instead of a government owned company was countered by TBGRI with the argument that no PSU had Good Manufacturing Processes for the production of Jeevani. Throughout the process of determining the equation of benefit-sharing, it was witnessed that the 50-50 division of profit earned between the Institute and the Community was the safest thing to do. And instead of giving the monetary amount directly to the Community, a Trust had been registered that was responsible for distributing the money equally among the community.

21 *Id.*

22 Chaturvedi, Sachin (2007) Kani Case, Report for GenBenefit, https://www.uclan.ac.uk/research/explore/projects/assets/cpe_genbe neift_kani_case.pdf. (Oct. 11, 2017).

In 2000, NutriScience Innovations LLC, a US-based supplier of nutritional and functional food ingredients applied for a trademark on Jeevani in the United States Patent and Trademark Office and had started the sale of the product without informing TBGRI.[23]A dispute ensued between TBGRI and NutriScience which led to the US Company abandoning its trademark application. Another such incident with regard to the trademark on Jeevani happened in the same year in the United States, where a similar company, Great Earth Inc. started to market an energy drink that had the same ingredients as that of Jeevani. The issue in this instance was that of TBGRIs inability to challenge this move, since it had not filed for any trademark on Jeevani in the United States Patent and Trademark Office and this technically meant that there was no Intellectual Property infringement with regard to the plant in the United States, where many companies now have started to sell products containing Jeevani. The plant materials for such products are now being purchased from sources other than AVP. The conclusion here is that a lot of commercially viable business is now being done based on this plant product with no benefits from such business coming to the Kani Tribe members. The recourse of contesting for a trademark is also very difficult since the cost of such a contestation is very high in the United States.[24]

3.2.2 The Monsanto India Limited Case: A Brief Background

This case was regarding the Genetic Manipulation of plants and the creation of hybrid seeds which claimed to have ill effects on not only the existing ecology, but also on the lives of the farmers who used these seeds for cultivation. Monsanto India Limited was setup in India in the early 1970s, which was much before any legal framework for Biological Diversity or environmental protection existed. The American giant is today well known for its efficiency in biotechnology and manufacturing Genetically Modified Crops. While gaining entry into the Indian Market in 1988, soon after the World Bank sanctioned a loan of $150 million to deregulate the Indian Seed Industry, this company took interest in the vast agricultural sector that was present in India.[25]

Their first product was the Bt. Cotton seed, which produced a certain pesticide which made the cotton Bollworm resistant. Monsanto however ran into certain legal and social

23 (Dec. 18, 2017), http://web.worldbank.org/archive/website00297C/WEB/IMAGES/KANI.PDF.
24 *Id.*
25 (Dec. 17, 2017,) The Privatisation of Seeds, https://en.reset.org/knowledge/privatisation-seeds.

issues with regard to their seed prices and also because of their strict seed usage terms and conditions. They charged around Rs. 900 for 450gms of seed and disallowed farmers to reuse the seeds in the second year of sowing. It had been reported widely that such practices of the Company played a huge part in the farmer debts and suicides that had occurred in the State of Maharashtra.[26]

In 2007, the Andhra Pradesh State Biodiversity Board complained to the Board of Monsanto and later to the National Biodiversity Authority regarding the bacteria gene information used by the company to develop the Bollguard-II cotton seed. This bacteria gene information was claimed by the Board to be indigenous to the State of Andhra Pradesh and demanded that the company should give a certain amount of royalty to the State of Andhra Pradesh for the same.[27]

In the recent years, Bio-Piracy cases have also been filed by the NBA against MahycoMonsanto for the genetically modified Bt. Brinjal, wherein the company accessed sixteen local varieties of Brinjal in the states of Karnataka, Tamil Nadu and others to develop a GM variety of the vegetable.

The Monsanto India case is important in order to discuss the issue of the effect of the legal framework and Biological Diversity procedures over large business houses such as Monsanto. The Monsanto Case was originally an issue of Intellectual Property Rights, namely that of patent and further a socio-legal issue of the company misusing its dominant position in the market. This position was used for unfair pricing of seeds which was claimed to be causing excessive debt and an ensuing suicide crisis among farmers in India. This even forced the Competition Commission of India to enforce a price-capping on the Company's product. The ABS issue in this particular case was not considered to be of an urgent nature. Environmental concerns however were limited to the extent of Genetically Modified plants feasibility to be introduced in the market and the prospective effects of the GM varieties on the native/indigenous variety.[28]

26 (Dec. 17, 2017,) http://www.thehindu.com/opinion/op-ed/The-battle-over-Bt-cotton/article15424211.ece.

27 Dr Vandana Shiva, How Monsanto Wrote and Broke Laws to Enter India, (Dec. 17, 2017) http://vandanashiva.com/?p=260.

28 Chasing Benefits, Issues on Access to Genetic Resources and Traditional Knowledge with reference to India's Biological Diversity Regime A post-Nagoya Protocol view on Access and Benefit Sharing, Kanchi

Legal Claims against Monsanto: The Bt. Brinjal Case[29]

The charge of bio piracy against Monsanto in the case of its genetically engineered Brinjal, which used 16 indigenous varieties of the vegetable, was taken up quite seriously under the BD Act, 2002. The NBA passed a resolution in this regard in the year 2011.[30] Certain legal procedures were agreed to be followed against Monsanto, Maharashtra Hybrid Seeds Company [(Mahyco) 26 per cent of which is held by Monsanto], University of Agricultural Sciences (UAS) and Sathguru Management Consultants Limited. The NBA decision charged these three entities with violation of the Biological Diversity Act, 2002 which included the violation of the provision for "accessing and using the local brinjal varieties for development of Bt brinjal without prior approval of the competent authorities".[31] The action taken was in pursuance of a complaint made by a Non-Governmental Organisation, Environmental Support Group (ESG) in Bengaluru, Karnataka. The State Biological Diversity Board informed NBA on 28 May 2011 that six local varieties for development of Bt. brinjal were accessed in the State by the particular companies without prior approval from State Biodiversity Board/ National Biodiversity Authority.[32]

First Issue: The violation of Sections 3 and 4 of the BD Act- Section 3 requires non-Indian individuals or entities (body corporates/associations/organizations) having non-Indian participation (in its share capital/management) who seek access to bio resources to obtain the prior approval of the NBA. The same requirement of prior approval of the NBA is stated in Section 4 for transfer of any research result related to biological resources to such entities. An exemption is provided by Section 5 (1), which holds that the prior approval of NBA is not required in the case of a "collaborative research project" involving Indian and non-Indian entities and institutions under the conditions that such project (1) "be

Kohli and Shalini Bhutani, (Oct. 10, 2017), http://awsassets.wwfindia.org/downloads/ chasing_benefits.pdf.

29 Aruna Rodrigues v. Union of India (2012) 5 SCC 331 (India).

30 Walid Abdelgawad. The Bt Brinjal Case: The First Legal Action Against Monsanto and Its Indian Collaborators for Biopiracy. Biotechnology Law Report, Mary Ann Liebert, 2012, 31 (2), 136 (Oct. 13, 2017), <http://online.liebertpub.com/doi/abs/10.1089/blr.2012.9926>. <10.1089/blr.2012.9926>. <hal-01131401>.

31 (Oct. 13, 2017), www.nbaindia.org/docs/20th_Proceedings_10_ 08_2011.pdf.

32 Letter from Karnataka Biological Diversity Board to The Secretary, National Biological Diversity Authority, dated 28 May 2011; (Oct. 13, 2017), http://www.esgindia.org/sites/default/files/campaigns/brinjal/press/b-bt-brinjal-kbb-nba-biopiracy-submissio.pdf.

approved by the Central Government," and ii) "conform to the policy guidelines issued by the Central Government."[33]

After examining the subject matter, NBA concluded that "the said research project seemed prima facie to fall outside the scope of guidelines issued by the Central Government." As a result, the Authority stated that the three parties of the sublicense agreement had no right to an exemption under Section 5 (1) and thus were required to have obtained NBAs approval.

Second Issue: The NGO, ESG had accused the contracting parties in this case of failing to give prior notice to the Karnataka State Biodiversity Board (KBB). This is mandatory under Section 7 of the BD Act in order to access biological resources "for commercial utilization." This allegation would have been relevant only if there was a "commercial utilization" of Bt eggplant technology. This may not have been the case for the sublicense agreement, which prima facie aimed to transfer technology to UAS-Dharwad without commercial uses. The agreement provided that Mahyco, as a sublicensor, "had agreed to provide access to the technology without any payment for such access." It granted to UAS-Dharwad "a royalty-fee, not-for-profit sublicense" so as to develop or distribute, other than by sale, licensed domestic eggplant products to resource-constrained farmers. Thus the sublicense agreement, it was contended did not provide for commercial utilization of Bt. eggplant technology.[34]

Third Issue: A violation of Section 41 (2) of the BD Act was contended by ESG. This section states that the "NBA and the State Biodiversity Board shall consult the Biodiversity Management Committee while taking any decision relating to the use of biological resource and knowledge associated with such resources occurring within the territorial jurisdiction of the Biodiversity Management Committee." The word shall here indicates the compulsory nature of the requirement to consult which was not been followed in this case.

Fourth Issue: The contracting parties in this case were accused of accessing six local varieties of Brinjal without the permission of the competent authorities. This was contended to have deprived the local communities of their right (recognized by the Biological Diversity Act) to equitable benefit sharing arising out of commercial use of these resources. This

33 Section 5(3) of the Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
34 *Supra at* 32.

allegation is linked to the first issue and requires that there be a prior violation of the rule related to the formal permission.[35]

By adopting this decision, the NBA issued a firm message to non-Indian entities with foreign participation and their Indians collaborators, indicating that the practice of bio-piracy from now on in India would be prosecuted legally.

Current Legal Status of Monsanto's Activities

In 2016, a moratorium was imposed by the MoEF on the release of the transgenic brinjal hybrid in India. The then Environment Minister, Sh. Jairam Ramesh commented that this moratorium period was to be used to incorporate newer scientific studies and testing procedures. He stated that it was important to build and regain public confidence in GM food, which was to be taken up during the halted period.[36] There also were suggestions for the moratorium period to be used for developing a separate regulatory authority and simultaneously hold a parliamentary debate on private investment in agricultural biotechnology.[37]

Monsanto recently in 2016 sub-licensed Bollguard I and II, Bt Technology to 49 seed companies. This technology was granted an Indian patent in 2008.[38] In 2015, Monsanto terminated one such sub-licence agreement with a particular company, Nuzhiveedu Seeds.[39]Monsanto alleged that the Indian company had pending 'trait value' of Rs. 165 crore that was due to be paid. In 2015 the maximum royalty fee on cotton seeds or 'trait value' was brought into regulation by the Government which set up a committee to execute its cotton price control. An order to control the prices of cotton was passed by the Agriculture Ministry in 2016 after similar such price control orders were passed by states such as Maharashtra, Andhra Pradesh and Telangana. This was done by the Ministry with the aim of bringing about uniformity in Bt. cotton seed prices as well

35 *Id.*

36 (Oct. 20, 2017), http://www.thehindu.com/news/national/Bt-Brinjal-Note-by-Ministry-of Environment-and-Forests/article16578296.ece.

37 (Oct. 20,2017), http://www.thehindu.com/news/national/Bt-Brinjal-Note-by-Ministry-ofEnvironment-and-Forests/article16578296.ece.

38 (Oct. 20, 2017), http://indianexpress.com/article/india/gm-technology-trait-fee-war-betweenmonsanto-and-indian-seed-firms-intensifies-4439264/.

39 (Oct. 20, 2017), http://www.business-standard.com/article/companies/high-court-stays-restorationof-monsanto-agreements-with-nuziveedu-seeds-117041000803_1.html.

as an increase in their affordability. This order has been challenged by Monsanto in a separate case.[40]

With regard to Nuziveedu, Monsanto had filed a case against the company for continuing sale of seeds using its patented Bt technology even after the termination of the sub-license agreement.[41] The Delhi High Court in 2017 ruled in favour of Nuziveedu Seeds Ltd, the Indian sub-licensee. The termination of the sub-licence was held to be invalid and illegal and the Court also held that the earlier agreement for the use of Monsantos Bt technology between the two parties would prevail.[42]

3.2.3 Neem, Turmeric and Basmati Patent Case

These three cases, which took place at three different points of time, are considered to be some of the most fundamental cases relating to biological resources, indigenous and traditional knowledge.

Traditional Knowledge, as considered by the Convention on Biological Diversity and the Nagoya Protocol, is a living accumulation of knowledge which gets passed on from one generation to another and forms a part of the very identity of communities and cultural groups, which must be protected by Intellectual Property rights at all times. The use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized culture can be defined as "bio-piracy". In other words bio-piracy means misappropriation of traditional knowledge with an intention to gain patent protection over that knowledge.[43]

40 (Oct. 20, 2017), http://www.livemint.com/Politics/OcprBoleBmUfGAaNgi2gJO/Centre-sets-upcommittee-to-fix-Bt-cotton-seed-prices.html.

41 *Id.*

42 Madhavi Sally, Delhi High Court favours Nuziveedu seeds in Monsanto's case, The Economic Times (March 29, 2017); (14.10.2017), http://economictimes.indiatimes.com/news/economy/agriculture/delhi-high-court-favours-nuziveedu-seeds-in-monsantos-case/articleshow/57882172.cms.

43 Saipriya Balasubhramaniam India: Traditional Knowledge and Patent Issues: An Overview of Turmeric, Basmati, Neem Cases (Apr. 18, 2017); (Oct. 14, 2017), http://www.mondaq.com/india/x/586384/Patent/Traditional+Knowledge+And+Patent+Issues+An+Overview+Of+Turmeric+Basmati+Neem+Cases.

3.2.3.1 The Neem Patent Case

Filed by W.R Grace and Department of Agriculture, USA, this patent was on the process of controlling fungi on plants with the aid of a foliar fungicide comprising solvent extracted neem oil and was granted by the European Patent Office (EPO) in the year 1991. These neem oil pesticides exhibited the ability to prevent fungal growth and kill fungal pests at various life stages.[44]

Since the 1980s, many neem related process and products have been patented in Japan, USA and in European countries.[45] The first US patent was obtained by Terumo Corporation in 1983 for its therapeutic preparation from the neem bark.[46] In 1985, Robert Larson from the USDA (United States Department of Agriculture) obtained a patent for his preparation of neem seed extract and the Environmental Protection Agency (EPA) approved this product for use in the US market. In 1988, Robert Larson sold the patent on an extraction process to the US Company, W.R. Grace & Co (presently known as Certis).[47] Having gathered their patents and clearance from the EPA, four years later, Grace commercialized its product by setting up manufacturing plant in collaboration with P.J. Margo Pvt. Ltd in India and continued to file patents from their own research in USA and other parts of world.[48]Aside from Grace, neem based pesticides were also marketed by another company, AgriDyne Technologies Inc., USA. The market competition between these two companies was intense. In 1994, Grace accused AgriDyne of a non-exclusive royalty-bearing license. During this period in India, a large number of companies also were developing stabilized neem products and were making them commercially available as well.[49]

A legal objection was filed by a New Delhi based research foundation by the name of Research Foundation for Science, Technology and Ecology, in co-operation with the International Federation of Organic Agriculture Movements and Magda Aelvoet,

44 CHANDRA, R. (2010). Knowledge as property: issues in the moral grounding of intellectual property rights. New Delhi, Oxford University Press.

45 *Id.*

46 (Dec. 27, 2017), http://www.neemfoundation.org/about-neem/patent-on-neem/.

47 *Id.*

48 Ethnobotany of India, Volume 5: The Indo-Gangetic Region and Central India. T. Pullaiah, K. V. Krishnamurthy, Bir Bahadur.

49 *Supra at* 44.

former green Member of the European Parliament.[50] Dr. Vandana Shiva, a prominent environmental activist called this instance as "pure and simple piracy". The oil from neem has been used traditionally by farmers to prevent fungus. It was neither a novel idea nor was it invented.[51]

The EPO identified the lack of novelty, inventive steps and possibly a relevant prior art in this particular matter and thus revoked the patent. Apart from this, several US patents were recently rejected on Neem-based emulsions and solutions."[52]

3.2.3.2 The Turmeric Patent Case

In 1995, two expatriate Indians at the University of Mississippi Medical Centre were granted a U.S. Patent on Use of Turmeric in Wound Healing. The claim covered "a method of promoting healing of a wound by administering turmeric to a patient afflicted with wound".[53] In 1996, The Council of Scientific & Industrial Research (CSIR), India, New Delhi requested the US Patent and Trademarks Office to revoke the patent on the grounds of existing of prior art. CSIR did not succeed in proving that many Indians already use turmeric for wound healing although turmeric was known to every Indian household for ages.[54]

Fortunately, it could provide documentary evidence of traditional knowledge including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association that contained relevant evidence of the same. The patent was revoked in 1997, after it was ascertained that there was no novelty.[55]

The United States Patent and Trademark Office, which had granted this patent initially, after looking into the evidence provided by the Indian Council of Scientific and Industrial Research (CSIR), revoked the patent and stated that the use of turmeric and its usage is

50 *Id.*

51 India Wins Neem Patent Case, Reported in The Hindu, Wednesday, (Mar. 9, 2005); (Nov. 14, 2017), http://www.thehindu.com/2005/03/09/stories/2005030902381300.html.

52 Saipriya Balasubramania, Traditional Knowledge and Patent Issues: An Overview of Turmeric, Basmati, Neem Cases. (Dec. 27, 2017), http://www.mondaq.com/india/x/586384/Patent/Traditional+Knowledge+And+Patent+Issues+An+Overview+Of+Turmeric+Basmati+Neem+Cases.

53 (Oct. 14, 2017) http://lifeintelect.com/blog/2013/10/24/traditional-knowledge-and-intellectualproperty-case-of-turmeric.

54 *Id.*

55 *Id.*

long engrafted into the traditional and indigenous knowledge of ancient Indians and it must therefore be respected and protected.

This case highlighted the inadequate and insufficient documentation of Indian Traditional Knowledge, because of which many such traditional practices and usages were being subjected to exploitation. It also pointed to the inefficiency of the Indian Patent Offices in the granting of patents wherein an average of five to six years is taken by it to grant one. Due to the delay in granting of patents in India, other persons in the meantime are successful in obtaining patents on such practices and usages from other jurisdictions.

3.2.3.3 The Case of Patent on Basmati Rice

Originating in India (earlier, inclusive of Pakistan), the Basmati rice fell into sudden controversy when the American company, RiceTec, in 1997 patented some types of this rice and termed it as 'American Basmati'.[56] The patent was objected by two Indian Organisations, The Centre for Food Safety and The Research Foundation for Science, Technology and Ecology. The Council for Scientific and Industrial Research had also objected to this patent. Once the evidence was readied, the Indian government filed an objection and challenged the patent in 2000. According to Dr Vandana Shiva, a leading environmental activist, the main aim for obtaining the patent by RiceTec Inc. was to fool the consumers into believing that there was no difference between spurious Basmati and real Basmati.[57]

Moreover, she also claims that the "theft involved in the Basmati patent was threefold: a theft of collective intellectual and Biological Diversity heritage on Indian farmers, a theft from Indian traders and exporters whose markets were being stolen by RiceTec Inc., and finally a deception of consumers since RiceTec was using a stolen name Basmati for rice that was derived from Indian rice but not grown in India, and hence are not of the same

56 Denis Vidal. In search of 'Basmatisthan' : agro-nationalism and globalisation. Jackie Assayag and C.J. Fuller (eds). Globalizing India : perspectives from below, Anthem Press, 2005. <ird-0129319>.

57 A Study of the Basmati Case (India-Us Basmati Rice Dispute): Geographical Indication Perspective, (Oct. 21, 2017). http://csbweb01.uncw.edu/people/eversp/classes/BLA361/Intl%20Law/Cases/ Study%20of%20Basmati%20Rice%20Intl%20Case.ssrn.pdf.

quality.[58]Eventually, RiceTec took back 15 out of the 20 claims it had made in its patent and the decision finally was made in India's favour.[59]

Although this case has a more significant purpose in Intellectual Property Rights Law, it has also gained prominence as one of the earliest cases relating to the issue of bio-piracy, biological resources, their genetic information and customary practices relating to cultivation and heritage. One of the steps successfully taken by India in this regard is the development of Traditional Knowledge Digital Library (TKDL), which secures all available aspects of Traditional Knowledge in one place, thus providing a ready reference in situations where such information is required.[60]

3.2.4 The Pepsico Seaweed Case

The Seaweed case is one of the most popular cases cited by the National Biodiversity Authority to illustrate how benefits have reached the local communities from the utilization of bio-resources. However, this case also highlights the inadequate Environmental Impact Assessment (EIA) methodologies adopted while granting permissions for commercial activities.[61] In this case, the company Pepsico India Holdings was contract farming for seaweed (Kappaphycus alvarezi) in the state of Tamil Nadu which was further being exported countries such as Malaysia, Philippines etc.[62]

This seaweed was being cultivated off the Gulf of Mannar in four districts of Ramanathapuram, Thoothukudi, Pudukkottai and Thanjavur in Tamil Nadu. 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. Since 2007, Pepsico India and AquaAgri have contributed over Rs 37 lakh to NBA's National Biodiversity Fund, making it the largest

58 *Id.*

59 (Dec. 27, 2017), http://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-ismostly-settled.html.

60 Protecting India's Traditional Knowledge, (Dec. 27, 2017), http://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html.

61 Curious case of seaweed, (Dec. 27, 2017), http://www.downtoearth.org.in/coverage/curious-case-ofseaweed-39207.

62 Pepsi forays into seaweed farming, (Dec. 27, 2017), http://www.thehindubusinessline.com/2002/08/02/stories/2002080202430100.html.

single royalty payment to the NBA.[63]The fund consists of Rs 97 lakh, of which royalties account for Rs 43 lakh and application fees make up the rest. The fund money is meant to be used for conservation of biological resources and the socio-economic development of areas rich in biological diversity.[64]

It has been reported though that the biggest inflow of money for benefit-sharing has remained unutilised. The Managing Director at Aquaagri Processing Pvt Ltd. which was set up in 2008 to primarily buyout Pepsico India Holding's seaweed business in Tamil Nadu, in an interview stated that the money to the benefit sharers was still stuck in procedure.[65]

What needs to be focused on however is the nature of the operation being conducted by Pepsico/AquAgri and the biological resource of seaweed. The operation of Pepsico/AquAgri was that of contract farming of seaweed, which was initially started as a corporate social responsibility initiative by Pepsico. The seaweed was grown by the fishing community of the above districts in an area leased from the Tamil Nadu Port Authority. So the question that arises is as to why there was even a requirement for NBAs approval for the cultivation and export of this seaweed. This is because under the BD Act of 2002, all seaweed (whether mined or cultivated) is clubbed together by the Commerce Ministry and requires NBA clearance for exports.[66]Another serious issue is that of the particular species of seaweed discovered as being alien to the area by scientists. This species was assessed by the scientists to have invaded the Gulf of Mannar Marine National Park which might have an impact on the flora and fauna existing there. The question of whether a thorough assessment was done by the NBA before giving its approval then becomes crucial.[67]

3.2.5 Bio India Biologicals: Exporting of Neem Leaves Case

This case was regarding the cultivation of "Neem Leaves" (Azadirachta indica), which was initiated by a Japanese firm which got into collaboration with Bio India Biologicals Company. The Indian company Bio India Biologicals sourced the neem leaves from

63 *Supra at* 61.

