Patents and Equitable Benefit Sharing of Indian Biological Diversity

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I. BIOLOGICAL DIVERSITY ACT, 2002 (BDA)

India, a signatory to the United Nations **Convention on Biological Diversity (Biodiversity Convention)**, 1992, which affirms nations' sovereign rights to use their biological diversity, attempted to realize the objectives expressed in the Biodiversity Convention by legislating the **Biological Diversity Act, 2002 (BDA)**. The BDA was enacted in 2002 with three main goals akin to the Biodiversity Convention, which are:

- conservation and sustainable use of biological diversity,
- addressing issues related to its access, and
- enabling **fair and equitable benefit sharing (FEBS)** arising from the use and knowledge of such resources with the local communities.

II. EQUITABLE BENEFIT SHARING IN INDIA

Biological components play a significant role in the existence of humankind. Hence it becomes pertinent for every individual to have access to such natural resources and share the benefits. This concept is popularly known as **Access and Benefit Sharing (ABS)**. The principle facilitates sharing of biological resources, specifically genetic resources, fairly and equitably between innovators/users and creators/conservers/providers, thereby enabling innovation and biodiversity conservation incentives.

The benefits arising from technological advancements and innovations using such resources must be utilized by the innovators and shared with the creators and conservers. The Biodiversity Convention, in its regulations, explicitly addresses ABS, and since India is a signatory, it practices the principles and fundamentals of ABS.

The **National Biodiversity Authority (NBA)** determines the equitable benefit sharing arising from using biological resources. In exchange for commercial exploitation of a genetic resource, an

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applicant is required to pay a fee, where 95% of its amount goes to the indigenous and local populous. Under BDA, the local people are referred to as **'Benefit Claimers'**, who are engaged in conserving biological resources and those who produce and maintain knowledge and information on the use of biological resources. The benefits could be monetary or non-monetary.

However, the provisions of BDA lay out certain restrictions and exemptions based on the identity of the persons accessing and using the biological resource (e.g., Indian or foreign; local or commercial enterprise) and the activity being performed (e.g., research for Intellectual Property Rights generation or collaborative non-commercial research under Section 5 of BDA).

Moreover, the extensive aspects of the BDA's framework, the longstanding history of the conservation movement, and international obligations in the form of international treaties to which India is a signatory must be understood to grasp the principle of FEBS.[1]

A) Biological resources under BDA

India is one of the world's prominent megadiverse countries. Having only 2.4% of the world's land area, it already encompasses 7-8% of the documented species. India is known for its agricultural diversity and is home to abundant varieties of plants, animals, fishes, and millions of microbes, insects, and other species. As per the Botanical Survey of India and the Zoological Survey of India, the nation acquires around 46,000 flora species and 81,000 fauna species.[2] Compared to other countries globally, India's ecological variety is unrivaled, and it is home to multifarious biological resources.

Biological resources are defined in **Section 2(c) of the BDA,** which refers to plants, animals, and microbes, or parts of them, including their genetic material and by-products that have actual or potential use or value. However, the definition explicitly excludes value-added products and human genetic materials. The **value-added product** has been elucidated under **Section 2(p) of the BDA** as the products that may contain unrecognized and physically inseparable formed portions or extracts of plants and animals. The reason for exempting value-added products from the BDA is to ensure and soothe the domestic industry's fear of impeding value-added product exports.[3]

Since the definition has quite a broad scope of interpretation, it is observed that some instances about questions like whether a particular resource is a biological resource or whether it is a by-

[1] http://ifs.nic.in/Dynamic/book/page8.pdf

[2] https://www.cbd.int/doc/world/in/in-nr-02-en.doc

[3] http://nbaindia.org/content/19/16/1/faq.html#:~:text=Value%20added%20product%20implies%20products,unrecognizable%20and%20physically%20inseparable%20form.

product or value-added product have been coming before the **National Green Tribunal (NGT)** and other judicial authorities.

A similar issue was addressed in [4], brought before the High Court of Uttarakhand (**Court**), which clubbed numerous writ petitions filed by several paper manufacturers for the sake of brevity. The Vishwanath Paper and Boards Ltd. (**Petitioners**) sought relief on several grounds, including whether the waste paper is included in the category of 'biological resources' defined in Section 2(c) or the category 'value-added products' defined in Section 2(p). The Petitioners companies were primarily using bagasse, rice husk, waste paper, and wheat straw as raw materials, which they claimed could not be considered biological resources under Section 2(c), and it is an industry, which does not come under the purview of 'commercial utilization' as set out in Section 2(f) of the BDA. Further, Petitioners acquire vast raw materials from states such as Uttar Pradesh, Bihar, and others. In contrast, only a small portion of these raw materials is obtained from Uttarakhand.

On the contrary, the State of Uttarakhand (**Respondents**) contended that waste paper is a biological resource. Instead of deciding whether waste paper qualifies as a 'biological resource', the Court dismissed the petitions at the admitting stage and ordered that the petitioner company not be prosecuted.

The NGT also cast a light on the dilemma through ***Asim Sarode v. State of Maharashtra***[5]. Order on 03 November 2015 was passed by NGT where manufacturers and entities using castor plants and other bio-resources for pharmaceutical drugs and cosmetic products claimed that castor oil is a value-added product and not a bio-resource. The manufacturing entities contended that castor oil is a finished product because it is sold in that state rather than in its raw form.