64 *Id.*

65 *Id.*

66 Latha Jishnu, The Curious Case of the Seaweed, Down to Earth, Monday, (Dec 27, 2017) http://www.downtoearth.org.in/coverage/curious-case-of-seaweed-39207.

67 *Id.*

Amarchinta village in Mahboobnagar district, Andhra Pradesh and Andhra Pradesh State Biodiversity Board helped the village get higher rates for their bio-resource.[68] Bio India Biologicals, based on the Japanese companies inputs decided to work with local communities for collecting the neem leaves without involving any middle men, brokers or traders and under the Biological Diversity Act principles.[69]

The company had identified two Neem rich villages and entered into an agreement with local communities, providing them five per cent on procurement price of leaves. The Biodiversity Monitoring Committee of the Andhra Pradesh State Biodiversity Board took care of the processes which included the signing of pacts with local communities and collecting leaves.[70]The leaves were collected from village Biodiversity Management Committee and were dried by undertaking a few special operations by the villagers of Amarchinta before it was handed over to Japanese Company. The NBA was paid a royalty @5% of FOB to the tune of Rs. 55,035.00 by the exporter which transferred a part of the royalty amount to Amarchinta BMC for planting neem saplings and creation of awareness about biodiversity conservation.[71] This is one of the instances where a transfer of a part of the Royalty received by the NBA was made to a BMC.

3.2.6 Czech Republic's Scientists Case[72]

This particular case was regarding the prosecution of two reputed scientists in the Court of the District Magistrate in Darjeeling, West Bengal which was reported in the year 2008. The scientists were charged under Sections 27[73] and 29[74] of the Wildlife Protection Act, 1972 by the West Bengal Forest Department, which dealt with illegal entry into a Protected Area that was punishable under Section 51of the Act.

68 (Dec. 27, 2017), http://www.thehindu.com/news/national/andhra-pradesh/A-sweet-tale-of-how-neemtrees-yield-money/article12549014.ece.

69 (Dec. 27, 2017), http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf.

70 (Dec. 27, 2017), http://www.downtoearth.org.in/coverage/the-hunt-for-benefits-39205.

71 *Id.*

72 C.R.Case 48 of 2008 before the Darjeeling Chief Judicial Magistrate.

73 Section 27, Wildlife Protection Act, 1972, No. 53, Acts of Parliament, (Sept. 9, 1972), (India); "Restriction on entry in sanctuary".

74 Section 29, Wildlife Protection Act, 1972, No. 53, Acts of Parliament, (Sept. 9, 1972), (India); "Destruction, Etc., In A Sanctuary Prohibited Without a Permit".

In addition to those charges, subsequent charges of the violation of Section 3 of the BD Act, 2002, were also made. This section states that no non-Indian entity (person/institution/ body corporate) can access any of India's biological diversity without express permission of the NBA.

The scientists were arrested by the Forest Ranger, Singalila North Range, Wild Life Division and were said to be found in possession of any many as 1500 species of butterflies, insects and moths, most of which were endangered in nature.[75] The scientists in their defence stated that this specie collection was for their personal research and was for a non-commercial purpose. Hence, they did not apply for permissions from the NBA.

However, the Court of the Chief Judicial Magistrate convicted both of the scientists and fined one of the convicted, Rs. 20,000 and the other Rs. 60,000 along with three years of imprisonment.[76] While this case raised concerns about the weakness of the procedural system as well as monitoring of access to biological resources, the issue of curtailment of freedom of research by the BD Act was also subsequently discussed in the scientific community.

Relevant Sections of the Wildlife Protection Act, 1972

Section 27 [Restriction on entry in sanctuary]	No person other than those mentioned under subsection (1) of Section 27 shall enter or reside in the sanctuary, except under and in accordance with the conditions of a permit granted under section 28.
Section 28 [Grant of permit]	(1) The Chief Wildlife Warden may, on application, grant to any person a permit to enter or reside in a sanctuary for all or any of the following purposes, namely:(a) investigation or study of wildlife and purposes ancillary or incidental thereto;(b) photography;(c) scientific research;(d) tourism;(e) transaction of lawful business with any person residing in the sanctuary. (2) A permit to enter or reside in a sanctuary shall be issued subject to such conditions and on payment of such fee as may be prescribed.

75 Litigating India's Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India); A Study of Legal Cases, Kanchi Kohli and Shalini Bhutani, Foundation of Ecological Security, November, 2016.

76 *Id.*

Section 29 [Destruction, etc., in a sanctuary prohibited without a permit]	No person shall destroy, exploit or remove any wildlife from a sanctuary or destroy or damage the habitat of any wild animal or deprive any wild animal or its habitat within such sanctuary except under and in accordance with a permit granted by the Chief Wildlife Warden and no such permit shall be granted unless the State Government being satisfied that such destruction, exploitation or removal of wildlife from the sanctuary is necessary for the improvement and better management of wildlife therein authorizes the issue of such permit.
Section 51[Penalties]	(1)Any person who [contravenes any provision of this Act [(except Chapter VA and section 38J)]] or any rule or order made thereunder or who commits a breach of any of the conditions of any license or permit granted under this Act, shall be guilty of an offence against this Act, and shall, on conviction, be punishable with imprisonment for a term which may extend to 3 [three years], or with fine which may extend to 4 [twenty-five thousand rupees], or with both.

3.2.7 Monsanto's Wheat Patent on Nap-Hal[77]

The Writ petition was filed in 2004 by the Research Foundation for Science Technology and Ecology, New Delhi imploring the Centre to take immediate action against the patenting of indigenous wheat by the Monsanto. A patent for a traditional variety of Indian Wheat called Nap hal was filed by Monsanto and this patent had been pending in the European Patent Office (EPO) since its application.

In 1998, the patent was finally granted to Monsanto after it acquired the wheat division of the Anglo-Dutch food giant Unilever.[78] Nap hal was a type of traditional wheat indigenous to India, which as a result of years of crossbreeding had low gluten and elasticity characteristic of soft milled wheat used most commonly for making chapatis and biscuits. This patent was subject to dispute in the Supreme Court in 2004 on the grounds that the US Company had stolen the existing traditional knowledge of the Indian farmers and was now terming it as their own invention, and thus responsible for Bio-piracy.[79]

77 Research Foundation for Science, Technology & Ecology & Another versus Union of India & Others [WP (Civil) No. 64 of 2004].

78 Patent No. EPO 445929 B1 filed vide Application No. 9130127.

79 Shan Kohil, 'Spicy IP Dellowship 2016-17, Biopiracy in the Context of Plunder of Wheat in India', Spicy IP, March 21st 2016; (13/12/17) https://spicyip.com/2016/03/spicy-ipfellowship-2016-17-biopiracy-in-the-context-of-plunder-of-wheat-in-india.html.

Bio-piracy does not involve the informed consent of local communities or benefit sharing of the money accrued from the commercial exploitation of traditional knowledge (TK) with the local community.

In India, the Plant Varieties and Farmer's Rights Act, 2001 has acknowledged that local communities are instrumental in bringing genetic diversity that is often relied upon by breeders, and has thus granted exclusive rights to these breeders while stipulating a benefit sharing mechanism under section 26(5)(a)[80]. Further the BD Act of 2002 has inserted provisions for the prevention of bio-piracy.

Section 6 of BDA, 2002 stipulates that no patent application can be filed, in or outside India, without the prior approval of the National Biodiversity Authority, if the underlying research comes from biological resources obtained from India. The BD Act has tried to create a benefit sharing mechanism with local communities with shared patent rights, technology transfer or monetary payment with the mechanism.

Lastly with respect to patent applications, the Indian Patent Act, 1970 requires "mandatory disclosure" regarding the source and geographical origin of the biological resource. The Supreme Court in this case issued notices to various departments of the Government of India directing them to take appropriate action to challenge the patenting of wheat before the European Patent Office (EPO). A petition was subsequently filed before the EPO and resulted with the EPO withdrawing the patent on grounds of no commercial viability. The effort of the Government in combating bio-piracy was commended in this case.

An important aspect that can be learnt from this and similar such cases, is of the need to form a system where there is a convergence of Intellectual Property Law and the law on Biological Diversity in India. This is necessary in the interest of preserving biological resources associated knowledge, since the misappropriation of such knowledge from local communities has often occurred through the usage of IPR, which has in the past had serious impact on communities. Even if such a structural framework exists, traditional knowledge could still be vulnerable to exploitation due to the lack of a systematic monitoring mechanism.

80 *Id.*

3.2.8 Japanese National's Case

In this particular case, two Japanese scientists were taken into custody by Wildlife Officials from the Athirapilly Forest[81], Kerala. They were accused of illegally smuggling exotic species of snakes, spiders, scorpions, turtles etc. The Forest Department charged them under various sections of the Wildlife Protection Act, 1972 and the BD Act, 2002 for the offence of smuggling. Upon investigation, it was reported that the two youths, who were scientists of a reputed institute in Japan were taking these reptiles for research purposes.

Section 3(1) of the Biological Diversity Act, 2002 states that access to biological resource and other activities mentioned under the BD Act cannot be undertaken by non-Indian individuals or entities (body corporates/associations/organizations) having non-Indian participation without prior approval of the National Biodiversity Authority. Any violation of the provision, which is a cognizable and non bailable offence, is punishable with imprisonment up to five years, or with a fine up to Rs.10 lakh. In cases where the damage caused exceeds Rs.10 lakh, the fine may be commensurate with the damage caused, or with both according to the Act.[82]

In this case, various sections of the Wildlife Protection Act, 1972 were also applied such as illegal trespass into protected areas of the forest without permission from the Chief Wildlife Warden[83], removal of any wildlife from a sanctuary[84], and their transport into another country without permission.[85]

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81 K S Sudhi 2015 Japan Nationals to be booked under Biological Diversity Act, The Hindu, June. 24, 2015; (Dec. 12, 2017), http://www.thehindu.com/news/cities/Kochi/japan-nationals-to-be-bookedunder-Biological Diversity-act/article7348752.ece.

82 Section 55(1), Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

83 Section 27, The Wild Life (Protection) Act, 1972, No. 53, Acts of Parliament, (Sept. 9, 1972), (India).

84 Section 29, The Wild Life (Protection) Act, 1972, No. 53, Acts of Parliament, (Sept. 9, 1972), (India).

85 Section 48 A, The Wild Life (Protection) Act, 1972, No. 53, Acts of Parliament, (Sept. 9, 1972), (India).

LEGAL AND ADMINISTERIAL OVERREACH WITHIN THE BIOLOGICAL DIVERSITY ACT*

4

Human beings thrive and flourish on the resources which they extract from the Earth. These resources are necessarily biological and genetic in nature which are found either in the wild, or are domestically produced or cultivated. In the early generations, when the needs and aspirations of humans were significantly less, these resources were considered to be in abundance. However, with the rise in the number of people and the simultaneous rise in the standards of living, there was a significant decline in the number of biological resources. From judicious use, there was a shift towards exploitation of resources that prima facie not only depleted the ecological balance, but also became a question of violation of the rights of indigenous people. Over time, the rights of indigenous people, whose livelihoods depended upon the natural biological resources were exploited and violated by the greed of multi-nationals who extracted precious resources and used them for their benefit.

As this became a pressing issue, there was a global consensus on the need for formulating certain guidelines, rules and regulations stipulating the manner in which these resources would be used, by whom would it be made available and what would be the essential conditions to be fulfilled by the party willing to take and give access to these biological resources. In the Stockholm Convention of 1972 and later in the Rio Convention of 1992, there arose this proposition of regulating biological resources and the nations unanimously agreed to formulate a uniform system. It was in the year 1992 when the Convention on Biological Diversity was adopted. This Convention was based on the premise that the Earth belonged to all human beings and vice-versa. Therefore, it is only fair that everyone within reasonable conditions is provided with access to Earth's resources in a manner that is sustainable, fair and non-exploitative. By means of this Convention, the world leaders agreed on three main principles, namely, '*conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources.*'[1]

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1 Article 1, United Nations Convention on Biological Diversity, 1992.

The National Biodiversity Authority, established under Chapter III of the Biodiversity Act, 2002 is the chief authority responsible for the Biological Resources and Genetic Resources in India. The Authority has been granted powers to prescribe conditions and regulations, when required for access to biological and genetic resources and to ensure that there is no exploitation of any kind. The NBA also has the power to provide penalties in case of any violation of the orders of the National Biodiversity Authority or the State Biodiversity Boards, and/or violation of any provision under the Act.

The role of the NBA as established under the BDA, 2002, is to conserve the biological and ecological resources present in India and to regulate access to them while ensuring equitable benefits arising from their commercial use. However, if one takes into account the activities carried out by this authority in all these years of its existence, it would not be entirely incorrect to say that despite the legislative provisions and policy mandates, the only regulation that has been laid down is with regard to the commercial use of these resources. The concept of conservation of biological diversity, despite being reflected in the legislative intent, has been largely left out of the Act. The focus of the Act remains the judicious use and exploitation of the resources to ensure revenue to the Central Authority (National Biodiversity Authority) and the indigenous communities by means of detailed procedures for equitable sharing of benefits. The inclusion of the term 'Benefit Claimers' in the Section 2 of the Act, is in consonance with the same.

4.1 Umbrella Powers of the National Biodiversity Authority; The State Biodiversity Boards

The tropical nation of India which has some of the highest numbers of biological resources, has suffered an unprecedented and unaccountable loss of biodiversity due to rapid urbanization and rampant commercialization. Referring to the annual reports and government documents available in the public domain, it has been estimated that a very insignificant amount of money has been collected by the NBA in lieu of fine and penalties from the domestic and/or foreign companies who request for commercial utilization of resources. To corroborate the said argument, it would be of aid to mention Section 3 (Utilization of biological resources and knowledge therefrom by Non-Indian Entities, to take prior NBA's approval); Section 4 (Results of research not to be transferred to certain persons without approval of NBA); Section 6 (No person to apply for IPR outside India,

based on research or information on biological resource obtained from India without approval from NBA); Section 21 (Determination of Equitable Benefit Sharing by NBA); Section 40 (Power of the Central Government to exempt certain biological resources). These sections, per se, are some of the major provisions of the domestic act, which look into revenue generation and assist in converting the use of biological resources into a profitable business, instead of curtailing these activities with the intention of conservation.

It has been a long standing debate, whether or not the State Boards (hereinafter referred to as the SBBs) should be given more decision making capacities and whether such a step would make any difference in improving administration and conservation. The plain reading of the Act clearly suggests that the NBA serves only a recommendatory role with respect to suggesting conservation strategies and the Central Government is not bound to adopt those measures.

Another observation about the administration of the Act is worth making. Since the time the legislation has come into play, numerous cases have been filed and have attracted the attention of the environmentalists and conservators. But, these cases have not been initiated at the national level, but through smaller villages, districts and talukas, that are under the direct control and supervision of the SBBs. The Biodiversity Management Committees which report to the SBBs stand in a better position to monitor and supervise the activities of biological resources being tapped by companies and body corporates that later use them for commercial gains. These authorities, by themselves do not have much say or power of decision making. For example, the case of BT brinjal[2] had created an upheaval in the country which the local NGOs and communities had taken to the NGT. The companies and their executives had collected the biological and genetic resource from the local farmlands of the villagers that was further researched upon in their laboratories. It would be only sensible to state that had the SBBs and the BMCs been granted certain powers of questioning and sanctioning, the issue would not have raised an uproar and questions

2 In the case of BT Brinjal, the National Biodiversity Authority of India in order to regulate access to and use of biological resources, had initiated a legal action for biopiracy against the U.S. transnational seed company Monsanto and its Indian collaborators. The aim of these proceedings was to denounce the use by these entities of indigenous varieties of brinjal to develop their genetically modified eggplant species, Bt Brinjal, without prior authorization. *See* Walid Abdelgawad, 'The Bt Brinjal Case: The First Legal Action Against Monsanto and Its Indian Collaborators for Biopiracy' *Biotechnology Law Report*, Vol. 31, No. 2, 2012, pp.136-139.

that were raised on the effectiveness of the administration of the Biological Diversity Act could have been averted. Similarly, the case of neem leaves which were being exported to Japan for commercial purposes did not gain legal urgency as the foreign company chose to follow the legal recourse of taking requisite permissions and gave the stipulated royalties and payments to the BMCs.

While looking at domestic cases of bio-utilization and commercial utilization of biological resources, the Indian companies were only required to give a prior intimation to the local SBB about their activity. Companies are seldom concerned about obtaining such approvals as even after half a decade of passing of the Act there has hardly been any reporting of violations. But since the threat of the depleting biodiversity reserves now looms large on the country and the detrimental effects of the same on long-term sustainability of economic growth have been adequately established, the State Boards have taken the violating parties to task. Recently, the Uttarakhand Biodiversity Board had issued notices to 350 companies[3] for violating the provisions of the Act. But on the contrary there have been instances where notices served by Boards such as the Telangana State Biodiversity Board have met with no response from the companies which goes on to show that recalcitrant companies must be dealt with a firm hand and judicial measures must be resorted to for keeping a check. The multinational giants also deny accountability to State Boards and continue with practices of transporting substantial biological and genetic resources.

The State Boards thus remain in no position to bargain as these organizations are not "Indian" over which the jurisdiction of these Boards resides. Moreover, reports of violation to the National Biodiversity Authority are often met with a delayed response, and meanwhile relentless commercial exploitation of state bio-resources continues unchecked despite the Board being aware of the exploitation.[4] This problem however shall now be taken care of, owing to the very recent judgment in the *Divya Pharmacy case*[5] after which the Indian companies too shall be required to share benefits in an equitable manner with the indigenous community. With this futuristic judgment in place, in order to maintain positive

3 (Oct. 15, 2018), http://www.dailypioneer.com/State-Editions/dehradun/350-companies-issued-notice-for-violating-biological-diversity-act.html.

4 Arushi Sharma, 'State Biodiversity Boards; Analysis of their Functions and Powers', (Oct. 17, 2018), https://blog.ipleaders.in/state-biodiversity-boards-analysis-functions-powers/#_ftn3.

5 *Divya Pharmacy* v. *Union of India and Ors.* [Writ Petition (M/S) No. 3437 of 2016].

outcomes, the SBBs must be given more powers, than merely being intimated by persons for obtaining biological resources. It shall prevent the NBA from being overburdened which earlier dealt with permissions and approvals only of the non-Indian companies. If the SBBs are granted this power and function to regulate the domestic companies in their commercial utilization of bio-resources, the SBBs would be in a better position to monitor, control and regulate the available resources as the BMCs which are under the direction of the SBBs are responsible for maintaining the PBRs which actually enlist and maintain an account of the available resources in their respective State.

4.2 Challenge of the Biodiversity Management Committees

The success of any SBB is widely understood on the number of BMCs that it sets up. Kerala, for example is a leading success story which has BMCs in all its villages whereas a number of states have expressed their struggle to form BMCs citing lack of consent from the local communities. It is noted[6] that the local community has expressed their disinterest and fears over setting up of BMCs as the role of this BMC is to list out the available biological resources and they fear disproportionate exploitation of the same if not granted protection. Approximately 300 representatives of panchayats and gram sabhas, supported by non-governmental organisations (NGOs) and citizens groups, took part in a rally in Delhi on 8 December 2004 to protest.[7] In a memorandum submitted to the then Minister of Environment, A Raja, they demanded that wider powers and functions to manage both habitats and species be vested with Panchayati Raj Institutions (PRIs) and existing ground-level bodies, including customary institutions. BMCs, they said, cannot be mere data providers for PBRs, and urgent steps had to be taken to ensure that the knowledge and resources being recorded in the PBRs were legally protected (for which there is no provision in the law) (Kohli et al 2009).

Many challenges that have been brought to light by the officials working in BMCs are those of political, financial and practical nature. The same has been reiterated by the former Chairperson of NBA, Dr. Pisupati Balakrishnan who in an interview in Down To Earth

6 Kanchi Kohli and Shalini Bhutani, 'Biodiversity Management Committees; Lost In Numbers', *Economic and Political Weekly*, Vol. XLIX, No. 16, April 19, 2014.

7 *Id.*

mentions that there is lack of leadership in the enforcement of the BDA in India. Many villagers who possess traditional knowledge and have access to certain biological resources, have to be explained the need for conservation and the importance of the law to regulate the indiscriminate use of their knowledge and the resources. This is an important challenge which is faced by many talukas in different states. The transparency which is mentioned in the Act, must be maintained at all times and an effective monitoring mechanism must be setup to ensure the working of the Act which requires the attention of the officials at NBA and the Central Government. In today's date, while citing the efficiency of the BMCs in getting benefits from ABS arrangements, it is an equally important task to ensure that there are no corrupt practices and that the local community actually gets the amount that they are entitled to. This underlines and highlights the need for delegation of more powers to the SBBs in this respect.

A final insight which can be made is with regard to the establishment of the Biodiversity Heritage Sites (BHS). Section 37[8] of the Act, read with the 2013 Guidelines[9] which lays down that the local communities shall be consulted before proposing a site to be declared as a BHS, creates a lacuna in practical implementation. The SBB may suggest to the NBA about declaring an identified site as a heritage site, and practically, it is completely in the domain of the Central Government upon the formalization of the same. One fundamental question that needs to be understood that comes to the mind of the author is the intention behind declaring BH sites. The legislative intent is that of conservation of not only biological resources, but also the confluence of traditional knowledge, tradition and customs of the local indigenous people and the unique biodiversity of the region. However, the Guidelines formulated states that within the management of BHS, the use of the resource shall be 'regulated' if not banned. For a country which is grappling with administrative opaqueness and is clouded with propagandas towards its biological wealth, such regulations only pretend to conserve the resources to be exploited in a regulated fashion. This does not solve the purpose of having such reserves at all. A similar point was raised by the post-colonial environmentalists who had contended that the British had derived the Forest Act not with the intention of conserving forests but to delineate the forests from

8 Section 37, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

9 Guidelines for Selection and Management of the Biodiversity Heritage Sites, 2013.

the local people and industry and exploit those resources for their own commercial gains. The same must not be the case with the Biodiversity Act.

4.3 Conclusion

So far, it has been established that the BDA, 2002 has not risen up to the challenges of conservation as were laid down by the CBD in 1992. Whereas the international convention stressed on conservation of biological resources and their sustainable use, India while adopting the convention focused only on the access and benefit sharing aspect of the same and on how well the resources maybe exploited to generate revenue. The administration of the legislation has also been questioned as the NBA which seems to possess most of the powers and retains the final decision-making, also assumes the role of both, the prosecutor and the judge, in case of any violation and discrepancy. This violates the basic norm of legal adjudication process. While the National Authority, in its composition ensures the representation[10] of a number of departments, such as the Department of Biotechnology, Department of Tribal Affairs, Department of Ocean Development, Department of Indian Systems of Medicines and Homeopathy etc. they have no involvement in the day to day affairs of the Authority which is important for granting permissions to non-Indian companies and domestic companies with foreign participation. Moreover, while deciding penalties, there is no member from the legal community to advice on the same. Not to mention the NBA having the powers to impose jail terms and fierce penalties without the legal advice from any designated legal member, does raise a doubt on the working and credibility of the Authority. It is urged that the administrative structure, responsible for the enforcement of the Biodiversity Act be revamped and many of the lacunae as stated be addressed in order to ensure better functioning of the legislation.

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10 Section 8(c), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

ADJUDICATION WITHIN THE BIOLOGICAL DIVERSITY ACT, 2002*

5

Sections 55-61 of the Biological Diversity Act, 2002 consist of the penalties which shall be imposed upon the violation of the provisions of the Act. The penalties consist of monetary fines and imprisonment varying from three to five years. The violations are non-bailable and cognizable. Thus, on imprisonment bail would not be granted as a matter of right but on the discretion of the courts. The National Green Tribunal (NGT) shall be a body of appeal for violations. Also, Sections 3 and 7 violations maybe appealed before the High Court and Supreme Court. When the Biodiversity Act, 2002 was formulated, the NGT did not exist, however, in the preamble of the NGT Act, 2010 it is stated that the tribunal shall have jurisdiction over the matters of biodiversity offences. This happens to be one of the first problems of the Act - deciding on an appropriate forum for the cognizance of offences. To illustrate the stated contention, the following case may be considered.

The Nagpur Bench of the Bombay High Court in the case of *Central India Ayush Drugs Manufacturers Association and Ors. v. State of Maharashtra and Ors*.[1] by order dated September 28, 2016 dismissed a preliminary objection raised by respondents as to the maintainability of the writ petition pertaining to challenging the vires of certain provisions under the Biological Diversity Act, 2002 before the Bombay High Court. The Bench held that the Bombay High Court has jurisdiction to entertain the writ petition pertaining to challenging the vires of certain provisions under the Biological Diversity Act, 2002 and that petitioners do not have any alternative remedy before National Green Tribunal to raise the issues asserted in the writ petition.

In the said writ petition, petitioners' *inter alia* sought the following reliefs:

1. A declaration that Rule 17 of the Biological Diversity Rules, 2004[2] does not apply to Indian entities or body corporates;

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1 *Central India Ayush Drugs Manufacturers Association and Ors. v. State of Maharashtra and Ors*, [WP No 6360 of 2015].

2 Rule 17, The Biological Diversity Rules, 2004, G.S.R. 261 (E), Acts of Parliament, 2004, (India).

2. As an alternative to the abovementioned point, a declaration that to the extent that Rule 17 of the Biological Diversity Rules, 2004[3] envisages equitable sharing of benefits by Indian entities, it should be declared ultra vires the provisions of the Act and therefore, unconstitutional;
3. A declaration that the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 notified on November 21, 2014 by NBA under the aegis of the Ministry of Environment, Forests, and Climate Change, apply only to transactions involving non-Indian entities and that the same do not apply to Indian entities not trading any biological resources with non-Indian entities;
4. A declaration that the ABS Regulations are ultra vires Sections 23[4] and 24[5] of the Biological Diversity Act, 2002.

The Division Bench of the Bombay High Court vide order dated December 2, 2015 issued notices to the concerned respondents (NBA, Maharashtra SBB, State of Maharashtra, and Union of India) and restrained them from taking any coercive action against the petitioners under the Biological Diversity Act, 2002 and Biological Diversity Rules, 2004. Subsequently, the respondents raised a preliminary objection to the maintainability of the writ petition before the Bombay High Court on grounds that the issues raised by the petitioners in the instant writ petition could be decided only by NGT by virtue of Section 14 of the NGT Act, 2010. Section 14 of the NGT Act reads as follows:[6]

(1) The Tribunal shall have the jurisdiction over all civil cases where a substantial question relating to environment (including enforcement of any legal right relating to environment) is involved and such question arises out of the implementation of the enactments specified in Schedule I.

(2) The Tribunal shall hear the disputes arising from the questions referred to in sub-section (1) and settle such disputes and pass order thereon.

(3) No application for adjudication of dispute under this section shall be entertained by the Tribunal unless it is made within a period of six months from the date on which the cause of action for such dispute first arose: Provided that the Tribunal may, if it is satisfied that the applicant was prevented by sufficient cause from filing the application

3 *Id.*
4 Section 23, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
5 Section 24, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
6 Section 14, The National Green Tribunal Act, 2010, No. 19, Acts of Parliament, 2010, (India).

within the said period, allow it to be filed within a further period not exceeding sixty days.

The respondents placed reliance on the decision of the Constitution Bench of the Hon'ble Supreme Court in the case of *L. Chandrakumar v. Union of India and Ors*.[7] and submitted that Tribunals such as NGT were constituted with a view to reduce frivolous litigation in High Courts and that reliefs claimed by the petitioners in the instant petition could be examined by NGT as the petitioners were challenging the vires of the BD Act and not the NGT Act or Rules that is the parent enactment of NGT.

The petitioners on the other hand argued that when there is a challenge to the vires of any Act or Rule, a Tribunal does not possess jurisdiction to look into the validity of the said challenged statutory provision. It was further argued that Section 14[8] of the NGT Act does not confer any jurisdiction beyond what is provided in the enactments mentioned under Schedule-I of the Act. Thus, it was contended that NGT only has the power to entertain an appeal as provided under Section 52A[9] of the BD Act and it does not have the power to adjudicate upon any challenge to the vires of provisions under the BD Act or Biological Diversity Rules, 2004 or any regulations made thereunder.

The Division Bench considered the provisions of the NGT Act and BD Act and of the enactments under Schedule-I of the NGT Act and interpreted that under Section 14[10] of the NGT Act, NGT has been conferred with only limited jurisdiction to deal with specific types of civil disputes. The Bench held that NGT has the power to entertain disputes subject to the fulfillment of the following conditions:

1. The disputes must be civil in nature;
2. Disputes must necessarily arise out of the implementation of the enactments specified in Schedule I; and
3. Disputes must involve a substantial question relating to the environment.

7 *L. Chandrakumar v. Union of India and Ors,* AIR 1994 SC 1266.
8 *Supra* at 6.
9 Section 52 A, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
10 *Supra* at 8.

The Bench held that only if the above mentioned ingredients are satisfied, the bar under Section 14(1) [11]of the NGT Act gets attracted such that jurisdiction in such cases lies solely with NGT. On the question as to whether NGT can adjudicate on the issues raised in the instant writ petition, the Bench, placing reliance on an earlier Division Bench judgment of the same High Court, where a similar contention under the City of Nagpur Corporation Act, 1948 was dealt with, held that NGT does not have the power to adjudicate upon any dispute arising out of a challenge as to the vires of any provision of any subordinate legislation mentioned under Schedule I of the NGT Act or any regulations made thereunder. The Bench reasoned that the scheme of the NGT Act does not permit NGT to decide upon the vires of any enactment that confers appellate or other jurisdiction upon it and accordingly dismissed the preliminary objection.[12]

The question that needs to be considered here is, if this recent judgment is relied upon, would it imply that the jurisdiction of the NGT may only be invoked when it confers fine and the jurisdiction of a court of law would be invoked if a jail term is to be awarded? It may be noted here that no legislation regulating aspects of the environment or forests, has such bifurcated avenues of justice delivery.

5.1 Remedies *versus* Penalties;[13] Analysing the Provisions of the Biodiversity Act, 2002

The study which is being referred to in this section, specifically addresses the conflict which plagues the Indian legal system with regard to Biodiversity offences. In this sphere, we also take into consideration the ABS agreements which are entered into by the NBA, on behalf of the benefit claimers and the companies/body corporates which intend to utilize the biological resource. The NBA, is an administrative body which has certain administrative powers. The governing legislation grants this body certain powers to punish the offenders by imposing fines and even sentences of imprisonment. This grant of power to administrative agencies is primarily done to avoid the burden on the judicial bodies of a country. This

11 Section 14(1), The National Green Tribunal Act, 2010, No. 19, Acts of Parliament, 2010, (India).

12 Malathi Lakshmikumaran and Vindhya S. Mani, 'Biological Diversity Act, 2002; An Overview', (Nov. 6, 2018), http://www.legaleraonline.com/articles/biological-diversity-act-2002-an-overview.

13 Tomme Rosanne Young, 'Administrative and Judicial Remedies Available in Countries with Users under their Jurisdiction and in International Agreements', Open-ended Working Group on Access and Benefit-Sharing, Fifth meeting, Montreal, 8-12 October 2007.

raises an important question and doubt, *is the National Biodiversity Authority a quasi-legal body?* De facto, the NBA is both the adjudicator and the plaintiff, which violates a basic principle of natural justice. Section 8[14] of the BDA states the NBA as a body corporate, having perpetual succession, a common seal etc. which translates into the NBA being a "company". A point of worry here is that there is no information on the process followed by the NBA through its 'expert committees' while disposing of applications and ruling of offences. The same has been reiterated by ex-chairperson of NBA, Dr. Pisupati Balakrishnan who in an interview was asked to give some suggestions in the current situation.[15]

The Act, here provides for both, remedy as well as penalty. A remedy is suggested within the clauses of the model ABS Agreement which is available on the NBA website, on the basis of which the ABS agreements are entered into; and a penalty is imposed under the Act upon violation of the sections by non-Indian companies/body corporates etc. The purpose of a penalty is to identify the violator and punish him in some way; whereas the purpose of a remedy is to "fix" or "cure" the person/entity/etc. who has, as a consequence of the violation, been injured or damaged or has suffered a financial loss. The primary difference between a remedy and a penalty relates to the person/entity who collects the funds that are awarded. In a penalty, any financial amount assessed (fines) are paid to the government of the country in which the action is brought. A financial remedy, by contrast, is paid to the person or persons who have suffered a loss caused by the violation.[16] A second important difference is the fact that, in the context of remedies, the claimant controls the claim. He brings the action, and he determines whether to continue or drop it. In the case of India, under the BDA, the claimant and the prosecutor is NBA. Under Section 61(a) of the Biodiversity Act, *the Central Government or any authority or officer authorized in this behalf by that Government; or any benefit claimer who has given notice of not less than thirty days in the prescribed manner, of such offence and of his intention to make a complaint, to the Central Government or the authority or officer authorized as aforesaid; may take cognizance of an offence.*[17] *Further, the presence of Section 61*[18] *in the BD Act makes*

14 Section 8, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

15 Balakrishna Pisupati, 'Protecting India's Biodiversity: Are we all Criminals?' (Nov. 8, 2018) https://spicyip.com/2018/07/protecting-indias-biodiversity-are-we-all-criminals.html.

16 *Supra* at 13.

17 Section 61(a), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

18 Section 61, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

it even harder to effectively deal with the offences under the Act. This provision states that "no Court can take cognizance of any offence except by a complaint made by the authorised officers". To elaborate, under Section 190 of the Criminal Procedure Code, a Magistrate can take cognizance of an offence through three means, namely: (1) complaint, (2) police report, or (3) information. Section 61 of the BD Act effectively limits the powers of a Magistrate to take cognizance of offences through only complaints and not the other two modes. This provision creates further ambiguity on the procedure of taking cognizance of an offence.

5.2 Remedies available from Administrative Agencies

Unlike the system formulated under the Indian Forests Act, Environment Protection Act and the Wildlife Protection Act, where there are provisions for search, seizure and/or arrest, the Biological Diversity Act has no such provision. It indicates a certain amount of procedural injustice. The Indian Forest Act has a specific chapter (Chapter 9) on penalties and procedures empowering forest officers to arrest, search and seize in connection with the offences punishable under it. Similarly, the Wild Life Protection Act has explicit provisions under Chapter 6, which vest the authorised officers with similar powers in respect of offences punishable under it. On the contrary, the BD Act only has a provision which states that "*all offences under this Act are cognisable and non-bailable*" (Section 58).[19] This means that the police can arrest anyone without an arrest warrant and that grant of bail is not a matter of right but a matter of discretion of the Court.[20] When one looks at the first and may be the only criminal case instituted under the Act till date, it becomes evident that the criminal proceeding was initiated after filing of a criminal complaint before the Magistrate. The complaint was filed by the authorised officers of the National Biodiversity Authority, Karnataka SBB and Karnataka Forest Department in the court of Judicial Magistrate, Dharwad. The subject matter of the complaint was the use of Indian germplasm for developing genetically modified brinjals (BT Brinjal) without the prior consent of the National Biodiversity Authority. In this instance, it is pertinent to note that no search, seizure or arrest was made by the authorised officers.

19 Section 58, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

20 Alphonsa Jojan, 'The Curious Case of the Indian Biological Diversity Act', (Nov. 12, 2018) https://spicyip.com/2017/11/the-curious-case-of-the-indian-biological-diversity-act.html.

Now, administrative remedies are those which are made available through government ministries, agencies and other bodies that are not formal courts. Most countries authorise administrative bodies to undertake some "administrative" decision making processes in response to claims. In other countries, the opposite justification applies – citizens do not normally want to take the difficult and confrontational approach of bringing an action in court. Instead, they prefer to act informally and personally by speaking directly to an agency official. Through these requests for personal interactions, individuals sometimes attempt to pressurise individual administrative officials to make a particular decision or grant an exception for them.

In both of these situations, government agencies and officials need to have clear administrative regulatory standards to guide their judgement. These tools enable the agency to control and manage claims, and to ensure that fair and replicable decision-making is happening throughout the agency.[21] Upon these deliberations, one may point out the ambiguity in the granting and assumption of powers to and by the NBA.

Another important point of consideration here is that the NBA enters into ABS agreements, which are formed on the basis of a contractual agreement. According to the model ABS agreement, under Clause 11[22] the dispute, if not resolved by negotiation in good faith, shall be referred to a sole arbitrator appointed by the Chairperson of NBA. This is in disregard of the provision under the Indian Arbitration Act which has completely different means and rules for the appointment of an arbitrator. There must be three arbitrators, one appointed by each party and a third one appointed by mutual agreement between the two appointed arbitrators. What is stated by the Model ABS agreement is that a sole arbitrator, appointed by the NBA chairperson, seems to be anything but fair. The respondents placed reliance upon the Constitution Bench judgment of the Hon'ble Supreme Court in the case of *L. Chandrakumar v. Union of India and Ors*. and submitted that Tribunals such as NGT were constituted with a view to reduce frivolous litigation in High Courts and that reliefs claimed by the petitioners in the instant petition could be examined by NGT as the petitioners are challenging the vires of the BD Act and not the NGT Act or Rules that constitute the parent enactment of NGT.

21 *Supra* at 16.

22 Agreement on Access to Biological Resources and/or Associated Knowledge for Commercial Utilization, (Nov. 15, 2018) http://nbaindia.org/uploaded/docs/agreement_2.pdf.

RELATIONSHIP BETWEEN INTELLECTUAL PROPERTY AND BIOLOGICAL DIVERSITY*

6

"Biodiversity can't be maintained by protecting a few species in a zoo, or by preserving greenbelts or national parks. To function properly, nature needs more room than that. It can maintain itself, however, without human expense, without zookeepers, park rangers, foresters or gene banks. All it needs is to be left alone."[1]

6.1 Introduction

All human beings have zeal to acquire property, as property plays an important role in human life. It provides us with dignity, status, control, power and security in society. The past couple of centuries saw the creation and rise of a new form of property which is intangible. This new property was termed as Intellectual Property (IP) as it is the creation of human ingenuity or intellect. IP includes all kinds of creative works and research innovations. The subject matter of IP is inclusive and not exhaustive; with the growth of science and technology along with the expansion of IP jurisprudence more and more forms of IP are now being recognised. The prominent fields recognised under the IP law are Patents, Trademarks, Copyright, Design, Geographical Indications, Plant Varieties, Traditional Knowledge and Integrated Circuits. Every form of IP is governed by its own specific legislation which carries provisions for registration, protection, infringement, regulatory authorities and remedies in case of infringement.

Mankind is greatly dependent upon natural and biological resources for his survival. Our food, medicines, furniture, cosmetics, all use resources from nature. However in recent times the 'use' of such resources has now been transformed into 'misuse' and 'over-exploitation' of nature's gift to man. Such unsustainable practices have reduced our lush green forests into barren deserts and wastelands. Mangroves have been cleared for fuel wood and prawn farming, which has led to a decrease in the habitat, essential for breeding of marine fish.

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1 (Mar. 7, 2018) https://www.thefreshquotes.com/biodiversity-quotes-and-slogans/.

On the other hand wetlands have been drained to increase agricultural land. These changes have grave environmental consequences and the money required to reverse such changes will be substantial.[2] The over-exploitation of natural resources along with rampant pollution of the environment and ecology has been a major cause for the decline of biological diversity. There is an urgent need to protect our natural environment and the other life forms around us, for it is reckless if not downright dangerous to keep chipping away at our own life support system and also it is immoral to drive other life forms to extinction.[3]

6.2 Relationship between IP and Biological Diversity (BD)

Biological Diversity and Intellectual Property can be related when intellectual property is based upon biological resources. There are a few international agreements which show the close relationship between these two subjects. These agreements prescribe basic principles and minimum standards to be adopted by member countries. India signed the Convention on Biological Diversity (CBD) held at Rio on 5 June 1992, and ratified the same on 18th February 1994. The CBD was a part of a set of agreements which were opened for signature at the United Nations Conference on Environment and Development (UNCED), also known as the Earth Summit.

The CBD has two important and interesting provisions relating to IPRs. They are:

Article 16.5 which states "that Contracting Parties shall cooperate to ensure that IPRs are "supportive of and do not run counter to the CBD's objectives". However, this is "subject to national legislation and international law"[4].

Article 22 which states that the CBDs provisions will not affect rights and obligations of countries to other "existing international agreements, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."[5]

The Convention on Biological Diversity visualizes a satisfying link between conservation, intellectual property, environmental protection, research and sustainable development.

2 Bharucha Erach, *Text Book of Environmental Studies for UG Courses*, (Hyderabad: Universities Press (India) Private Ltd , 2005) at p. 89.

3 (Jan. 8, 2019), https://www.cbd.int/convention/guide/default.shtml?id=changing.

4 Article 16(5), United Nations Convention on Biological Diversity, 1992.

5 Article 22, United Nations Convention on Biological Diversity, 1992.

The correlation between BD and IP is moulded at the International level by several other conventions and treaties which include but are not limited to World Intellectual Property Organisation (WIPO) and the Agreement on Trade Relates aspects of Intellectual Property (TRIPS) Council of World Trade Organization (WTO).

The CBD reaffirms the sovereign rights of States over their Genetic Resources (GRs) and pursues the idea of sustainable use of its components and the fair and equitable sharing of benefits arising out of its utilisation. The Convention also requires the member nations to protect and conserve assets of Traditional Knowledge at national level. Biological diversity in India is protected and its use is regulated by the provisions laid down in the Biological Diversity Act, 2002. This Act also contains certain provision that deal with IP.

Article 253 of the Constitution of India[6] allows the Parliament to make legislations for giving effect to international agreements, also Article 51[7] calls for the State to foster respect for international law and treaty obligations. Accordingly the Indian Parliament has passed several legislations and/ or made amendments to existing ones for the protection of IP in India. Legislations were made to comply with the international standards and general norms laid down at the International Conventions/Treaties/Agreements.

India made 3 amendments in its Patents Act of 1970 to bring India's patent laws into compliance with WTO TRIPS Agreement. Along with this Amendment Act a new set of Patent Rules were also introduced in 2003.[8] As per this amendment the term of protection for patent was increased to 20 years. Another important change was that now microorganisms could be patented if they met the New, Utility and Non-obviousness (NUN) test. Since microorganisms form a part of biological diversity hence it can be said that this amendment brought in a clear linkage between biological diversity and IP.

6.3 Concept of Biological Diversity

Biological diversity, at its humblest, means the diversity of all life forms in the world. The term biodiversity is used to describe the huge variety of life on this earth and the

6 Article 253, The Constitution of India, 1950.
7 Article 51, The Constitution of India, 1950.
8 (Jan. 9, 2019) https://wipolex.wipo.int/en/legislation/details/7620.

natural pattern it forms.[9]Further the concept biodiversity includes variety of habitations (environments) in which organisms live, the number of species and the variation within each species.

The definition of biological diversity in the BD Act has been provided under Section 2 (b) and it states "biological diversity" means the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems."[10] This definition is largely inspired by the definition provided under the CBD.[11] The Act also defines the term "biological resources" to mean 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".[12]

After going through the important definitions, the provisions under the Biological Diversity Act, 2002 which relate to IP need to be examined.

6.4 Provisions under BD Act, 2002 vis a vis Intellectual Property

Preamble to the BD Act, 2002 includes the terms like biological resources, associated traditional knowledge and contemporary knowledge specifically relation to conservation, sustainable utilization and fair and equitable sharing of benefits arising out of utilization of genetic resources. Further it states that the State is sovereign over their biological resources. From this it is clear that State's sovereignty over biological resources includes traditional and contemporary knowledge. Here, State sovereignty is inclusive and not exhaustive in nature. No person can use these resources without obtaining authority from the State. State can authorize to use the resources keeping in mind the idea of sustainable use and benefit sharing with the local community from where the resources are obtained.

Biological resources as mentioned above comprises of plants, animals, any parts of them including by-products and microorganisms. Some of the subject matter of Biological

9 *Supra* at 2 at p. 79.
10 Section 2(b), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
11 Article 2, United Nations Convention on Biological Diversity, 1992.
12 Section 2(c), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

resources can also be protected under Patents Act or the Plant Varieties Protection Act[13], (PVPFRA) subject to certain restrictions as provided under those legislation's. For example, Section 3(j) of the Patents Act, 1970 provides that plants, animals or parts thereof cannot be patented however it does allow for microorganisms to be patented.[14] On the other hand the PVPFRA allows for plant varieties to be protected for up to 18 years in case of trees and vines and 15 years for extant varieties.[15]

Foreigners and Non Resident Indian (NRIs) are prohibited from accessing biological resources and making any use of the associated knowledge for research, commercial use, bio-survey, or bio-utilisation without the prior approval of the National Biodiversity Authority (NBA). The same restriction applies to body corporates and associations which are not incorporated or registered in India, or if incorporated or registered in India, but have any foreign participation in the capital or management.[16]

Section 6 of the BD Act, 2002 directly and clearly highlights the link between biological diversity and intellectual property. It states that "no person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application."[17] On careful examination it is observed that the approval needs to be taken for "inventions" based on any research or information on biological resources. Thus, applications for IP such as trademarks, copyrights, designs and geographical indications may not require prior approval from the NBA as works under them are not termed as new inventions. Another important aspect of Section 6 is that it grants exemption for application under the PVPFRA therefore any person may apply for protection under the PVPFRA without approaching the NBA. It is to be noted here that the burden has been shifted to the authority under the PVPFRA to endorse a copy to the NBA of its decision to grant any right under that Act.

13 The Protection of Plant Varieties and Farmers Rights Act, 2001, No. 53, Acts of Parliament, 2001, (India).

14 Section 3(j), The Patents Act, 1970, No. 39, Acts of Parliament, 1970, (India).

15 Section 24(6), The Protection of Plant Varieties and Farmers Rights Act, 2001 No. 53, Acts of Parliament, 2001, (India).

16 Section 3(2), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

17 Section 6, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

After reading Section 6 in its entirety one can also safely come to a conclusion that any application for protection of Plant Variety under any foreign legislation would require the prior approval of the NBA as the exemption has only been granted for protection of Plant varieties under the legislation framed by the Parliament of India.[18]

Another important provision that deals with IPR is Section 18(4) which states that the NBA on behalf of Central Government is empowered to oppose the grant of intellectual property rights in any country outside India or any biological resources or knowledge associated from India.

Section 19 (2) of the BD Act, 2002 says that any person who is having intention to apply for patent or any other form of intellectual property protection in or out side India as referred in Section 6 (1) shall make an application to the NBA in the prescribed manner and form. The procedure for seeking prior approval before applying for intellectual property protection is laid down under Rule 18 of The Biological Diversity Rules, 2004.

Further, the NBA plays an important role in determining equitable benefit sharing, grant of joint ownership of intellectual property rights to the NBA or to such benefit claimers, subject to any other regulations.[19] Guidelines for equitable benefit sharing are mentioned under Rule 20 of BD Rules, 2004. As per this rule the authority may impose terms and conditions while granting approval to any person for access or transfer of results of research or applying for patent and IPR or for third party transfer of the accessed biological resources and associated knowledge.

All the above provisions mentioned under the BD Act, 2002 and the Rules clearly indicate as an evidence that there is a close link between biological diversity and intellectual property.

6.5 Protection available to Biological Diversity under Intellectual Property Regime

The extension of IPRs to living beings and knowledge/technologies related to them is relatively recent. In 1930, the U.S. Plant Patent Act was passed, and gave protection to

18 *Id.*

19 Section 21(2)(a), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

asexually reproduced plant varieties under IPRs. Several other countries subsequently extended such forms of protection to plant varieties.[20]

Any person who invents something new or novel after doing research on biological resources can avail various rights under different subjects of Intellectual Property Rights.

First of all, being a new invention[21] it comes within the meaning of patent and the inventor/ researcher can avail the rights and get his invention registered under the Patent Amendment Act, 2005. Patent is a monopoly right granted by the Government to the inventor for a limited period of 20 years. Due to registration he can avail all the statutory rights and remedies in case of infringement. Registration alone protects the interest of inventor. At the time of filing the application for registration, the patentee has to disclose the details of geographical origin of the resources used for his research purpose. If he fails to disclose or wrongly disclose the geographical origin, any interested person can file an application to oppose granting of patent, after publication before granting of patent or after granting of patent within one year as per Section 25 of Patent Act, 1970[22].

Indian Patent Act prohibits certain inventions even if they are new, involve an inventive step, useful, non-obvious and have industrial applications. Sections 3 and 4 of the Patent legislation describe the non-patentable inventions. According to Section 3 (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds,

20 Chaudhuri Sabju Kumar, 'The Impact of IPR on Biodiversity' (Mar. 3, 2018) https://www.researchgate.net/publication/28805051.

21 Sec. 2 (1) (l) of the Patent Amendment Act, 2005 defines new invention.

22 Section 25(1), The Patents Act, 1970, No. 39, Acts of Parliament, 1970, (India):

Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground:

(j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention.

Section 25(1), The Patents Act, 1970, No. 39, Acts of Parliament, 1970, (India):

Section 25(1), The Patents Act, 1970, No. 39, Acts of Parliament, 1970, (India):

Section 25(2), The Patents Act, 1970, No. 39, Acts of Parliament, 1970, (India): At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:

(j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention.

varieties and species and essentially biological processes for production or propagation of plants and animals is non-patentable. TRIPs requires that all signatory countries must provide for adequate protection on the following subject matter in the National Legislations:

1. Patenting of micro-organisms and "microbiological processes"; and
2. Some "effective" form of IPR on plant varieties, either through patents or some sui generis (new) version, or by a combination of both.

This Agreement allows the member countries to exclude animals and plants per se from patentability as it was argued by several nations that patenting of life forms can have serious moral and ethical implications.

Further any invention which, in effect, is traditional knowledge (TK) or which is an aggregation or duplication of known properties of traditionally known component or components is non – patentable.[23] These two exceptions come within the definition of biological resources under the BD Act. This shows the interrelation between BD and IP.

Biological resources comprising of plants, animals and micro-organisms and the traditional knowledge connected to them are essential to indigenous community life in the developing countries. They provide reasonable alternative means of health care and nourishment along with occupation and income generation.[24]

Current IPR system is not suitable for the protection of TK. TK is a knowledge acquired or held by indigenous people from centuries as they lived close to nature and environment. To this extent it can be said that the TRIPs Agreement is incompatible with Human rights. It hinges the rights of indigenous and local communities over the natural resources and/or biological resources and knowledge associated with such resources. The existing IPR regime does not protect the inventions that are based on the prior existing knowledge or knowledge held in public domain. TRIPs agreement is silent about TK and innovations that are in public domain. TK is valuable and most important attribute of biological diversity. It is an important source of sustainable development. TK is associated with many fields'

23 Section 3(p) of The Patent Act, 1970, No. 39, Acts of Parliament, 1970, (India).

24 Aditya Mishra, 'Biopiracy: The Vanishing point of Traditional Knowledge', (Jan. 2, 2018) http://lawmantra.co.in/biopiracy-the-vanishing-point-of-traditional-knowledge-by-sidhant-tigga-and-sachin-mishra.

like agriculture, medicine, art, music, folklore etc. It also has contributed to forest, seed, soil conservation and crop biodiversity. Pharmaceutical companies are using TK of tribal people to identify plants and their ingredients for developing new medicines without sharing the benefits with these communities.

India being a signatory to the TRIPs agreement, in order to give effect to Article 27.3 (b) in part II of the Agreement had to "…. provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof".[25] India adopted sui generis system and made a separate legislation known as Protection of Plant Varieties and Farmer's Rights Act, 2001.Whereas United States and some other countries gave protection to plant varieties under the patent legislation.

The Plant Varieties Act provides for the establishment of an effective system for protection of plant varieties, the rights of farmers and plant breeders. It encourages the development of new plant varieties.[26] Such protection is necessary as India has largely been an agricultural economy and is also very rich in plant varieties. Research on plant genetic resources requires prior approval from the authorities set up under the BD Act, 2002. This highlights the link with intellectual property on Plant Varieties.

Any invention that may be a product or process can get protection under the different subject matters of Intellectual Property Rights. The inventor/ researcher or creator can avail registration and protection for the invention under multiple subject matters of IPR such as Patent, Trademark, Copyright, Design, Plant Varieties and Geographical Indications. This type of protection depends upon the nature of the work and the type of commercial exploitation required. In case of violation the owner of the IP can file an infringement suit under the appropriate enactment to get appropriate/suitable remedy.

6.6 Conclusion

Our sustainability on this earth depends upon our sustainable use of biological diversity. Biological diversity is the hallmark of life on the earth. IPR encourages commercialisation of

25 Article 27.3 (b), Agreement on Trade Relates Aspects of Intellectual Property Rights.

26 Ahuja V K, *Law Relating to Intellectual Property Rights*, (New Delhi: Lexis Nexis Butterworths, 2007) at p. 513.

seed development, monoculture, and protection of new plant varieties, microorganisms and genetically modified organisms. But our rich biodiversity is at stake. Developed countries are not rich in biological resources, but they are rich in research and development. They use the biological resources accessed from the developing countries. Genetic information flow from developing countries to developed countries without protection, by way of patent or plant breeder's rights or other types of IP.[27] There is a need to bring a balance between IPR and sustainable use of biological diversity. Sustainable use of biological resources is the need of the hour, if we misuse, over use or abuse our natural and biological resources it will cause damage to human life on this earth.

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27 *Supra* at 18.

ACCESS AND BENEFIT SHARING SUCCESS STORIES*

7

7.1 Red Sanders generates prosperity

Red Sanders case: The Red Sanders case of the year 2015 paved the pathway for the National Biodiversity Authority, State Boards and local communities to utilize the Access and Benefit-sharing of the biological resources. In this case, Andhra Pradesh Government conducted a global E-auction for sale of high economic value Red Sanders by the Indian and foreign bidders before accessing the biological resources. The successful purchasers had to pay 5 percent to the National Biodiversity Authority or State Biodiversity Board. Ninety-five percent of the total benefits were to be transferred to the Biodiversity Management Committee at the local level. Access and benefit sharing arrangement was one of a kind which proved its utility in the State not only by providing the people a source of income but also by engaging them at the decision-making level which had the potential of encouraging them for the sustainable utilization of the genetic resources. Consequently, people from all walks of life in the state such as indigenous people, tribal people, and forest-dwellers would be benefited from the auction. This innovative instance of access and benefit sharing has changed the way companies have been utilizing genetic resources[1].

7.2 Growing Seaweed leads to growing economy

PepsiCo-seaweed: A multinational company like PepsiCo has also signed access, and benefit sharing agreement where ABS has been implemented successfully. PepsiCo India Holdings Private Ltd. has entered into access and benefit-sharing agreement with the National Biodiversity Authority (NBA) for the export of seaweed (Kappaphycus alvarezi) cultivated by the fishing community in the State for Rs.37 lakhs in 2007. PepsiCo has exported approximately 2000 metric tons of seaweed to countries like Malaysia, Philippines, and Indonesia. The beneficiaries of the agreements are spread across four districts in the State. The company paid the NBA to access the genetic resources from the Gulf of Munnar

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1 (Nov. 20, 2018), http://nbaindia.org.

area in the southern Indian state of Tamil Nadu. The company has signed a yearlong agreement with the NBA to export the seaweed for commercial utilization in the food and cosmetics industry.[2]

7.3 Neem proves its value yet again

Bio India Biological-Neem: The other reported instance to show access and benefit sharing are Bio India Biological-Neem case. National Biodiversity Authority collected 55,035.00 (about USD 924) from Bio India Biological for the export of 2000 kilograms of neem to Japan. People from the village named Amarchinta in the southern Indian state of Andhra Pradesh bundled the leaves and dried them before handing it to the company for the export by entering into an undertaking with the company for a few special operations. The National Biodiversity Authority 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." The BMC has reportedly utilized the money for awareness programs, planting of saplings and fencing[3].

Novozymes Biologicals Inc. of USA has also signed an access and benefit sharing agreement with the National Biodiversity Authority for commercial use of bacteria of Bacillus and Pseudomonas to screen for plant growth from Malampuzha forest division in Kerala. The sample of the bacteria would be used in a laboratory for the promotion of crop production of tomato, lettuce, rice, etc. Novozymes is a multinational corporation with expertise in microbiology, biotechnology, and gene technology. The National Biodiversity Authority has charged Novozymes 5% annual royalty from the sale of the product derived from the biological resource since 2004[4].

2 National Biodiversity Authority, 'Access and Benefit Sharing Experiences from India' (Nov. 20, 2018), http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf.

3 Hem Pande, 'Implementation of ABS Mechanism in India' (Nov. 20, 2018), https://www.cbd.int/doc/meetings/abs/icnp-03/presentations/icnp-3-India-H-Pande.pdf.

4 Kanchi Kohli and Shalini Bhutani, 'Chasing 'Benefits': Issues on Access to Genetic Resources and Traditional Knowledge with reference to India's Biodiversity Regime A post-Nagoya Protocol view on Access and Benefit Sharing'(Nov. 21, 2018), http://awsassets.wwfindia.org/downloads/chasing_benefits.pdf.

7.4 Habib goes herbal

Uttarakhand State Board has entered into access and benefit-sharing agreement with a reputed cosmetic company Habib Cosmetics Private Limited on 15 April, 2015. This is a significant step towards the implementation of the Biological Diversity Act, 2002 and first of its kind by any Biodiversity Board after the notification of Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 by Government of India. The share of benefits generated by the Habib Cosmetics Private Limited, a sum of Rs 3,22,991/- has been shared with Uttarakhand State Biodiversity Board for the year 2013-14 which would be utilized by the Board as per rules.[5]

7.5 Indigenously sharing indigenous knowledge

Access and benefit sharing arrangements also have been signed between a research institute called Tropical Botanical Garden and Research Institute (TBGRI) and a pharmaceutical company called Arya Vaidya Pharmacy on one side and the Kani tribes on the other side. Kani is a tribal community inhabiting the Agastyamalai forests of Kerala for the development of a drug called 'Jeevani' based on the traditional knowledge of the Kani tribe. 'Jeevani' is a restorative, immune-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant arogyapaacha, used by the Kani tribals in their traditional medicine. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by their healers, known as Plathis. The knowledge was divulged by three Kani tribal members to the scientists of TBGRI who isolated 12 active compounds from arogyappacha (Trichopus zeylanicus), and developed the drug 'Jeevani'. The technology was then licensed to the Arya Vaidya Pharmacy Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations. A Trust Fund was established to share the benefits arising from the commercialization of the TK-based drug 'Jeevani'. The operations of the Fund with the involvement of all relevant stakeholders, as well as the sustainable harvesting of the arogyappacha plant, have posed certain problems which offer lessons on benefit sharing over genetic resources and associated traditional knowledge. This experience has provided insight for developing benefit sharing provisions

5 (Nov. 21, 2018), http://www.sbb.uk.gov.in/files/act/abs_agreement.pdf.

in the National Biodiversity Policy and Macro level Action Strategy as well as the legislation on biodiversity.[6]

The Gram Mooligai Company Limited (GMCL) is a public company registered in India. Its shareholders are made up of small groups comprising of members of a community of medicinal plant gatherers. GMCL procures plants and plant products sold as unmodified by-products directly from these groups, at remunerative rates but specifies the quality parameters for harvesting. The company also promotes sustainable harvesting practices among the communities. The company sells the herbs and shares 70 percent of the returns with the communities. In addition to this, the company is also involved in the production of simple medicinal formulations based on traditional knowledge. These formulations are now available in the mainstream markets. It is also an example that indicates how a domestic company can involve local communities in the development of products and markets, with an emphasis on the sustainable use of genetic resources and equity in transactions. It is also an instance of how knowledge related to genetic resource use can be effectively utilized to widen the economic opportunities of the communities.[7]

Dabur India Pvt. Ltd., one of India's largest Ayurvedic medicine and natural consumer products manufacturer has agreed with the State Board of Himachal Pradesh to pay thirty five lakh to access the biological resources of the State.

Similarly, the Honey Bee Network also has examples of domestic benefit sharing with local indigenous innovators.[8]

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6 C.R Bijoy, 'Access and Benefit Sharing From The Indigenous Peoples' Perspective: The Tbgri-Kani 'Model', (Nov.21, 2018), https://www.researchgate.net/publication/228379307_Access_and_Benefit-Sharing_from_the_Indigenous_Peoples'_Perspective_The_TBGRI-Kani_'Model'.

7 M.S. Suneetha , Balakrishna Pisupati and Sanjay Kumar, 'Framework for Benefit Sharing Guidelines for India', *Asian Biotechnology and Development Review* Vol. 11 No. 2, 2009, pp. 55-88 .

8 (Nov. 30, 2018), http://apbiodiversity.ap.nic.in.

TERMINOLOGIES UNDER THE BIOLOGICAL DIVERSITY ACT, 2002*

8

8.1 Understanding what is (Not) Biological Resources with reference to Value Added Products.

With Biological Resources being defined as 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, that does not include human genetic material, it is necessary to understand the term Value Added Products, as the same has been specifically excluded from the ambit of the scope of biological resources, and the Regulations under the Biological Diversity Act, 2002 (hereinafter "the Act").

The term "Value Added Products" is defined under Section 2 (p). It says "*Value added products" means products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form."*

As such the interpretation of the term falls prey to the ambiguity in the implementation of the Act. It may be noted that coconut oil is considered to be a Value Added Product of Coconut by the Coconut Development Board.[1] But access to coconut oil requires the prior approval or intimation of access from the NBA/SBA, as the same may further be utilized for the purposes of bio-fuel.

One view ordains that the term Value Added Product must not be so interpreted that the force of the Act is deemed redundant. The rule of legislative construction - *Ut Res Magis Valeat Quam Pereat*[2]*,* requires that the term "Biological Resource" be so broadly interpreted that although there is "value addition", *per se* to a given biological resource, where the

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1 *Indian Coconut Journal*, Vol. LVIII, No. 2, June 2015.

2 A Latin maxim and rule of construction which means that the construction of a rule should give effect to the rule rather than destroying it.

substance of such resource remains unchanged, such product should not be excluded from the purview and applicability of the Biodiversity Act, 2002.

In *Vishwanath Paper and Boards Ltd. v. State of Utatarakhand & Others*,[3] where the petitioners procured "Waste Paper" as a raw material from another state, it was questioned by the State Biodiversity Board, that prior approval was required thereof. The Court however did not go into the particulars of determining whether "waste paper" is a value added product, as claimed by the respondents.

The scientific advancement of technology has made it impossible to keep the ingredients of any product inseperable. In light of the same, it is to be noted that any material or product that has traces of a biological resource, which can be identified through one or more of the separation techniques, makes it redundant to treat any product as a Value added Product, pursuant to the definition.

Recommendation

One of the primary recommendations that could be made in this regard is that the NBA and other stakeholders while drafting notifications that are issued for certifying any class or categories of products, as Value Added Products, should consult and take the consensus of other agencies such as the Coir Board, Coffee Board, Coconut Board, *etc.*

8.2 Exemption of Local communities, Vaids and Hakims from the Biodiversity Act, 2002

Access to biological resources is regulated under the Biodiversity Act, 2002. The Act clearly bars certain persons and prohibits certain activities to be undertaken without the prior approval of the National Biodiversity Authority[4] (hereafter "NBA") and in certain cases from the State Biodiversity Boards[5] (hereafter "SBB"). The prohibition is not applicable for everyone and the Act itself has created exemptions for accessing and seeking prior approval for obtaining biological resources for certain purposes. Proviso to Section 7 states as follows;

3 Writ Petition No.1425 of 2016 (M/S).
4 Section 3, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
5 Section 7, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

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

The legislation provides for exemption to the local people and communities of the area, including the growers and cultivators of biodiversity, and vaids and hakims, practising indigenous medicine. The justification for granting such exemption requires to be looked into, in order to ascertain the intention of the Government which has granted the exemption.

Regulation 17(c) of Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 exempts local people and communities from seeking approval of the NBA or SBB and reads as follows;

> *"local people and communities of the area, including growers and cultivators of biological resources, and vaids and hakims, practising indigenous medicine, except for obtaining intellectual property rights;"*

The Regulation 17(c) clearly lays down the exemption. For the purpose of this article, "*the growers and cultivators of biological resources*" are not taken into consideration and only vaids and hakims, local people and communities are discussed.

Understanding about Local Communities

The usage of the word "local community" in the Act is seen quiet prominently. Whereas, it is not clear as to what constitutes Local community and who come within its purview. On a general understanding of the words, it is clear that local community includes such groups, who are in close relationship with the natural resources as they depend upon it and are considered not only users but also as potential environmental stewards, and their efforts are promoted or rewarded by international institutions, complementing and at times by-passing the actions of the nation state.[6]

6 Estelle Fach, 'Legal Empowerment of Local communities: a role for International Environmental Law?' (Oct. 23, 2018), https://www.scps.nyu.edu/export/sites/scps/pdf/global-affairs/estelle-fach.pdf.

The words "*local community*" is not expressly defined under any particular statute hence, the same requires to be extracted from the general dictionary meaning. The term community refers to "*a group of people with a common characteristic or interest living together within a larger society*"[7]. Whereas the term '*local*' can be characterised of, or relating to particular place. Hence the usage of term 'local' excludes a broader interpretation, which is based solely on the common interests of the people living in the community. In the context of the Act, the usage of local communities or people means, "*individuals living in a particular area utilising the resources for the common and beneficial interest*."

The objective behind granting such exemption to the local communities and people, goes with the logic that they are the custodian and inhabitants, deriving benefits from such biological resource for their livelihood, and know fully well the consequences of over utilisation or exploitation of resources for which the protection measures for securing and conserving the biological resource for sustainable living are required. The Rio Declaration on Environment and Development in the year 1992, under Principle 22[8] has recognised the role of indigenous people and their communities and other local communities as follows;

> *"Indigenous people and their communities, and other local communities, have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development."*

Further, the Convention on Biological Diversity also speaks under Article 8(j) about the In-situ conservation as follows;

> *"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:"*

7 Definition of 'Community', Merriam-Webster Dictionary, (Oct. 23, 2018), https://www.merriam-webster.com/dictionary/community.

8 Principle 22, Rio Declaration on Environment and Development, 1992.

Local communities and indigenous people have knowledge for conservation and protection of sensitive ecological resources. Hence, the Biological Diversity Act, 2002, which follows the CBD, provides exemption to these categories of people.

Traditional systems of medicine

The Indian systems of Medicine include Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy, which rely on one form of biological resources or the other. The traditional systems of medicine in India have been recognised by the Government and are presently regulated by the Ministry of AYUSH[9].

The primary reason for enacting the legislation is that the knowledge systems and practices of the local and indigenous communities have been accessed by outsiders freely in the past without sharing the benefits arising out of such knowledge sharing. It is quite clear from the speech made by the then Minister for Environment and Forests at the time of consideration of the Biological Diversity Bill, 2001, where he had observed that, "*to respect and protect the knowledge of local people relating to biological diversity*" and "*… provided necessary safeguards to protect the interests of local people, growers and cultivators of biological diversity as well as Indian researchers.*"[10]

Local communities, Vaids and hakims are the repositories of traditional knowledge, as they are aware of the methods of utilising the bio resources and the methods for their conservation and rejuvenation. Vaids and hakims practice traditional medicine system and in order to promote and encourage such traditional systems, free access to biological resources and research by Indian citizens are exempted from any kind of approvals. However, when such research leads to the commercial utilisation, the provision of the Act becomes applicable.[11] The essence of Indian medicine system lies in the biological resources that are available in the country and the practitioners of such medicine system require protection and promotion, which is the objective behind the provision. There were apprehensions raised about there

9 (Oct. 23, 2018) http://ayush.gov.in/about-the-systems.

10 Lok Sabha Debates – Consideration of the Biological Diversity Bill, 2001, Thirteenth Lok Sabha, 11th Session, dated 2 December, 2002, (Oct. 23, 2018) http://164.100.47.194/Loksabha/Debates/Result13.aspx?dbsl=4790.

11 K. Venkataraman, 'Access and benefit sharing and the Biological Diversity Act of India: A Progress Report' *Asian Biotechnology and Development Review*, Vol. X, No. 3, July, 2008, pp 69-80.

being no scope of any research being undertaken by vaids and agriculturists. However, by granting exemption to them their interests have been safeguarded as they can go anywhere and have access to whatever they need in this field. At the inception the village committees were assigned the task to take care of these people to see that their ideas are accommodated.

The Convention on Biological Diversity also recognises the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles based on the biological resources and its sustainable use.

8.3 "Commercial Utilization" and "Traditional Practices" under the Biological Diversity Act, 2002: Definitional Perspective

The Biological Diversity Act, 2002 defines commercial utilization under Section 2(f) of the Act. It states "commercial utilization means end user of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping".

Section 2(f) of the Biological Diversity Act, 2002 read with Explanatory Note on the Section by National Biodiversity Authority[12] provides that the end use of a biological resource for commercial use such as Drugs, Industrial Enzymes, Food Flavours, Fragrance, Cosmetics, Emulsifiers, Oleoresins, Colours, Extracts and Genes used for improving crops and livestock through genetic intervention are exempted for the following purposes:

- *Conventional Breeding;*
- *Traditional practices in use in any agriculture;*
- *Traditional practices in use in any horticulture;*
- *Traditional practices in use in any poultry;*
- *Traditional practices in use in any dairy farming;*

12 (Jan. 31, 2019), http://nbaindia.org/content/565/56/1/explanatorynote.html.

- *Traditional practices in use in any animal husbandry; or*
- *Traditional practices in use in any bee keeping,*

However, neither the Section nor the Explanatory note provides any definition of 'Conventional Breeding' or 'Traditional Practices'. Further, no light has been thrown on the pecuniary scale to which commercial utilization of biological resources can be done through conventional breeding or traditional practices by local people. For example, if an individual collects milk in conventional manner and sells it to companies like Amul, would it be covered under 'Conventional Breeding'. Similarly, if local people collect honey or silk in traditional manner and sell it to companies like Patanjali, would it still come under "Traditional Practices"? Would use of modern technology by the local people for extraction of biological resources still be regarded as "Traditional Practices" though it might not *stricto sensu* satisfy the threshold of continuing custom? Further, would such exemption be valid even if commercial utilization of biological resources through conventional manner of extraction of biological resources leads to degradation and overexploitation of such resources? An 'explanation' or 'definition' of such wide ambiguous terms must be provided under the Act to restrict its scope and bring greater clarity to the meaning of these terms.

Also, whether the multinational companies purchasing biological resources from such local people (who are exempted under the Act) would also be exempted from the ambit of the Biological Diversity Act, 2002? For example, if local people exempted under the Act sell honey collected in traditional manner to Dabur, would Dabur also enjoy the exemption? If so, it would give the multinational companies an alternative indirect way of exploiting the biological resources without proper access and benefit sharing as intended by the Act. These are few contentious issues which are yet to be resolved.

The exemption to traditional practices under the Biodiversity Act is inspired by similar protection provided to traditional practices under the Convention of Biological Diversity and India being a party to the Convention has attempted to incorporate such exemption in its national legislation. Thus, referring to Convention of Biological Diversity can give us better insight into the ambit of such exemption.

Article 8 of the Convention of Biological Diversity, 1992 discusses In-situ Conservation. Article 8(j) of the Convention of Biological Diversity, 1992 provides that "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". Article 10 of the Convention of Biological Diversity, 1992 deals with the obligations of the contracting parties with respect to sustainable use of components of biological diversity. Article 10(c) of Convention of Biological Diversity, 1992 requires each contracting party to "protect and encourage customary use of biological resources ***in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.***"

On analysis of these provisions, it can be safely concluded that Convention of Biological Diversity intended to provide exemption to only such traditional cultural practices which are in harmony with the conservation and sustainable use requirements of the biological diversity. Further, the exemption should only be restricted to those traditional cultural practices satisfying the threshold of 'custom'. The exemption must be availed by the local people in a manner which leads to preservation of the knowledge and customary traditional practices and values attached with such practice. Further, if the activities of the local people are such that it leads to large scale commercial exploitation of the biological resources, thereby causing loss to the Biodiversity, then the National Biodiversity Authority may adjudge or interpret such activities to be falling out of the scope of the exemption.

Being a signatory to the International Treaty on Plant Genetic Resources for Food and Agriculture which recognises food security and agriculture to be of paramount importance and considers it imperative for countries to develop a system to share such resources among them through Multilateral System, the Government of India through Ministry of Environment and Forests notification dated 18 December, 2014, in the exercise of powers conferred under Section 40 of the Act authorized Department of Agriculture Cooperation and Farmers Welfare to notify such crop species from those listed in Annexure-I of the Treaty which are being considered relevant for exemption from Section 3 and 4 of the

Act for the purposes of utilization and conservation for research, breeding and training for food and agriculture. In pursuance of the aforementioned notification and fresh office memorandum of 16 February, 2015[13], the Department of Agriculture Cooperation granted exemption to all 64 crops listed in Annexure-I of the Treaty. The wordings of the Ministry of Environment and Forests' notification and consequent Office Memorandum of Department of Agriculture Cooperation are very specific with respect to the purpose of exemption. The exemption has only been provided "*for the purpose of utilization and conservation for research, breeding and training for food and agriculture.*"

Definition of Commercial Utilization under Section 2(f) of the Biological Diversity Act, 2002 includes uses which are traditionally not considered as part of "food and agriculture" such as fragrance, cosmetics, oleoresins, genetic intervention etc. The definition in Section 2(f) brings home the point that such 'end use' of biological resources for commercial utilization does not include conventional breeding, traditional practices in agriculture etc. which can be said to be, more or less, in line with the intent of the Treaty. The legislature did not intend agriculture, food etc. to fall under 'commercial utilization'. In other words, if the exempted plant resources i.e. the crops listed by the Department of Agriculture and Cooperation, are used for commercial utilization as defined under the Act, such as cosmetics, fragrances etc., the same shall not be exempted.

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13 (Jan. 31, 2019), http://www.indiaenvironmentportal.org.in/files/file/Guidelines%20for%20the%20Implementation%20of%20International%20Treaty%20for%20Plant%20Genetic%20Resources.pdf.

BIOLOGICAL RESOURCES UNDER THE BIOLOGICAL DIVERSITY ACT, 2002: THE AMBIT*

9

9.1 Can the use of Biological Resources from Waste be regulated under the Biological Diversity Act, 2002?

Waste generation rates are increasing at an alarming rate; a World Bank report found that in 2016, cities across the world produced approximately 2.01 billion tonnes of waste[1] and given the current trend this number is only set to increase with a projected waste generation of approximately 3.40 billion tonnes by 2050.[2] To counter this ever growing pile of waste, conferences are regularly being held at international levels to generate ideas for more effective waste management techniques. Probably the best mechanism of waste management is its re-use by recycling the waste material or extracting those parts which can be useful in some other form. Using waste as a resource will not only help in reducing the burden of its disposal but will also reduce the demand for extraction of new raw material from nature[3] which will further help in conservation of natural or biological resources and will ensure sustainable form of development.

The Biological Diversity Act, 2002 (hereinafter BD Act) of India provides that the any use of biological resource or knowledge associated with it will attract the provisions of access and benefit sharing upon such user. The rationale behind such a law is that the communities who have been preserving the local flora and fauna and who hold the knowledge associated with these resources should also benefit from the commercial use of bio-resources accessed from their local area. There are several exemptions to this general rule of sharing benefits. Some of the exemptions can be found in the definitions itself, for e.g. Section 2(c) which

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1 (Jan. 24, 2019), https://datacatalog.worldbank.org/dataset/what-waste-global-database.

2 *Id.*

3 'Waste: a problem or a resource?', (Jan. 24. 2019), https://www.eea.europa.eu/downloads/ed86ac17b9aa4213b80c0f49c5896d8c/1472651944/waste-a-problem-or-a-resource.pdf.

defines biological resources excludes value added products and human genetic material from the ambit of the BD Act.[4] Also Section 2(f) defines commercial utilisation and excludes conventional breeding and traditional practices in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.[5]

Despite there being several exemption as mentioned above under the BD Act it is interesting to note that biological resources collected from 'waste' have nowhere been exempted under the Act. It is therefore clear that biological resources collected from waste, would also attract the provision of the biological diversity law. This means that the regulatory authorities under the BD Act i.e. the National Biodiversity Authority and the State Biodiversity Boards can regulate the access to such biological resources and can also impose benefit sharing obligations on persons or companies which make use of such resources. The argument of the regulatory bodies is that the waste of one industry can always be the raw material of another industry and therefore they should also come under the ambit of the BD Act. The major question to be decided however is whether such users of biological resources from waste should also be made to share benefits, and if yes, then should the rates of sharing benefits for them be at par with other commercial users of biological resources.

The reason for this deliberation is that many of such users are actually helping reduce waste, and by using waste as a resource they are additionally helping in "conserving biological diversity" which also happens to be one of the three objectives of the BD Act.[6] Therefore, is it fair to force a person to share benefits under such circumstances is a question which needs to be answered.

The reasoning as mentioned above was put forward by an applicant before the Patent Office so as to seek exemption from being regulated by the BD Act. The applicant filed a patent application titled "Process for the isolation and stabilization of low molecular weight Aminoglycans from waste egg shells". As per Section 6 of the BD Act any application for any form of intellectual property based on any research or information on a biological resource from India would require the prior approval of the National Biodiversity Authority.

4 Section 2(c), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
5 Section 2(f), The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).
6 Preamble, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

Therefore, by law the applicant was supposed to take prior approval by the NBA.[7] The Patent office in accordance with Section 6 of the BD Act sent a notice to the applicant stating the they must take prior approval of the NBA or that they must prove that the biological resource i.e. the egg shells were not collected from India. The applicant submitted that egg shells are waste and by using them the applicant is only helping in contributing in waste management which is also a policy of the Government. It further submitted that by doing this they were advancing the two objectives of the BD Act which is conservation of biological diversity and sustainable use of biological resources. They also contended that the use of waste egg shells will not cause long term depletion of the biological diversity in India and hence their activity cannot be regulated by the BD Act. The Patent office accepted the argument made by the applicant and proceeded for grant.[8]

Another issue which had come before one of the State Biodiversity Boards was with regard to a company which was using microbes found in sewage. The contention of the company was that since it was extracting the microbes from the sewage which is a municipal waste and of no use to anybody hence they should not be brought under the ambit of the Act. However the Sate Biodiversity Board rejected the contention on the ground that the waste was being used as a raw material by the company and hence they must share benefits as per the law under the BD Act.

There are two differences in the instances. The first is that the 'egg shells' case was before the Patent office while the 'microbes from sewage' case was before the State Biodiversity Board. The second difference is that in the egg shells case the applicant was purchasing the egg shells and after extraction of the required compound it would ensure the safe disposal of the waste which would thus help in waste management whereas in the 'microbes from sewage' case the company involved was only extracting the microbes from the municipal waste and hence making no contribution towards waste management. These may have been the reason for the difference in opinion between the two authorities.

The author is of the opinion that even in the egg shells case the Patent Office should have asked the applicant to take prior approval from the NBA since it is the NBA which has been given jurisdiction to decide whether a particular activity will be regulated under the

7 Section 6, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

8 (Jan. 26, 2019), http://ipindiaservices.gov.in/PatentSearch/PatentSearch/ViewDocuments.

BD Act or not. The Patent Office could not have made this decision by itself under the existing laws. It is of course a totally different question as to whether the NBA would impose benefit sharing on the applicant in the egg shells case.

Therefore use of biological resources from waste or any other source unless clearly exempted by the BD Act will continue to fall under its ambit. However, in keeping the waste management goals in mind the regulatory bodies under the BD Act may exempt the users of such resources from benefit sharing or impose benefit sharing at "reduced rates" depending upon the amount of waste that such companies are helping to manage and also how much of biological resources they are helping to conserve by taking their raw material from waste rather than from new resources.

9.2 Synthetic Biological Resources and the Biological Diversity Act, 2002

The practice of using plants for therapeutic purposes is probably as old as mankind itself. Oldest recorded evidence of preparing drugs from medicinal plants was found in Nagpur on a Sumerian clay slab and this is estimated to date back to approximately 5000 years.[9] Humans have been dependant on nature and natural products to heal from all kinds of diseases. All the early civilizations have recorded the use of medicinal plants. *Ayurveda* which translates to 'Science of Life' originated in India many thousands of years ago.[10] Similarly the Zoroastrians also used herbal plants and this can be found in their holy book *Avesta.* Phototherapy and medicinal plants is widely discussed in the *Dorandiyud* which is one of the five books which make up the *Avesta*[11]. Hippocrates from the Greek civilisation considered to be the father of medicine recorded the use of over 300 medicinal plants and classified them according to physiological action.[12]

With the advancement in science we have now shifted from direct use of the plants to plant based medicines in the form of pills, liquids, injections etc. The first shift was from herbal medicine to homeopathy and then to allopathy. Proponents of all these three methods claim

9 J. Qiu, 'Traditional Medicine: A Culture in Balance' Nature, Vol. 448, No. 7150, 2007, pp. 126-128.

10 (Jan. 25, 2019), https://www.ayurveda.com/pdf/intro_ayurveda.pdf.

11 Fatemeh Jamshidi-Kia, Zahra Lorigooini and Hossein Amini-Khoei, 'Medicinal Plants: Past history and future perspective', *Journal of Herbmed Pharmacology*, Vol. VII, No. 1, January, 2018, pp. 1-7.

12 Biljana Bauer Petrovska, 'Historical review of Medicinal Plants,' *Pharmacognosy Review*, Vol. VI, No. 11, pp. 1-5, (Jan. 25, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358962/?report=printable.

that their method is the best. While it may be true that herbal medicine and homeopathy have lesser side effects, however for immediate results or in cases of emergency, even the supporters of the Indian systems of medicine have advocated the use of allopathy.[13]

To make a medicine from a plant, animal or microorganism one needs to first identify the bioactive compound. A bioactive compound is something which when brought in contact with a living tissue will have an effect, cause a reaction or trigger a response.[14] Once the scientists are able to identify the bioactive compound they then begin to analyse the compound for its purposes or benefits that it may provide.[15]

After the initial analysis is done the next step is to find a way to synthesize the compound in the laboratory.[16] This is because using plants as raw material is difficult as a continuous fresh supply may not be available, also since the bioactive compounds are found in very small quantities hence their extraction becomes a very costly process. To add to this shortage, the pharma companies require huge amounts of the compound to conduct several tests and clinical trials over many years to finally come to a conclusion that the drug is effective and safe. Large quantities are also required to maintain adequate supply of the drug in the market.[17] Therefore to meet this continuous supply, producing the bioactive compound synthetically in the laboratory is the only viable option and consequently the physical access to biological resources as raw material has become less relevant.[18]

The question that now arises is whether the use of such synthetic biological compounds will attract the provisions of the Biological Diversity Act, 2002 (hereinafter BD Act). The claim made by biotech industries and pharmaceutical companies is that since they

13 (Jan. 25, 2019), https://www.deccanchronicle.com/lifestyle/health-and-wellbeing/090717/doctors-now-rely-on-a-combination-of-allopathic-and-ayurvedic-drugs.html. *See* also (Jan. 25, 2019), https://www.sciencedirect.com/science/article/pii/S0975947618303486.

14 Abdelkarim Guaadaoui, Soumaya Benaicha, Naima Elmajdoub , Mohammed Bellaoui & Abdellah Hamal, 'What is a bioactive compound? A combined definition for a preliminary consensus' *International Journal of Nutrition and Food Sciences*, Vol. 3, No. 3, 2014, pp. 174-179.

15 (Jan. 26, 2019), http://scitechconnect.elsevier.com/plant-to-pill-turn-plant-medicine.

16 *Id.*

17 Albert Alexander the first person to be treated with penicillin died because of shortage of supply of the drug. *See* Jonathan Wood, 'Penicillin: the Oxford story', (Jan. 26, 2019), http://www.ox.ac.uk/news/science-blog/penicillin-oxford-story.

18 K. Divakarn Prathapan and Priyadarsanan Dharma Rajan, 'Commentary, CBD obstructs biological research that needs international collaboration', (Jan. 26, 2019), https://india.mongabay.com/2018/07/17/commentary-cbd-obstructs-biological-research-that-needs-international-collaboration.

are not physically accessing biological resources (or accessing biological resource only for the initial isolation of the bioactive compound) hence their activities cannot be brought under the ambit of the BD Act. They are ready to share benefits on the purchase price of the plants or animals which was used as raw material to isolate the bioactive compound however they contend that once the isolation stage is complete and they have synthesised the compound in the laboratory thereafter they should not be compelled to share benefits on further use of the synthetic biological resources.

On the other hand the argument made by biodiversity conservation activists is that the BD Act does not only require sharing of benefits for access or use of biological resources but it also calls for benefit sharing when the intention is to use "knowledge associated with biological resources occurring in India"[19] Therefore, although the synthetic biological resource may have been produced in the laboratory and is not a naturally occurring biological resource however if the knowledge associated with the original biological resource is used then the user shall be liable to share benefits with the local communities. This line of thought does give rise to a few questions, *firstly* what should be the rate of benefit sharing since the user is not acquiring the raw material from nature and is only using the knowledge associated to biological resources, *secondly* with whom should the benefits be shared if the uses of that plant is in public domain and is common knowledge to the entire society.

The use of synthetic resources over biological resources as mentioned above is the more popular choice by the industry; therefore it is incumbent upon the regulatory bodies under the BD Act to give a clarification as regards to benefit sharing by such users of synthetic biological resources.

9.3 Biological Diversity Act, 2002 and the Silk Industry

The demand for silk has always been at the peak, with pre-historic records also pointing towards a bustling commercial trade around the Asian and Eurasian regions. This remains to be the scenario due to the quality of the textile which reflects its lithesome feature, durability and softness. Hence, the popularity of silk around the world has always kept the product in great demand and it also been referred to as the "Queen of Textiles". As a result, the commercial trade in silk has positively affected the lives of many people too,

19 Section 3 and Section 19, The Biological Diversity Act, 2002, No. 18, Acts of Parliament, 2003, (India).

especially those who have tended to gain livelihood opportunities from its labour-intensive employment, minimum capital investment and compensatory nature. Therefore, these factors contribute to recognize sericulture industry as an appropriate sphere to engage in socio-economic development of the rural Indian Society.[20]

Although China remains to be the world's largest producer of silk in the world (India is the second largest producer), India carries a rare distinction of being able to produce all the five known silk varieties of commercial importance which are mulberry, tropical tasar, oak tasar, eri and muga. At the heart of this discussion are the silkworms and their host plants. Seri-cultural practices have a beneficial influence in the preservation and conservation of the biodiversity as it indirectly aids in sustaining the habitat of flora and fauna ranges. Thus, the contribution of this industry impacts the ecological balance by preventing soil erosion, maintaining natural ecosystem and controlling the climate of the environment.

Consequently, it can be also contended that the environment and the ecology of the place have a role to play in the type and quality of silk being produced. For example, Kovai Kora cotton sarees are produced from a blend of cotton and silk, which finds its origin in Coimbatore. The place of origin impacts the production of these sarees as the climatic conditions of Coimbatore prevents the yarns from snapping. Similarly, the natural golden fabric provided from Muga silkworms is possible because of the ideal temperature and humidity which it receives from the climatic conditions of Assam. Therefore, it is common for these silk varieties to come within the ambit of the protection provided by geographical indications (GI) as such products pertain to a particular geographical origin and retain qualities or a reputation based on its origination.[21]

Despite seeing the influence of the silk industry in biodiversity conservation, it is not covered within the realms of the Biological Diversity Act of 2002. Even though silkworms and their host plants are considered to be biological resources, 'silk' is treated as a Normally Traded Commodity as per Section 40 of the Act.[22] However, time is also catching up with

20 (Jan. 22, 2019), http://texmin.nic.in/sites/default/files/note-on-sericulture-March2016.pdf.

21 (Jan. 22, 2019), https://www.wipo.int/geo_indications/en.

22 Section 40, The Biological Diversity Act 2002, *Power of Central Government to exempt certain biological resources*.—Notwithstanding anything contained in this Act, the Central Government may, in consultation with the National Biodiversity Authority, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities.

the silk industry and it is also deteriorating due to factors such as the depletion of different species of host plants and their various morphotypes along with decline in important wild races of silkworms due to the environmental pollution caused by tea, petroleum, cement, coal and fertilizer industries within their respective regions.

This crisis has been looming over the minds of various stakeholders. Hence, scientifically sound and commercially viable rearing techniques, through continuous research and development, are being developed and established to overcome such environmental effects on activities of the silk industry. Much information on these commercial techniques in the nation has not been available in the past but the Central Sericulture Research and Training Institute in Mysuru has started genetically modifying silkworms to strengthen them against diseases such as Grasserie disease.[23] It has also been reported that silk farmers would start testing their usage which would save them from a loss of 20% annually due to the disease in general. Similar reports have come from research laboratories outside of India wherein biotechnology companies have genetically-engineered silkworms to produce artificial silk[24], one such company being Kraig Biocraft Laboratories, Inc.[25]

On technical grounds, if a silkworm with GI had to undergo a similar modification, it may not qualify for the respective GI anymore as its qualities may alter with respect to the ones noted in the GI. However the entity which invents the process to get more quantity or better quality of silk from a silkworm, could apply for patenting that process or product. Now if these research institutes make use of biological resources (silkworms or plants on which silkworms feed) from India, or the knowledge associated with such biological resources from India then such activity would fall under the Biological Diversity Act.

In the situation mentioned above, it would be mandatory for the commercial entity to make an application to the National Biodiversity Authority for its approval under Section 6 of the Biological Diversity Act before approaching any patent office in the world to apply

23 Indian silk farmers testing genetically modified, disease resistant silkworm, (Jan. 23, 2019), https://geneticliteracyproject.org/2016/05/16/indian-silk-farmers-testing-genetically-modified-disease-resistant-silkworm.

24 University of Notre Dame, 'Scientists genetically engineer silkworms to produce artificial spider silk', Science Daily, (Jan. 23, 2019), www.sciencedaily.com/releases/2010/09/100929142137.html.

25 (Jan. 23, 2019), https://www.kraiglabs.com/spider-silk-company.

for a patent.[26] Thus, the Access- Benefit Sharing framework could probably be introduced under such circumstances only in case of the silk industry. During the course of providing its approval, the NBA would also look into the cases where "benefits from the IP" or the "IP itself" would have to be shared with the respective indigenous and local community by the applicant.

9.4 Alcohol Industry and the Biological Diversity Act, 2002

India has the third largest alcohol industry in the world with an estimated market size of $35 billion per annum[27]. The huge population of India along with the rise in spending power of the urban middle class has led to this sharp increase of alcohol consumption. It has been estimated that by 2022, 16.8 billion litres of alcohol would be consumed in India.[28]

Potable alcohols are of various types ranging from whiskey, rum, gin, vodka, wine, beer and a few others. Each type requires the use of different raw materials and a different process to be followed to achieve the desired results. What is common though, is the fact that the raw material used is a biological resource. For e.g. one of the main ingredients for producing beer is barley although alternative starch sources (adjuncts) such as rice, wheat or corn may also be used.[29]Wine has been consumed since thousands of years, and is usually prepared from grapes. Wine can be prepared from other fruits as well but the International Organisation of Vine and Wine and other international standards require to be prepared only from grapes.[30] While Beer and Wine is prepared by employing fermentation process; Whiskey, Tequila, Vodka and others which fall under the umbrella term "liquor" are further made to undergo the process of distillation and may thus be termed as a more

26 Section 6, The Biological Diversity Act 2002,

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

27 (Feb. 1, 2019), https://www.forbes.com/sites/krnkashyap/2017/03/27/how-startups-are-catering-to-indias-35b-liquour-market-the-3rd-largest-in-the-world/#47e51b451501.

28 *Id.*

29 E. Pires and T. Brányik, *Biochemistry of Beer Fermentation*, (London: Springer, 2015).

30 (Feb. 2, 2019), http://www.oiv.int/public/medias/4776/oiv-wine-labelling-standard-en-2015.pdf.

refined drink. Whiskey is generally prepared using malted barley, wheat or oats.[31] Vodka can be prepared from any starch or sugar rich plant matter although today vodka is generally prepared from corn, rye, wheat etc. but it can also be prepared from potatoes[32].

It is clear from the above elaboration that potable alcohol is prepared mainly by using biological resources and as mentioned above India is one of the leading producers of alcohol in the world. The question that then arises is whether the alcohol industry should also be made to share benefits under the BD Act. Currently the regulatory bodies under the BD Act have not brought the Alcohol Industry under its scanner however the reason for such exemption to this industry has not been clearly established.

According to some, alcohol would be exempted under Section 2(f) for adopting a traditional practice for production of a consumable substance. Section 2(f) exempts conventional breeding or traditional practices in use of any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping. The reasoning given is that any agro-based industry involved in consumable products would be exempted as they are providing food to the society and hence they should not be burdened with the additional obligations to be met under the BD Act. However to say that the Legislature while exempting food items under Section 2(f) also intended to exempt alcohol, seems to be rather farfetched.

Another reasoning given for not targeting the alcohol industry is that since the raw materials used in alcohol production are mentioned under the 'Normally Traded as Commodities List' hence alcohol can also be exempted. As per the Notification issued by the Ministry Of Environment, Forest And Climate Change "products that are derived from the items listed… and traded as a matter of common practice shall also be treated as normally traded as commodities."[33] Section 40 of the BD Act[34] allows the Central Government to exempt certain biological resources from the ambit of the Act when they are being traded as a commodity. A counter to this line of thought however, is that alcohol should not be treated as a normally traded commodity since it is a highly regulated commodity in India.

31 Inge Russell and Graham Stewart, *Whisky: Technology, Production and Marketing*, (Elsevier, 2003).

32 (Feb. 2, 2019), https://www.livescience.com/41298-what-is-vodka.html.

33 Notification – S.O. 1352(E) dated 7 April, 2016, Ministry of Environment, Forest and Climate Change, Government of India,(Feb.2, 2019), http://ismenvis.nic.in/Database/Notification_07th_April_2016-SO1352E_12862.aspx.

34 Section 40, TheBiological Diversity Act, 2002, No. 18, Acts of Parliament, 2003,(India).

The alcohol industry is one of the top revenue sources for State Governments, funding up to one-fifth of most State Government Budgets. In some states the revenue generated assumes second, third or fourth place in terms of contributions made to the State's coffers.[35] This is because of the extremely high taxes that are imposed upon the industry.[36] Therefore, it may not be a reasonable advice to further burden this industry[37] by asking them to share benefits for use of biological resources, and hence they should be exempted from the ambit of the BD Act. Having stated that, it is of equal importance to note that the exemption may come either in the form of a direct notification by the Central Government or by making suitable amendments to the BD Act because as per the current wordings of the BD Act we cannot exempt alcohol industry. Also any attempt to interpret the current law in a manner so as to exempt the alcohol industry would lead to opening of a pandora's box for other industries as well.

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35 (Feb. 2, 2019), https://www.thehindubusinessline.com/economy/the-alcohol-economy/article20697419.ece1.

36 (Feb. 2, 2019), https://www.livemint.com/Industry/iw9WTTb6VcCpcTUeRXPhXJ/Budget-2018-Which-industry-pays-the-most-taxes.html.

37 This view is opposite to the view taken by the Niti Aayog.

Niti Aayog suggested to increase the taxes on tobacco, alcohol and other products as a sin tax. However the author is of the view that increasing taxes does not stop the poor, habitual drinker because no matter what the taxes he will continue to drink, what it does do is reduce the money available for food of the children in that family. *See* (Feb. 2, 2019) https://timesofindia.indiatimes.com/india/panel-suggests-higher-sin-tax-on-tobacco-alcohol/articleshow/67170586.cms.

CHALLENGES IN IMPLEMENTING THE BIOLOGICAL DIVERSITY ACT, 2002: AN INDUSTRY PERSPECTIVE*

10

10.1 Introduction

The Biological Diversity Act, 2002 (BD Act), was enacted to meet India's international obligations under the Nagoya Protocol of the Convention on Biological Diversity (CBD). It has been in force for the more than 16 years. However, the BD Act, 2002 is more skewed towards the Access and Benefit Sharing (ABS) component in the whole scheme of things, while conservation and sustainable utilization of biological resources remains in obscurity, and why not..? There have been very many regulations focused mostly on conservation and sustainable utilization like the Forest Act, Wild Life Protection Act, Environment Protection Act so on and so forth. What these earlier legislations did not have was a provision for ploughing back the benefits derived out of the utilization of the Biological Resources (BRs) to the communities or the conservers. In this context the Act is aptly positioned at incentivizing the conservation, encouraging sustainable utilization and a participatory financing mechanism for conservation efforts. The users (Industry/ Researchers) are aware of the spirit of the BD Act 2002 and most of them if not all are willing to participate in the equitable benefit sharing process. However, there remain areas of ambiguity, uncertainty or lack of clarity for the effective and timely compliance to the various provisions of the Act. Certain challenges in the implementation of the Act are common across all sectors – industries or researchers, while there are a few challenges that are sector specific.

Bagley in 2015 has summarized that the Nagoya Protocol has temporal scope and breadth of coverage. Similarly the challenges posed by our own ABS regulation are due to the breadth of the scope and temporal nature of the regulations. Temporal challenges arise from the question of what biological resources are covered by the Act from a time perspective. Specifically, whether the Act applies only to biological resources physically accessed after

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* Suhas Nimbalkar, Partner, Eitimo Ventures LLP, Bengaluru, A consulting and advisory firm on issues related to BD Act, 2002 and the ABS Provisions.

the Act came into force, or to BRs which are utilized after the Act came into force but were accessed prior to the Act came into force, or to genetic BRs physically accessed at any time and utilized after the Act came into force. Challenges due to breadth of the scope not only include existing issues of what constitutes BRs but also encompasses issues faced from the emerging scientific developments of whether the definitions of BRs, should or will be interpreted broadly enough to include digital information which is used in synthetic biology research in the current time.

It has been more than fifteen years since the BD Act, 2002 has been passed and one definite experience from the industry perspective has been that the differential interpretation of the BD Act, 2002 and the BD Rules, 2004 by each of the institutions under the Act, has made it one of the most challenging legal frameworks. Further, treating any violations as criminal offence due to conspicuous absence of options for compounding of offences under the Act is making research, development and benefit sharing a nightmare for several stakeholder groups such as biotech start-up companies.

The challenges in the implementation and compliance of the BD Act 2002 could be broadly categorized into operational challenges, interpretational and amendment challenges.

10.2 Operational Challenges

The operational challenges are the simpler challenges and can be resolved by making few operational changes at the level of the regulatory authorities or by coming out with specific policies for operations. To put this in perspective, a couple of instances may be considered –

a. ***Sectoral Approach:*** Currently the applications from different sectors (Like Agriculture, Ayurveda, Bio-pharma, Nutraceutical, Cosmetics etc.) are treated and examined in a similar way, although the different sectors function differently. The different sectors access a range of biological resources ranging from abundantly available cultivated sources (Agriculture) to highly endangered resources from the wild (bio-pharma). In the agricultural sector the BRs accessed are not only cultivated products but may also include proprietary materials from other companies. In such situations the most common question asked is whether the ABS collected on the proprietary material would flow back to the owner of the breeder's right as he/she would be the creator, maintainer and conserver of such BRs. Hence having different application forms (to

capture sector specific information) for accessing BR/TK under different sectors will help to evaluate the applications more objectively and also reduce the burden on the regulators.

b. ***Online Application Process:*** It has been a good move to introduce the online application process by the NBA as well as a few of the SBB's. However there needs to be an effort to continuously improve upon the same. User experience with the online application process has not been effortless. The online portal is not stable and logs off every 3 to 5 minutes of remaining idle, hence hindering the filing process as a lot of data needs to be typed in accurately which mostly requires cross verification with the hard copies and is time consuming. The online portal requires one to feed data for the place of access of BR/TK, while many a time many BRs can be accessed from the same location. In such cases there should be an option to choose the place of collection. Also most of the data is already present in the excel format and there could be a provision to upload these data files in the required formats, which would make the process easier and faster. The payment portal for online application does not work seamlessly and one needs to select the offline application box to proceed further. Further communication after the online filing is through mail or hard copies. However a provision to upload the required additional data on the online portal would help to speed the process and keep the traceability of all the communications.

c. ***Announcements of Meeting Schedules:*** There has been a positive change in the way the Authority is functioning from the time it was constituted 16 years ago. Meetings of Expert Committee and the Authority are being held at regular intervals. An advance notification of the upcoming meetings of different ECs and the Authority on the website will enable the applicants to know the schedule of meetings and plan accordingly for quicker response by making submissions before such meetings are held. This kind of advance notifications of upcoming meeting is hosted by other regulators and has helped both the applicant and the regulators greatly. It is a small step but will bring transparency to the process.

d. ***Information on the BMCs:*** A list of active BMCs (details of GP, taluka, district and state) on the web sites of NBA and the different state biodiversity boards will help the applicant to understand the jurisdictional area of the place of intended collection and enable the easy filling up of the applications and any communications with respective BMCs.

e. ***Incentivize participation:*** Incentives have been used as an effective tool to ensure willful participation in many areas. Similarly some forms of incentives could be brought out for the stakeholders that are complying with the Act and honoring the ABS obligations. For example a 'mark' can be issued on the end products highlighting that a part of the benefits accrued from the product is shared with the community. This will help to differentiate the product from others from a consumer's point of view and could generate more business. Also a certificate of compliance could be issued that can be displayed in offices, as many industries would want to showcase their efforts towards environmental conservation. Moreover, reductions or exemptions on certain levies could be thought of, that will attract more stakeholders to get on board.

10.3 Interpretational Challenges

The interpretational challenges arise due to different interpretation of the terms and provisions in the Act. These issues are a notch higher in terms of complexity and with regard to the means required to bring changes for proper implementation and ensuring compliance from stakeholders. Some of the concerns and challenges that these pose are -

a. ***Normally Traded as Commodities List (NTAC):*** The list of NTAC currently includes mostly plant resources, while there are a range of biological resources that are being traded as commodities since time immemorial like animal based products such as milk and other dairy products, leather, wool, antibodies or anti-venom etc., commonly consumed fish and aquatic BRs both from saline and fresh water ecosystems; substances derives from insects such as honey, silk, lac etc.; microbial mediated products like curds, cheese, wine, bread, vermi-compost, farmyard manure etc.; animals used as pets, farming, dairy, draught animals. These need to be included in the NTAC list at the earliest, and the list can be updated from time to time to include or exclude certain BR subject to further deliberations.

The items not listed in the NTAC but in common practice are also exempted from regulation; however the burden of proof of what is a common practice lies on the user. There is no clarity on the kind of documentation needed or admissible before the Authority as a proof of common practice. This challenge arises due to the temporal nature of the provision and how far back in time one would need to go to deem a practice as common practice, and starting from which point of time has to be considered.

A curious case of NTAC arises in the agricultural sector more specifically the seed sector. For example, rice/paddy (plant or seed) is listed as NTAC which means one could buy rice/paddy seeds, process (grade, quality check, treat with fungicide and package) them and sell as seeds. The important point to note here is that the seeds are also classified as essential commodity under the Ministry of Agriculture and Farmers Welfare. Now in such instances would this require one to share the ABS component? How would this scenario change if one has licensed the seeds (proprietary material) either from a public institution or private organization? The persons working in the seed sector feel that an unfair treatment has been meted out to them in spite of them working for the farmers' welfare. What would be the situation if all these seed companies start to withdraw their business in India? Are we in a position to meet the seed demand of the farmers in India only through the government bodies? Is it not a requirement towards achieving our food security goals? We need to take a more practical approach in dealing with such scenarios and come up with pragmatic operational policies to handle these matters.

b. ***Commercial Utilization***: The Biodiversity Act defines activities covered under commercial utilization. However, there remains a grey area as to the quantum of these activities that would be considered as 'commercial activity' and not merely 'practice' by traditional health practitioners (vaids & hakims). Benchmarking this will help in better understanding of the term 'commercial utilization' and reduce debates in this area. It will not only help in better compliance but will also help the authorities to objectively monitor the commercial utilization.

Certain activities might appear commercial *prima facia* but may not involve commercial intent, like the industry that produces products used in religious functions such as incense sticks, flowers etc. The traders feel that the profit margin of this industry is thin and they struggle to make ends meet. In such circumstances, factoring in the ABS component would increase their prices and make them non-competitive.

c. ***Demonstrative use of Biological Resources:*** A broader view needs to be taken in cases where the biological resources are being accessed and used only to demonstrate or evaluate the technology for its functionality, feasibility and marketability. The ABS could be levied on the user of the technology who would be repeatedly accessing and using biological resources for commercial utilization, and not the technology developer. This will help to promote innovations in the technology development companies. Examples could be of positive contributors like volatile extractors, juice extractors pulping machines etc. However inhibitor technologies like insecticides,

pesticides, anti-microbial agents would need to access the BR only to demonstrate the safety and efficacy while in essence no BR would either be used by the technology developer or the technology user. Hence attracting ABS provisions in such scenarios is debatable. While some of the inhibitor technologies like the insect resistance GMO plants would have already agreed on an ABS mechanism when the developer of these technologies would have proposed to integrate these technologies into the Indian BR (Indian germplasm). Moreover, levying an ABS to test these technologies (as they need to use different insect pests from India since the technology is going to be adopted in India) would seem unfair.

Many a times there is a need to establish efficacy and safety due to the statutory requirements by other regulations. The experiments designed to generate such data often use biological resources specific to the region. The procedures required to access such BRs not only need to be simplified but also fast tracked as these are time bound commitments that need to be satisfactorily met with. Not completing these procedures in a time bound and efficacious fashion would have far reaching business implications. Moreover, the ABS component for use needs to be re-visited as such use of BRs does not fall in the same category of use that requires extraction from BRs.

Another example would be of accessing the commercial varieties/hybrids of competitor companies (used as checks) to compare with the developers variety/hybrid. Should this kind of use really attract the ABS component? Does it really require access permissions? If yes, then would it not be practical to have a different access form and process the application within a week's time. This will enable the user to timely sow for comparative analysis. Activities in agriculture are highly time bound and nature dependent hence faster decisions will ensure higher compliance.

d. ***Use of BRs as Techniques/Tools:*** Many of the technologies like tissue culture although more recent than conventional processes of propagation have been adapted widely and are used only to ensure a uniform, disease free and easy to transport propagules for agriculture. It is similar to having a seedling nursery but with more controlled conditions. These are just tools for ensuring better agricultural productivity and if used for BRs listed as NTACs they should not attract ABS. The decision for ABS should be based on the BR and its use (commercial or as NTAC) and not on the technology being used. This will aid in adoption of good technologies for improving agricultural productivity ensuring improved farm income and more importantly, food security. In the present times tissue culture is a common practice, but the question that needs

to be addressed is the manner in which it is to be established as a common practice (of temporal nature) and what are admissible as documentary proofs.

e. ***Collection of ABS by NBA & PPVFRA:*** In the agricultural sector the case of a person or entity who has agreed for ABS mechanism for accessing germplasm for research can be considered. After the initial round, once the new variety developed through research is registered with PPVFRA then the applicant has to also contribute towards the gene fund with PPVFRA whose objectives are similar to the ABS collected by NBA. Will this not result in collection amount generated by ABS by two regulators? An innovator/breeder has to pay ABS for accessing a BR and also for developing a new variety/product after years of research. This is quite a dampener for any innovator. In the present times, where double taxation is being done away with by introducing instruments like GST, levy of ABS in duplication appears not in sync with the changing times. More clarity on this aspect should be brought. This can be achieved by checking if the applicant has already signed up for paying ABS with NBA. If that is the case, then an exemption can be made from contribution to gene fund with PPVFRA or conversely if applicant has not signed up for paying ABS with NBA then he may be obligated to contribute to the gene fund with PPVFRA. It gets more complex because of the fact that the contribution to gene fund with PPVFRA is time bound (for 15 years in most crops) while the contribution for ABS to NBA have to be continued as long as the product is commercialized.

f. ***Exemptions in true spirit:*** As per Section 17 (d) and 17 (g) of the ABS Guidelines Notification dated 21 November, 2014 it is mentioned that the exemption is accorded to certain activities among others like Section 17(d) - accessing biological resources for conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping, in India; Section 17 (g) -biological resources, normally traded as commodities notified by the Central Government under Section 40 of the Act.

Moreover, even the Gazette Notification dated 17 December, 2014 on designation of crops listed in the Annex-I of the ITPGRFA states that - *Now, therefore, in exercise of the powers conferred by section 40 of the Biological Diversity Act, 2002 (hereinafter referred to as the said Act), and in fulfilment of the obligations of the Government of India to the ITPGRFA for providing facilitated access to the plant genetic resources for food and agriculture, the Central Government, in consultation with the National Biodiversity Authority, hereby declares that the Department of Agriculture and Cooperation may, from time to time specify such crops as it considers necessary from amongst the crops listed in the*

Annex I of the ITPGRFA, being food crops and forages covered under the Multilateral System thereof, and accordingly exempts them from Section 3 and 4 of the said Act, for the purpose of utilization and conservation for research, breeding and training for food and agriculture.

In the agricultural sector, the seed companies are mostly engaged in research using conventional breeding methods of cross-breeding and selection to develop new varieties and many a times use the biological resources that are listed under NTAC and Annex-I of ITPGRFA. It will greatly help this sector if the Act, Rules and the Guidelines are implemented in the true spirit.

10.4 Amendment Challenges

The third category of challenges is posed due to certain provisions of the Act that need to be amended. Most regulations are amended within the first few years of their coming into due to the challenges that crop up that were not foreseen at the time when the regulation was adopted. The Patent Act and the PPVFR Act both having linkages with the BD Act have undergone several amendments and policy updates that has ensured greater stakeholder participation in the implementation. Similarly BD Act 2002 needs to be amended appropriately to stay abreast with the changing scientific developments, altered socio-economic conditions and current business practices to encourage and ensure ease of compliance.

a. ***Section 3 (2):*** The major area of contention is Section 3(2) c (ii) where the quantum of share or management has not been specified and hence includes almost all the companies which have taken the IPO route, since by law the companies going public have to keep a certain percentage of their shares in the open market and would have no control over who should or should not buy their shares. In this circumstance there seems to be a contradiction between the two regulations, where one requires a company's shares to be in the open market while the other treats the company differently if its shares are bought by a foreign entity or individual. In the current scenario of globalization and promotion for FDI in businesses in India, it poses a major hurdle especially for the start-ups who are struggling with other compliances. Moreover, they function on a shoestring budget and not to begin the work with immediate effect adds to their troubles. This dampens the enthusiasm of the Indian researcher.

Alternatively, fast tracking and quickly processing the application for accessing biological resources or traditional knowledge for research purpose by start-ups could be explored. In most of the cases that involve research on biological material, the commercialization of the research results takes a minimum of five years, while the initial years could be just exploratory in nature to study the feasibility of the concept or idea. In such cases, the authorities could expend a lesser time on the discussion of benefit sharing aspects which could be revisited after a year of accessing the BR/TK, thus, helping to fast track the applications received from start-ups.

b. ***Violations:*** More pragmatic approach needs to be taken for cases of violations detected, as these could be due to sheer ignorance, unawareness and naivety and not necessarily wilful violation. The Act is positioned to allow only prospective approvals for any activity involving BRs like, access for bio-survey, bio-utilization, research, commercialization, transfer of research results, transfer of accessed BRs, obtaining IPR or even licensing IPs, which in effect translates to the fact that one cannot touch any Indian BRs without prior permission.

As the Act stands today most of us doing any of the activities like bio-survey, bio-utilization, research, commercialization, transfer of research results, transfer of accessed BRs, obtained IPR or even licensing IPs would be violators. A level playing platform needs to be provided for all stakeholders to ensure there is reduction in the number of violations. This could be achieved by few course correctional measures like –

i) ***New Approach to Approvals***: Long timelines for getting approvals from the regulator has become a great hindrance for timely compliance. The applicants do not have a pleasant experience in the time they have to spend in getting the approvals from NBA. The timeline for approvals as it stands today takes four months to more than 12 months in certain cases. The timelines have reduced as claimed by the regulators (from as long as 5 years) but for being business friendly these timelines are still not practical. How can you expect business houses to raise investments and wait for a year or more even to begin the exploratory work? In such cases, an amendment, new policy or operational change can be considered. Retrospective approvals or immediate conditional approval could be considered that would enable the researcher or company to embark on the research project immediately while the regulators could deliberate on the application and revert to the applicant with their approval or otherwise post which the applicant could continue with the new terms of agreement or discontinue the work as the case may be.

ii) ***Retrospective ABS:*** A system of retrospective ABS collection could be introduced. This will build confidence within the business community and the system will be more inclusive of all the stakeholders. A recent office memorandum dated 10 September, 2018 from the MoEF&CC to NBA to consider the applications for retrospective clearance had generated a great positive feeling in the industry; many companies from different sectors utilized this opportunity and filed the applications with a hope to regularize their work. However, this window of retrospective consideration was open for a short period of 100 days and ended on 18 December, 2018, and many companies could not get the benefit from this mostly due to the lack of timely dissemination of this important message to all the stakeholders. Also added to the fact that many companies were not in a position to furnish the mandatory information required for completing the Forms due to unavailability of such information, information present with different departments within the organization, or information present in different regions across the globe. Retrospective clearing measures would enable the stakeholders who have missed out on the opportunity to take advantage of this provision. In true spirit, the objective of the Act should be to generate awareness, sensitize, enable participation for conservation, sustainable use of BRs and equitable sharing of benefits with the benefit claimers and not to create violators and treat them as criminals.

iii) ***Mechanism of penalties:*** Like any other regulation the BD Act 2002, provides for penalties for the contravention of its provisions; however the difference being that contravention of any section of the BD Act is treated as criminal offence with no provision for remedies or penalties commensurate with the level of violations under different Sections. Moreover, a mechanism of fair penalties by means similar to compounding of offences could also be worked out for quick disposal of cases by avoiding the longer route of judicial intervention. Many other laws have provisions for similar kind of penalties, to enable quick decision and better compliances.

10.5 Conclusion

The intended purpose of the Biodiversity Act, 2002 was to ensure conservation, sustainable use of Biodiversity and to ensure fair and equitable sharing of the benefits arising out of the use of Biodiversity. While the Act was conceptualized in 1992 and adopted in 2002 a lot has changed since then in terms of science, technology, the country's economic policies and

socio-economic environment. Hence, the changing times demand that the Act undergoes suitable changes so as to be in sync with the current times because in practice, the provisions criminalize unauthorized access to biodiversity and bring in commercial uncertainty. Foreign companies are unable to get quick permissions to access Indian BRs – even for research purposes. Indian companies also face difficulties while commercializing the results of their research. Protection of Indian BRs has become synonymous with cumbersome process, long tedious waiting period and uncertainty in interpretations making it commercially unviable to operational science based industries. We should take course correction measures before we turn the country into only a trading hub and do away with any scientific innovations and progress. Even research collaborations and sharing of research results with institutions overseas is prohibited without permission, which inhibits generation and exchange of knowledge about BRs that would otherwise have been useful in conserving them. Uncertainty on what conditions have to be satisfied in order to obtain permissions combined with criminal penalties for access without "prior permission" makes it difficult to integrate the requirements of the ABS into the business models thus inhibiting any commercial venture from even investing to generate this knowledge.

If the Act has to be implemented then the different stakeholders have to be consulted and appropriate corrective measures have to be adopted, as fast as possible. The industry is already complying with various regulatory regimes in different spaces and is not shying away from honoring the equitable benefit sharing obligation, however the need of the hour is to facilitate and enable the industry to participate in this journey of conservation and sustainable use of BRs. We need to ensure that the economy is balanced only then can the objective of re-integration of the accrued benefits from the use of BRs can be achieved. Impediments in routine functioning of the industry will dry up the very prospect of financing the conservation efforts. As of March 2018, there were only about 2000 odd applications with NBA, which is a clear indication that the number of stakeholders participating in the process is not commensurate with the actual number of stakeholder that utilize the BRs for any of the purposes mandated in the Act. This does not project a positive impression that the Act has been implemented successfully. This could be attributed not only to some of the challenges discussed above but also many more underlying issues that have not been discussed here or that have not yet been encountered due to lack of experience in certain areas of implementation. Nevertheless, the capacity of the regulators

at all levels (NBA, SBB and BMC) needs to get a boost on an urgent basis. The regulators are under staffed, if the huge mandate that they need to fulfill is considered. They function with officers in ad hoc capacities and often suffer from high rates of attrition due to the impermanency of the jobs, lack of incentives and professional growth. Mechanisms to monitor after access and secure check points are not currently in place, making way for willful defaulters to operate without fear.

The Act is uniquely positioned to enjoy the advantages of self-restraint, responsible use and feedback financing and one should not be taking this away from the visionaries who conceptualized this mechanism by misconstruing the text of the Act, and by not putting it to practice in its true spirit.

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CHALLENGES IN IMPLEMENTATION OF THE BD ACT IN STATE OF KARNATAKA*

11

The environment that we live in encompasses the interaction between diverse living species of flora, fauna, natural resources and the climate that sustains such diversity. The well-being of human life on earth is directly dependent on the environment and the conservation and protection of the delicate balance that sustains life has become paramount in the recent years.

The increasing exploitation of the ecosystems and the biological resources across the world and its ill-effects on the human economic growth brought about the urgent need to safeguard the environment and this concept gained momentum in the early 20th century, when numerous International Conventions were adopted for the conservation of the natural environment. Notable amongst these conventions were the International Whaling Commission, 1946, Ramsar Convention on Wetlands, 1971, United Nations Conference on Human Environment, 1972, CITES, 1973, Convention on Migratory Species, 1979, United Nations Convention on the Law of the Sea (UNCLOS), 1982 etc. This world-wide awareness and recognition of the importance of the natural environment and the need to protect and conserve biological resources gave rise to the Convention on Biological Diversity (CBD) at the United Nations Convention on Environment and Development (UNCED), popularly known as the "Earth Summit", held at Rio de Janeiro, Brazil in 1992.

The main objective of this convention is to achieve 'sustainable development', a phrase coined by the Bruntland Commission, where, the needs of the present generation is met without compromising the ability of the future generations to meet their own needs. This formed the crux of the CBD and is emphasised in the three objectives of the convention, ie., conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The CBD is a near universal multi-lateral environmental convention and re-affirms the sovereign rights of each nation over their biological resources and provides for the

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development of national strategies for the conservation and sustainable utilization of biodiversity. The CBD brought an end to the age-old notion of the natural environment and the biodiversity being the 'common heritage of man-kind' and brought in institutional frameworks for the regulation of the use and exploitation of bio-resources. 196 countries are currently party to this Convention and India was among the first nations to ratify the Convention in 1994.

The CBD has two supplementary protocols; the Cartegena Protocol on Bio-safety, 2000, aimed at regulation of the way genetically modified organisms and living modified organisms are utilized and the Nagoya Protocol, 2010, aimed at the fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge.

11.1 The Biological Diversity Act, 2002

In pursuance of the obligations of ratification by India to the CBD, national legislation to achieve the objectives of the Convention, the Biological Diversity Act, 2002 (BD Act, 2002), was notified by the Parliament of India and came into force after the assent of the President on 5th February 2003.

The object of enacting this Act is to provide for "Conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits arising out of commercial use of biological resources and associated traditional knowledge".

The BD Act, 2002 is implemented in the country in a three-tier administrative structure. The National Biodiversity Authority (NBA), established in 2003, is an autonomous body and performs facilitative, regulatory and advisory functions for the Government of India on issues of conservation, sustainable use of biological resource and fair equitable sharing of benefits. At the regional levels, the State Biodiversity Boards (SBBs) focus on the implementation of the Act in the respective States. Finally, at the local level, the Biodiversity Management Committees, to be constituted by all elected local bodies, are responsible for promoting conservation, sustainable use and documentation of biological diversity at the local level.

The Karnataka Biodiversity Board (KBB) was established as per Section 22 of the Biological Diversity Act, 2002, in 2003 and the Government of Karnataka notified the Karnataka Biological Diversity Rules in 2005 (KBD Rules, 2005) as per the powers conferred under the Section 63 of the Biological Diversity Act, 2002.

The prime objective of the Board is to foster the institutional setup for documentation, sustainable use and development of the rich biodiversity of the state of Karnataka for effective implementation of the Biological Diversity Act, 2002 and facilitate the formation of Biodiversity Management Committees (BMCs) at elected body levels, documentation of the People's Biodiversity Registers (PBRs) and the declaration of Biodiversity Heritage Sites (BHS).

As per the BD Act, 2002, entities referred under the Section 3 (viz. not a citizen of India, non-resident Indians, body corporate, association or organization not incorporated in India or those incorporated in India which have **any** non-Indian participation in the share capital or management), are required to take prior approval of the National Biodiversity Authority for obtaining any biological resources occurring in India.

Likewise, Indian entities referred under section 7 and 24 of the BD Act, 2002, read-with Rule 15 of the KBD Rules, 2005, are mandated to submit prior intimation in Form-I to the KBB for obtaining any biological resources for commercial utilization (with exemption provided to local people and communities, including growers and cultivators of biodiversity and vaids and hakims, who have been practicing indigenous medicine as per the section 7 of the BD Act, 2002).

Further, the entities accessing bio-resources, upon due approvals, are also required to submit the Access and Benefit Sharing (ABS) obligation to the Boards as per the ABS Regulations, 2014, notified by the Ministry of Environment, Forests and Climate Change on 21st Nov 2014. The ABS Regulations, 2014, prescribe the percentages of the benefit sharing component that ranges from 1-3% for traders and 3-5% for manufacturers utilizing bio-resources for commercial purposes (as per Regulation 3). The entities also have an option of sharing benefits based on the annual gross ex-factory sales of the products and these range from 0.1-0.5% on graded scales (as per regulation 4). The ABS percentages for transfer of

research results, intellectual property rights and third party transfer of bio-resources or the associated knowledge are also laid down in the ABS Regulations, 2014.

The offences of non-compliance of the provisions of the Act are cognizable and non-bailable as per Section 58 and attract penalties under Sections 55 and 56 of the BD Act, 2002.

The KBB has facilitated the formation of over 5000 BMCs out of the 6228 local bodies in the State and the process of documenting the People's Biodiversity Registers (PBRs) in all the BMCs are underway, with over 1900 PBRs documented so far. The Board has devised an institutional set-up for this activity with the support of the State Forest Department officers who are nodal officers in the District levels for effective co-ordination and monitoring of the progress. This institutional framework along with the technical support of the Technical Support Group at District levels has been fundamental in effective documentation of PBRs in the State.

But, it is not without challenges of realizing the goals of constitution of BMCs and documentation of PBRs. The Board is currently striving to integrate the functions of the BMCs together with the Panchayati Raj Institutions, through amendments in the State Rules for naming the chairperson of the local body as the chairperson of the BMC. The Board has also proposed for the inclusion of BMCs as one of the 'Standing Committees' of the local body for meaningful participation for effective conservation and sustainable utilization of bio-resources at local levels.

The other main mandate of the State Biodiversity Boards is the regulation of commercial utilization of bio-resources industrial sectors and entities. The commercial utilization of biological resources has to be intimated to the State Biodiversity Boards concerned (Section 7 of the BD Act, 2002) along-with sharing of benefits as per the ABS Regulations of 2014 notified by the Ministry of Environment Forests and Climate Change.

There is a lot of literature available addressing the requirements of compliance under the BD Act, 2002 and the challenges, depicted from the viewpoint of the research/industrial sectors, but, hardly anything has been written about the challenges the regulator faces in terms of ensuring compliance from the stakeholders.

This chapter focuses on the efforts and the initiatives taken up by the KBB in effective implementation of the ABS provisions of the Act in the State of Karnataka.

11.2 Good Practices - Access and Benefit Sharing

Implementation of any statute requires awareness creation and information to be made available to all the concerned stakeholders for compliance. The KBB has undertaken all possible avenues for generating wide-spread awareness about the BD Act, 2002, at the local body levels and the various industrial sectors operating in the State.

1. The KBB has published numerous handouts, brochures, guidance manuals and booklets with simple depiction and description of the requirements under the Act for dissemination in the sector-specific focus group meetings and workshops conducted by the Board.
2. Advertisements in the print media, Radio jingles, Radio, Television programs have been broadcast for creating awareness of the BD Act, 2002 and its provisions.
3. The Board is currently implementing a large scale unique project aimed at assessing the availability of medicinal plants in the forests of Karnataka for sustainable commercial utilization.
4. The ABS Regulations, 2014, under Regulation 3, provides for a large range of ABS percentages that are required to be shared by different stakeholders and it becomes ambiguous as to the specific percentages to be shared by each individual stakeholder. The KBB categorized the bio-resources commercially utilized by industries into different ABS percentages based on the threat status of the plant bio-resources and also based on the source, whether, wild, mixed or cultivated.
5. Regulation 4 of the ABS Regulations, 2014, provides for an option for commercial entities to submit ABS based on the annual gross ex-factory sales of the products manufactured by them. But the ABS Regulations, 2014, do not provide for a specific pro forma for the submission of the same. The KBB has developed a unique proforma for commercial entities in the State to submit ABS based on the annual gross ex-factory sale of the products.
6. Online portal for submission of all the required proforma has also been created for the convenience of the stakeholders.

7. Consultation forms developed to obtain the consent or otherwise of the local bodies or BMCs for commercial utilization of bio-resources.
8. Amendments in the State Rules for naming the chairperson of the local body as the chairperson of the BMC.
9. The Board has also proposed for the inclusion of BMCs as one of the 'Standing Committees' of the local body for meaningful participation in the implementation of the BD Act, 2002.
10. Recommendation of the fee that may be levied by the BMCs for commercial utilization of bio-resources from their jurisdiction.
11. Quick disposal of applications through the constitution of a large Expert Panel on ABS comprised of subject experts to review and scrutinize the applications received by the Board.
12. A simple ABS agreement-approval format has been developed, without complex legal jargon, to ensure easy understanding of the terms and conditions for effective compliance by entities.
13. Efforts to initiate integration and harmonisation of licensing procedures are also underway with various State Licensing Authorities to ensure compliance of the provisions of the BD Act, 2002 and the KBD Rules, 2005, during the grant or renewal of industry licenses and to obtain the list of registered entities.
14. Successful integration of processes with the State Forest Department for the collection of the ABS for Red Sanders and Sandalwood auctioned off in the State and an Expert Committee was constituted to draft the modalities for the disbursal of the ABS amounts accrued in the Board to the respective BMCs.

11.3 Challenges in implementation of ABS provisions in Karnataka

Despite the best efforts of the Board for effective implementation of the provisions of the BD Act, 2002, in the State, several challenges remain, that needs to be addressed in the coming days, if the objectives of the Act are to be realised:

1. Large mandate (of implementation) in the Board without adequate staff.
2. Resistance from industrial sectors in compliance - Need for repeated communications/ letters to be sent out to industries. Industrial associations play a big role in negatively influencing individual companies.

3. No exemptions to small scale industries resulting in resources (time and money) spent by the Board in obtaining ABS being more than the ABS itself.
4. Trade linkages in the bio-resource trade in the country are ad-hoc and complex and linking access points to jurisdictional BMCs is difficult.
5. Location of the trader/vendor may not be an indication of the jurisdictional BMCs
6. Lack of responses from BMC with regard to consent requests by the Board and hence ABS agreements and approvals are more or less centralised.
7. Without adequate financial infusion, the BMCs may not be effective in carrying out its functions.
8. Absence of empirical data and studies on the availability of bio-resources in the wild, making it extremely difficult at the SBB level to take decisions regarding sustainability of bio-resources coming from wild sources.
9. Co-ordination between SBBs of the country is instrumental for effective implementation and control of pilferage of bio-resources from one state to the other. Since SBBs are in differential stages of implementation, regulation in the way business of biodiversity is carried out for sustainability is hampered.
10. Support of the Licensing Departments of the State is essential for holistic implementation of the statute.
11. Many citizens may, in certain cases of justifiable bonafideness, break the law and serious enforcement can cause immense hardship to small time entrepreneur/traders/businessmen – cannot condone past sins.
12. There is no provision for compounding cases of non-compliance through penalties or fines.
13. There is a large scope for varied interpretations of certain provisions of the Act resulting in loss of resources in establishing solutions.

11.4 Lessons learnt and way forward

India has been in the forefront of implementation of the several International Environmental Laws and Treaties including the CBD and the Nagoya Protocol. With 220 Internationally Recognised Certificates of Compliance (IRCC) approved by the National Biodiversity

Authority (out of the total 322 issued world-wide), India is leading the path in the implementation of the Convention. The Karnataka State Biodiversity Board is one of the pioneers in the implementation of the objectives of the BD Act, 2002 related Rules and Notifications in the country. Streamlining the efforts required in implementation is crucial, since, from the time when the Act was brought into force till the present time, there have been very significant progress in science and technology which needs to be harmonised and the gaps between various legislations governing industrial sectors must be filled through lessons learnt from the implementation of the Act spanning over 15 years.

1. Integration and harmonization of industrial licensing procedures with the requirements under the BD Act, 2002 for effective compliance and ensuring 'ease of business.'
2. Development of an online portal for sharing of information in real time and effective communication, co-operation between State Biodiversity Boards and the National Biodiversity Authority.
3. Effective engagement with sector specific stakeholders – with practical redressal of issues.
4. Streamlined guidelines for uniform ABS implementation throughout all states of the country.

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CASE COMMENT
DIVYA PHARMACY v. UNION OF INDIA*

12

The primary issue in the case of *Divya Pharmacy* v. *Union of India*[1] *decided by the Uttarakhand High Court on 21 December, 2018 was whether purely Indian entities with no foreign participation in their share capital or management were required to share benefits from the use of biological resources or knowledge associated therewith, as provided under the Biological Diversity Act, 2002.*

Swami Ramdev and Acharya Balkrishna founded a Trust by the name - "Divya Yog Mandir". Divya Pharmacy is a commercial arm of the Trust and was the Petitioner in the present case. The Petitioner is involved in manufacturing of ayurvedic products and has agreed to the fact that Biological Resources are the main ingredient and raw material for manufacture of the same.

The Petitioner was aggrieved by the notices sent to them by the Uttarakhand Biodiversity Board (UBB) to pay Fair and Equitable Benefit Sharing (FEBS) as provided under the Biological Diversity Act, 2002 (hereinafter Act) and the Rules and Regulations framed thereunder.

12.1 Petitioner's Contentions

The Petitioner contented that it was not required to make any payment to the UBB as FEBS did not apply to Indian entities. The argument was based on several definitions provided in the Act. The Petitioner's first contention was with regard to the definition of "fair and equitable benefit sharing" as provided under Section 2(g) which says "fair and equitable benefit sharing" means sharing of benefits as determined by the National Biodiversity Authority (NBA) under Section 21. Section 21 further provides that "the NBA while granting approvals under Section 19 or Section 20 shall ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits

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1 Writ Petition (M/S) No. 3437 of 2016.

arising out of the use of accessed biological resources…." The Petitioner contended that from the definition of FEBS it is clear that the same can only be imposed by the NBA and not by the State Biodiversity Boards.

The second contention of the Petitioner was a follow up to the previous one. It argued that Section 19 and Section 20 are applicable only to persons referred to in Section 3(2) of the Act. Section 3(2) refers to two classes of persons; in context of a natural person it refers to persons who is not a citizen of India, or is a citizen but a non-resident as defined under the Income Tax Act, 1961 and in the context of a legal person it applies to organizations which are either not incorporated or registered in India or have a non-Indian participation in its share capital or management. The Petitioner contended that since it does not fall in any of the categories mentioned under Section 3(2), Section 19 and Section 20 did not apply to it and thus it is not liable to pay FEBS as provided under Section 2(g).

The Petitioner further contended that Indian entities are governed by the law provided under Section 7 of the Act which only speaks of prior intimation to the SBBs and prior intimation cannot be read as prior approval, as the elementary principle of statutory interpretation is to give plain meaning to the words used. Thus, the Petitioner concluded that that there is no provision in the Act where a contribution in the form of "fee" monetary compensation, or a contribution in any manner is required to be given by an Indian entity.

12.2 Respondent's Contention

The Respondents contended that the Act differentiated between Indian and foreign entities **only with respect to jurisdiction of the authorities** to whom they need to report and obtain permission/ approvals from. The Act **does not** differentiate between Indian and foreign entities with respect to whether or not FEBS should be paid, "and if a distinction is made between a foreign entity and Indian entity in this respect, it would defeat the very purpose of the Act, and would also be against the International Treaties and Conventions to which India is a signatory."

The Respondents further contended that when Section 7 is read with Section 23(b) it becomes clear that the SBBs duty is not limited to a mere bystander who would only receive prior information from the Indian users of biological resources. On the contrary,

it is stipulated that the SBB has powers "to regulate by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilisation of any biological resource by Indians". They also claimed that regulation by way of imposition of fees is an accepted form of regulatory mechanism. Also reference was made to Section 24(2) which provides that "the SBB, in consultation with the local bodies and after making such enquiries can prohibit or restrict any such activity, if it is of opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity," therefore the UBB was well within its powers to demand FEBS from the Petitioner.

The counsel for Respondents further relied on Section 52 A which provides that any person aggrieved by any determination of benefit sharing by NBA or SBB may file an appeal to the NGT. This again goes on to show that the legislature intended to allow SBBs to demand FEBS and it is only for this reason that an Appellate Authority has been provided against any determination of FEBS by SBBs. The Respondents also argued that FEBS was one of three objectives of the BD Act and was mentioned in the Preamble and therefore its importance cannot be undermined. The counsel submitted that in the present context, a simple and plain reading of the definition provided and going by the literal method of interpretation, would defeat the purpose of the Act and would be in negation to India's obligations under the CBD and other international agreements. The definition clause of the Act of 2002 starts with the words "In this Act, unless the context otherwise requires". The learned counsel hence argued that the definitions of different words and phrases given in Section 2 of the Act of 2002 are the ones which have to be applied under normal circumstances, but when the application of the definition loses its purpose, the context requires a different examination.

12.3 Courts Observation

The Hon'ble High Court observed that on plain and simple reading of the provisions under the BD Act it is obvious that a purely Indian entity is not subject to FEBS, however the Court cautioned that "what may seem obvious may not always be correct." It mentioned various provisions of the BD Act and International Agreements, and also discussed the history behind these legislations so as to be able to throw light upon the real intention of the Legislature in drafting the said law.

The first observation was the opening phrase of Section 2 which read as "Unless the context otherwise requires…", the Court emphasized that the said phrase is often inserted in legislations so that the Judges may be able to mould the definition of a particular word as per the context. This is done because the literal interpretation of a word may not always serve the purpose for which the law was passed. In this context the court referred to G. P. Singh's "Principles of Statutory Interpretations" which stated that where the context makes the definition given in the interpretation clause inapplicable, a defined word when used in the body of the statute may have to be given a meaning different from that contained in the interpretation clause; it also referred to *Vanguard Fire and General Insurance Co. Ltd., Madras v. Fraser & Ross,*[2] wherein the Hon'ble Supreme Court held that "It is possible for the word to have a somewhat different meaning in different sections of the Act depending upon the subject or context. That is why all definitions in statutes generally begin with the qualifying words, similar to the words used in the present case."

The Court further observed that the beneficiaries under the Act are the indigenous and local communities and the benefit that they get as FEBS is over and above the market price of their biological resources. The Hon'ble Court also emphasized on the importance of International Treaties and Conventions on municipal laws by referring to several cases including that of *Commr. Of Customs v. G. M. Exports*[3] wherein the Hon'ble Supreme Court held that when a statute is made in furtherance of an international treaty obligation then a purposive interpretation is preferred over a narrow literal interpretation, it further said "In a situation in which India is a signatory nation to an international treaty, and a statute is made to enforce a treaty obligation, and if there be any difference between the language of such statute and a corresponding provision of the treaty, the statutory language should be construed in the same sense as that of the treaty. This is for the reason that in such cases what is sought to be achieved by the international treaty is a uniform international code of law which is to be applied by the courts of all the signatory nations in a manner that leads to the same result in all the signatory nations." Therefore the Hon'ble High Court of Uttarakhand stated that ambiguities in our national statute have to be seen in light of the CBD and the Nagoya Protocol so that we may be able to determine the true meaning of FEBS. Thus, the Court held that since the Nagoya Protocol does not make any distinction

2 AIR 1960 SC 971.

3 (2016) 1 SCC 91.

between foreign entity and an Indian entity as regards their obligation towards local and indigenous communities hence the national legislation also cannot make such distinction.

The Hon'ble High Court also emphasised, that when interpretation of provisions of socially beneficial legislations like the one in the present case, is in question, then a purposive interpretation is required. "FEBS in the form of a "fee" or by any other means is a benefit given to the indigenous and local communities by the Act, and the Regulations, which again have to be examined in the light of the international treaties where the importance of FEBS has been explained." The Court also questioned the arguments of the Petitioner on the ground that how could the Parliament on one hand recognise the rights of indigenous and local communities over their biological resources and associated knowledge and on the other hand allow Indian entities to violate these rights?

For reasons mentioned above the Hon'ble High Court finally held that the SBB has got powers to demand Fair and Equitable Benefit Sharing from the Petitioner, in view of its statutory function given under Section 7 read with Section 23 of the Act and the NBA has got powers to frame necessary regulations (in the instant case, the ABS Guidelines of 2014) in view of Section 64 of the Act which provides for the power to make regulations by the NBA, read with Section 18(1) which contains the powers and functions of the NBA, and Section 21(2) (4) which allow the NBA to frame guidelines for access and benefit sharing. The Court however declined to pass judgment on the retrospective operation of the provisions as the same had not been demanded by the SBB.

12.4 Implications of the Judgment

The judgement of the Uttarakhand High Court is going to have far reaching implications across India. The judgement must also be applauded for it is the first judgement wherein the High Court has dealt in great detail about the scope of the BD Act with respect to use of biological resources by Indian commercial entities. A number of cases had earlier been filed in different High Courts and the National Green Tribunal however the judgements from those Courts are still awaited. The above declaration by the Court will also lift the morale of the State Biodiversity Boards who are fighting tooth and nail across multiple jurisdictions in India against cash rich commercial entities to bring them under the ambit of the Act.

Many purely Indian entities are engaged in use of biological resources as raw material for production and manufacture of various types of products. Up until the *Divya Pharmacy* judgement, the plea taken by the industry was that Section 7 of the BD Act uses the term "intimate" which by no stretch of imagination could be interpreted as "prior approval" from the State Biodiversity Board. The Hon'ble Court wisely turned down this argument saying that it is the intent of the Act that must be looked into rather than the plain reading of the provisions.

The judgement has also been welcomed by local communities whose knowledge and local flora and fauna has for years been exploited by the companies without any sharing of benefits. The judgement will ensure that the companies enter into ABS with the SBB and that the benefits reach the local communities for their wellbeing.

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STAKEHOLDERS GUIDE TO THE BIOLOGICAL DIVERSITY ACT, 2002*

13

13.1 Simple Questions

1. What is Biodiversity?

Biodiversity is made up of two words 'bio' meaning life and 'diversity' meaning variety. Put together they mean the variability in life forms. So everything you see around you (including microscopic things that you cannot see for e.g. bacteria) which has life i.e. all plants, trees, animals, birds, insects, corals will fall under biodiversity.

The Biological Diversity Act, 2002 (hereinafter BD Act) defines 'biological diversity' under Section 2(b) as "the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems".

2 What is Biological Resources?

Resources mean a source of supply. Biological Resources means all plants, animals and micro-organisms in whole or their parts and including their genetic material and by-products which have actual present value or potential value in future.

The BD Act defines 'biological resources' under Section 2(c) as "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."

3. What is meant by genetic material?

Genetic Material refers to any part or material of a plant, animal or micro-organism containing units of hereditary material (DNA). A gene is the basic physical and functional unit of heredity and is made up of Deoxyribonucleic acid (DNA).

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4. What is Sustainable use of biological resources?

'Sustainable use' means the use of resources in such a manner that it does not cause long term depletion of the resource, and this can be done by limiting the use for only that which is necessary and preventing over-exploitation of resources. It is the wise use of resources to maintain intergenerational equity wherein the demands of present generation are met, while keeping in mind the needs for future generations as well.

5. What is meant by Access and Benefit Sharing?

Access and Benefit Sharing (ABS) is a mechanism (through an agreement) by which persons or entities are allowed access to biological resources for commercial or research purposes. In return for this access, those persons or entities have to share a small part of the benefits gained by them through the use of the accessed biological resources with the local people who have provided the biological resource or the knowledge associated therewith. Access and Benefit Sharing agreement may be entered into with the NBA for persons falling under Section 3, or the SBB for persons falling under Section 7 of the BDA.

6. What is the punishment for non-compliance of different provision of the Act?

For non-compliance of any its provisions, the BD Act, 2002 provides for an imprisonment which may extend to 5 years or with fine which may extend to Rs 10 lacs (fine may exceed this amount also) or both for contravention of Section 3, 4 and 6 of the Act.

The Act also provides for an imprisonment which may extend to 3 years or with fine which may extend to Rs 5 lacs or both for contravention of Section 7 of the Act.

7. I have been sent a notice from the SBB for non-compliance under the Act. Whom should I contact as I feel this is unnecessary harassment as I am not involved in any activity governed by the Act?

You have to reply to the notice sent to you by the SBB. After this the SBB may accept or reject your reply. If the SBB rejects your reply and passes any order it is only then that you can appeal against the order in the NGT under Section 52A of the Act.

8. I have made a new invention by genetically modifying the plant cells. I wish to apply for Patent over the new variety. What should I do?

As per Section 6 of the BDA any person (irrespective of nationality) seeking to apply for any intellectual property right anywhere in the world, based on research or biological resource obtained from India, must take prior approval of the NBA. This mandatory approval from the NBA may also be obtained after filing the application (only in case of patents) but before the sealing of the title by the patent authority.

9. I am a Ph. D research scholar. I am working on the Biodiversity Laws in India. Do I need to seek permission from any office under the BDA?

No. The Act only requires people working with biological resources to take approvals. A person working on biodiversity laws need not take any prior approval from the NBA or SBB.

10. What are Biodiversity Heritage Sites?

Biodiversity Heritage Sites (BHS) are well defined areas which have rich biodiversity comprising of any one or more of the following components: richness of wild as well as domesticated species or intra-specific categories, high endemism, presence of rare and threatened species, keystone species, species of evolutionary significance, wild ancestors of domestic/ cultivated species or their varieties, past pre-eminence of biological components represented by fossil beds and having significant cultural, ethical or aesthetic values and are important for the maintenance of cultural diversity. Under Section 37 of the Act State Governments in consultation with local bodies may notify areas of Biodiversity importance as Biodiversity Heritage Sites.

11. Does this Act have superseding effect over other environmental laws in India?

This Act is to be read harmoniously with other environmental laws in India. Also Section 59 of the Act states that it is in addition to and not for replacing any law. Therefore, along with requirements of other existing laws, the provisions of this Act also need to be complied with.

12. Are all biological resources covered under the Act? Is there any exemption?

The Act protects all biological resources prima facie. However under Section 40 of the Act, the Central Government may declare that the Act will not apply to certain items including biological resources which are normally traded as commodities.

13.2 Researcher Questions

1. I am an Indian Researcher do I also need to seek approval before collecting biological resources?

The Act does not lay down any approval to be taken by Indian researchers for scientific/ educational study w.r.t biological resources in India, subject to clauses mentioned in State specific BD Rules

However if the results of the research are used for commercial purposes then an intimation needs to be made to the SBB under Section 7.

Further, the results of the research cannot be shared with any person mentioned under S.3 of the Act without prior approval from the NBA unless the research has been exempted under Section 5 of the Act.

2. I am not an Indian citizen but I am working with an Indian Research Organization on biological resources. What is my liability under the Act?

You must apply to NBA for approval before doing any research work with biological resources in India. You could also ask the Indian Research Organisation that you are working with to help you in this regard.

Working on biological resources without any approval is a criminal offence for which there is imprisonment up to 5 years with or without fine.

3. I am an Indian Researcher working on certain plants in India. Will I be liable under the Act if I publish my research results on the Internet?

If you are Indian researcher working on certain plants occurring in India in an Indian laboratory, you can publish your research results in scientific journals (print or electronic), newspapers, seminars, conferences, personal blogs or any other media without being liable under the BDA.

4. We are an Indian Research Organisation will we be liable under the Act if we send any samples for tests to be conducted in foreign countries?

Yes, sending biological samples outside India to even a service provider for analysis will be liable under the BDA. However, if the project that you are working on is a collaborative project

1. Conforms to the Policy Guidelines 2006, of collaborative research and
2. The project is endorsed as a collaborative project from the head of the line department ex: DG-CSIR, DG-ICAR etc.) then it is exempted under Section 5 of the BDA.

5. I am a researcher on migratory birds. I do not collect any bird species but I do observe them, there flying patterns, etc. and am going to use that knowledge for determining the migration habits of the birds. Can I be held liable under the Act?

No. Observing or even recording of plant or animal behaviour by videography or camera trapping has not been found to fall under regulated activities covered by the BDA therefore you cannot be held liable for such activity under the Act.

6. What is the process for obtaining approval from the NBA if I am a researcher falling under Section 3 of the Act?

A researcher falling under S. 3 of the Act needs to apply to the NBA in an application under Form I of the Biological Diversity Rules, 2004 along with the fees which is currently Rs 10,000. The NBA will consult the concerned SBB and BMCs along with any other experts if required. The decision by NBA of whether to accept or reject the application must be made within 6 months of filing of the application.

If the NBA accepts the application it will send a Clearance Letter along with a Model Agreement to the applicant. The applicant is required to sign the agreement and send it back to the NBA after which the NBA will grant the final approval.

7. Plant X is available widely all over the world; however I have found a special use of it from a local tribe in India. What is the process to be followed if I wish to make commercial use of that knowledge in India and in other countries?

If the person who has found the special use of the plant, is an Indian then he needs to intimate the SBB under Section 7 of the BDA, and if the person falls under S. 3

then he needs to apply to the NBA. In the person (Indian or Non-Indian) wishes to apply for an intellectual property right based on that knowledge then he must seek prior permission from the NBA.

8. I am doing my Ph.D. from an Indian University. Do I need to seek approvals from the SBB or is it the University's job to get the required approvals from the respective SBB?

Every person is individually liable for any contravention of the BDA. So even if your University has not got any approval it is your personal responsibility to be on the right side of the law. Although Indian Researchers do not need any permission for pure research work however there are other situations where they may need approvals under the Act. For more information read question 1.

9. I am an Indian researcher working on reptiles in South India. Do I need separate approvals from each SBB or can I get one approval from the NBA?

As an Indian researcher you do not need permission from any authority under the Act so far as your work is confined to research only. However if the results of research are to be used for commercial purposes then you must apply **to each** of the concerned SBBs from whose jurisdictions you wish to collect the biological resources.

10. The central Ministry of Science and Technology has issued us a direction to transfer certain plants to a foreign organisation for research purposes. Do we still need permission from the NBA?

Yes. The National Biodiversity Authority is an independent body which has been formed with a specific purpose for protection of the biological resources of the country, therefore irrespective of any direction from any Ministry, the approvals from the NBA are mandatory with respect to any situation which falls under its jurisdiction.

However, if the project that you are working on is a collaborative project (1.Conforms to the policy guidelines 2006, of collaborative research and 2. The project is endorsed as a collaborative project from the head of the line department ex: DG-CSIR, DG-ICAR etc.) then it is exempted under Section 5 of the BDA.

13.3 BMCs FAQs

1. Do we get salary for being a member of BMC?

No, you don't get any salary for being a member of the BMC.

2. How do we get funds for running the BMC?

Initial funds for setting up the BMC, and providing for basic facilities like stationary etc. is to be granted by the State Government or the State Biodiversity Board. Thereafter BMCs will get funds from the benefit sharing programme under which 95% of the accrued benefits deposited with the NBA will go to the concerned BMCs and/ or benefit claimers. Further, BMCs have the power to levy charges for access of bio-resources for commercial utilization from their respective jurisdiction (see regulation 5 of the ABS Regulations, 2014)

3. Are all local bodies required to prepare PBRs or is it only the BMC for the Village Panchayat which prepares the PBR?

As per the Biological Diversity Rules, 2004, Rule 22 sub-rule 1 read with sub-rule 6, every local body is required to prepare its own People's Biodiversity Register.

4. What is the BMCs role in the ABS agreement?

Section 41(2) of the BDA and Regulation 14 of Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014 (ABS Guidelines) clearly state that the BMC will be consulted by the NBA or SBB before granting any approval for access to biological resources. Therefore the role of the BMC in an ABS Agreement is restricted to consultation and giving advice.

13.4 Other FAQs

1. I am a fruit vendor. Do I also have to seek permission or share my profits?

As per the proviso to Section 7 BDA and Regulation 17 of the ABS Guidelines local people and communities are exempted from the ambit of the Act, therefore you do not need to seek approval nor do you have to send any intimation to the authorities under the BDA.

2. Do Indian Government organisations like ICAR also need to seek permission before obtaining any biological resources?

The BDA does not provide any express exemption to any research institute. However under Regulation 17 of the ABS Guidelines Indian citizens or entities accessing biological resources and/ or associated knowledge with respect to biological resources of India for research purposes have been exempted from approval of NBA or SBB.

Note this exemption is only for research done in India. If any bio-resource is sought to be exported out of the country or the results of the research are to be utilised for commercial purposes or the result of the research is to be published outside of India then prior approval of the NBA or SBB (as the case may be) is necessary.

3. I have got a job in USA. I wish to take my *Tulsi* plant to keep as a house decor. Do I need to take permission from anybody in India?

Yes you must take permission from the NBA before taking any biological resource outside the territory of India. The size or quantity of the biological resource is irrelevant. Also you would have to inform the Custom Authorities about the same.

4. How is the money collected under the ABS scheme spent?

The money collected through the Access and Benefit Sharing Agreement is divided in two parts. 5% of the total amount is kept by the NBA/SBB as the case may be, 95% of the money collected is passed on to the benefit claimers if they are identified else it is deposited with the concerned BMC.

5. How does the NBA or SBB monitor the purchase and sale of biological resources and the future sharing of benefits by the entities that have been granted approval for access under the Act?

The entities that have been granted approval for access under the Act have to furnish the financial reports for each year to the NBA or SBB, the benefit sharing component as agreed in the agreement has to be paid to the NBA or SBB and the same to be in alignment with the financial reports.

13.5 Industry FAQs

1. I have paid the farmer/ grower for the supply of the biological resources. Do I need to make any further payments as per the Act?

Yes. Access and Benefit Sharing under the BDA is exclusive of other expenses incurred by the persons or organisations.

2. We are an Indian Company registered under the Companies Act, 2013. We are involved in manufacturing products made by use of biological resources. Which body should we approach for permission?

The differentiation of entities under the BDA is not the same as in Indian Companies Act, 2013. You need to make sure if the company falls under sec 7 or the sec 3 of the BDA and obtain required approvals before accessing bio-resources.

Section 3(2)(c) is clear that a body corporate having **any** non-Indian participation in its share capital or management must take prior approval from the NBA.

As per Section 7 of the BDA any Indian Company or organisation can obtain biological resources for commercial purposes, only after giving prior intimation to the SBB concerned.

Therefore you should approach the SBB from whose State you intend to procure the biological resources.

3. We are an Indian Company registered under the Companies Act, 2013. Less than 10% of our share capital is held by foreign investors but we do not have any foreign person or entity in our management. Whom should we apply for access of biological resources?

Section 3(2)(c) is clear that a body corporate having **any** non-Indian participation in its share capital or management must take prior approval from the NBA. So irrespective of how much share capital is held by foreign investors you are still required to apply to the NBA.

4. How much share of my profits will I have to contribute for the Access and Benefit Sharing Program?

The ABS Guidelines **do not** stipulate for benefit sharing to be calculated on profit earned. There are two modes of calculation of benefit sharing. The first is computed on

the **purchase price** wherein a trader of biological resources has to pay 1.0 to 3.0% of the purchase price while a manufacturer has to pay 3.0 to 5.0% of the purchase price.

The second method of computation is based on the annual ex-factory **sale price** of the product that was manufactured using biological resources. In this method the benefit sharing will be based upon the annual gross ex-factory sale of product; in case of it being less than Rs. 1 crore, benefit sharing will be 0.1 per cent, for Rs. 1 to 3 crore, it would be 0.2 per cent, for above Rs. 3 crore, the benefit sharing will be 0.5 per cent.

The applicant can choose either method for benefit sharing.

5. Is access and benefit sharing a Tax or a cess?

It is neither; it's an obligation under the BD Act

13.6 Advanced Questions regarding Biological Resources applicable under the BDA.

1. Is the use of Synthetic bio-resources covered by the BDA?

The use of synthetic bio-resources is not expressly covered in verbatim in the BD Act, 2002. However, if the synthetic bio-resource is a result of associated knowledge from India or from the knowledge associated with biological resources occurring in India then the utilization of these synthetic bio-resources are covered under the Act, unless proved otherwise by the applicant.

The preamble of the BDA defines that the objective of the Act is for conservation of biodiversity, sustainable use of its components and fair and equitable sharing of the benefits out of the use of bio-resources, their associated knowledge and for matters connected therewith.

2. I am a manufacturer of bagasse ash am I liable to seek permission under the BD Act?

Yes, as per sec 2(c) Biological Resources means all plants, animals and micro-organisms in whole or their parts and including their genetic material and by-products which have actual present value or potential value in future. The Act does not see what the end product is but rather what are the raw materials used. Since bagasse is a by-product of sugar cane hence its use attracts the provisions of the BD Act.

3. Is the manufacturer of essential oils from plants liable under the BDA?

The manufacture of essential oils from plants requires plants as the raw materials for its production and plants are bio-resources under the BD, Act hence manufacture of essential oils from plants or any bio-resources will attract the provisions of the BD Act and will be liable under the Act.

4. Is the manufacturer of cosmetics who uses essential oils to make health and beauty products liable under the BDA?

Yes, as per S 2(f) of the BD Act, 2002 commercial utilisation is defined as "end uses of biological resources for commercial utilisation such as drugs, industrial enzymes, food flavours etc." Since essential oils derived from plant sources are considered as extracts of biological resources, commercial utilisation of the same is liable under the BDA.

5. Will the use of Molasses (by product of sugar cane while producing sugar) in herbal products make me liable under the BDA?

As per sec 2(c) Biological Resources means all plants, animals and micro-organisms in whole or their parts and including their genetic material and by-products which have actual present value or potential value in future. Hence the use of molasses in herbal products will be liable under the BDA if the herbal products are for cosmetics, drugs, health supplements and perfumes and are being sold at a commercial scale.

6. I use waste paper to produce cartons and brown paper boxes. Am I liable?

The various types of pulpwood which is the raw material for manufacturing paper has now been included in the Normally Traded as Commodities List (hereinafter NTAC) on 7th Nov. 2017 by S.O.3533(E) therefore the use of such bio-resources will not attract the provisions of the BD Act.

7. We extract fish oil and make capsules for health benefits, are we accountable under the BDA?

Fish is a bio-resource. Fish oil is taken from the fish and hence fish oil is also a bio-resource. As per sec 2(f) of the BD Act, 2002, commercial utilization is defined as 'end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts ....' Since fish oils are derived from animal bio-resources and are extracts of biological

resources, utilized for manufacture of capsules as a nutraceuticals product, the same is liable under the BDA.

8. Whether, commercial utilization of the microbes isolated from garbage or sewage can be classified as Bio resource?

Yes, as per sec 2(c) Biological Resource means all plants, animals and micro-organisms in whole or their parts and including their genetic material and by-products which have actual present value or potential value in future.

The source where the bio-resources are accessed from is immaterial.

9. We are an Indian company engaged in making products from cow urine and cow dung. Are waste products of animals also considered as biological resources? Do we need to seek approval or relay information to any office?

Yes, as per sec 2(c) Biological Resources means all plants, animals and micro-organisms in whole or their parts and including their genetic material and by-products which have actual present value or potential value in future.

Use of cow urine and cow dung for purpose of making products having application in cosmetics, drugs, health supplements and perfumes will attract the provisions of the BDA. However if the cow urine or cow dung is being used for preparing farm yard manure by the farmer for their own use then it will not be liable under the BD Act.

10. I have a restaurant; we provide veg and non-veg dishes including fruit juices to our customers. What is our liability under the Act?

No, you will be not liable under the BDA since these bio-resources are normally traded as commodities. Also local people and communities are exempted from liability under the Act for use of biological resources for livelihood purposes.

11. I own a milk company. We sell packaged milk across the State of Karnataka. I have not intimated the Karnataka State Biodiversity Board. Can I be prosecuted under the BDA?

Since, milk consumed as food is traditional practice under dairy farming, approvals for the same under BDA is not required as it does not fall under the definition of commercial utilisation provided in Section 2(f).

12. I am a fish and meat wholesaler having my business across India every day we purchase tonnes of meat and sell it to our retailers? I already have licence to purchase and sell meat. Do I need any other approvals under the BDA?

As per sec 2(f) of the BD Act, 2002, commercial utilization is defined as 'end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes use for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping'

Since, fish and meat consumed as food are traditional practices in animal husbandry, approvals for the same under BDA is not required.

Also it is common knowledge that meat and fish are normally traded as commodities although they have not been included in the NTACs list however they can be defended as an NTAC.

13. We own fish trawlers and we catch fish from Indian waters as well as International waters. Do we have to pay any access fee?

Fish is a bio-resource but if it is being used by local community for livelihood purposes then it will be exempted as per Section 7 of the BD Act. Also food is exempted under 2(f).

14. The notification on NTCs states that those bio-resources which are not expressly mentioned under NTC list may still be proved to be a normally traded commodity, however the burden of proving the same will lie upon the person claiming exemption. What evidences need to be submitted to prove that a product is a normally traded commodity?

Proof of long term usage in day to day life, ease of availability, ease of access (non-restrictive access w.r.t to age, gender, region etc.) necessity in sustenance of routine life.

15. If an Indian doing research in a foreign university takes sand from India then is he liable under the BD Act?

Sand is a natural resource just like water, coal, minerals etc. All natural resources may not be bio-resources and sand, water, coal minerals are such examples. Since the BD Act only covers bio-resources hence sand is not under the ambit of the Act.

However sand (water, minerals etc.) may have microbes in them and since microbes are covered by the Act hence the person will have to take permission from the NBA.

16. Are Contract Research Organisations (CROs) liable under the BD Act for access to bio-resources?

As per current industry practice most CROs do not access biological material themselves but are rather provided the biological material by the Contracting Party for whom the CROS do the required research therefore CROs as long as they themselves do not access the bio-resource they are not liable under the BD Act.

17. Are Contract Research Organisations (CROs) liable under the BD Act for transfer of Research Results?

As per Section 4 of the BD Act CROs will be held liable if they send research results outside India without approval from the NBA, if the biological resources on which they have conducted tests are from India.

However if the contracting party obtains biological resources from outside India and there is absolutely no use of any biological resource from India then CROs need not take any permission from the NBA for any transfer of research results.

18. Is alcohol a normally traded commodity, and if no then can alcohol manufacturers be held liable under the BD Act?

Alcohol should not be considered as a normally traded Commodity rather it may be placed as a highly regulated commodity since it is not available to one and all. In spite of the fact that alcohol should be treated as a highly regulated commodity it will still not fall under the ambit of the BDA since it is considered as a common practice and is hence exempted.

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