The order laid down that ABS under the BDA is applied to both agricultural and other natural bio-resources. Following, ABS does not apply to castor oil which is an agricultural bio-resource when used for general commodities, but it does apply when castor oil is used for commercial reasons in pharmaceuticals and cosmetic items, as well as bio-resources and bio-utilization for commercial use. Therefore, the entities were ordered to make ABS payment to Maharashtra State Bio-Diversity Board, given the continued commercial usage of castor oil.

Yet another critical case is ***Bio-Diversity Management Committee vs. Western Coalfields Ltd. and Ors***[6]**,** which provided legal ramifications to the coal as a 'biological resource' under the BDA.

[4] 2016 SCC OnLine Utt 1094
[5] Application no.25 of 2015
[6] MANU/GT/0169/2015

The Bio-Diversity Management Committee (**Petitioner**) of village Eklehara filed a petition before NGT at Bhopal bench demanding 2% royalty from Western Coalfields Ltd.'s (**Respondent**) revenue of Rs 1,470 crore, for commercial excavation of coal from their territory, considering coal to be a 'biological resource'. The Ministry of Environment and Forest (Environment Ministry) and NBA were made respondents to the petition.

The Respondents contended that the Biodiversity Convention and BDA do not attract any provision to regulate minerals or fossil fuels. Its key focus remains genetic materials, people's knowledge, and information on biological resources. Further, it was submitted that the definition of the biological resource set forth in Section 2(c) is extensive and only comprises plants, animals, microorganisms, and their genetic material along with the by-products, and because coal does not fit into any of the foregoing categories, it cannot be classified as a biological resource. Coal is a flammable, sedimentary, and fossil rock that takes around 300 million years to build up. It cannot be equated to a living thing, hence it cannot be classified as a biological resource under the definition of BDA. The Respondents went on to say that the Biodiversity Convention defines 'genetic material' as any material of plant, animal, microbial, or other origins that has a functional unit of heredity. Under optimal conditions, the half-life of DNA, being the functional unit of heredity, was estimated to be 521 years. Such optimal circumstances for DNA survival were dried state, vacuum-packed, and frozen at around 80°C. Supporting the mentioned submissions, the Respondents cited a study published in Proceedings of the Royal Society of Biology conducted in 2012 by a New Zealand scientist. Unlikely, coal dates back 63 to 300 million years. It is generated at high temperatures and pressures, and as a result, it is turned into a fossil. Given the above scenarios, the Petitioner's assertion that coal comprises the genetic material of plants stands invalidated. Moreover, the fact that under Section 2(c), value-added products had been explicitly excluded from the definition of biological resources, coal cannot be brought under the same.

The NGT upheld the Respondents' above contentions, concluding that coal is not a biological resource under the BDA. Therefore, the Petitioner cannot rely on the BDA provisions that allow it to charge for ABS. However, it refrained from going to the merit of coal being treated as a value-added product or not.

B) Measures for implementing FEBS

While granting clearance for an **Intellectual Property Rights (IPR)** application or a transfer of biological resources or knowledge, the NBA can evaluate equitable benefit sharing by implementing any of the following measures:

- granting the NBA or the benefit claimers joint ownership of IPR,
- technology transfer,

- locating production or research & development facilities to improve living conditions for the benefit claimers,
- associating Indian scientists, benefit claimers, and local residents for biodiversity research & development,
- establishing a venture capital fund to assist and compensate the benefit claimers, and
- awarding monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem appropriate.

C) Determination and Mode of FEBS

The NBA prepares benefit-sharing standards, which are published in the Official Gazette. However, the benefit-sharing approach is subjective and varies from case to case. The benefit amount is mutually agreed upon by those seeking approval from the NBA and local entities and benefit claimants. In addition, the NBA allows 5% of the benefits as administrative and service charges.

The applicant can pay for benefit sharing in ranges of 0.1 to 0.5 percent of the yearly gross ex-factory sale of the product, which is calculated using the annual gross ex-factory sale minus government taxes as shown below:

Annual Gross Ex-Factory Sale of Product	**Benefit Sharing Component**
Up to Rupees 1,00,00,000	0.1 percent
Rupees 1,00,00,001 up to 3,00,00,000	0.2 percent
Above Rupees 3,00,00,000	0.5 percent

- When the applicant commercializes the process, product, or innovation himself, the monetary share ranges from 0.2 to 1.0 percent, depending upon the sectoral approach, and is calculated based on annual gross ex-factory sales minus government taxes.
- Based on the sectoral approach, the monetary sharing ranges from 3.0 to 5.0 percent of the fee received (in any form, including the license/assignee fee) and 2.0 to 5.0 percent of the royalty amount received annually from the assignee/licensee where the applicant assigns/licenses the process/product/innovation to a third party for commercialization.

D) Liabilities imposed in violation of the BDA

To date, all offenses under the BDA are cognizable and non-bailable. However, the Biological Diversity (Amendment) Bill 2021, which is under consideration, has proposed decriminalizing such

offenses and recognizing them as civil offenses. The penalties for violating the provisions of the BDA are listed below:

Section	Cause		Penalty
55(1)	Contravention of Sections 3 or 4, or 6 of the BDA. Sections 3, 4, and 6 are related to persons not allowed to undertake biodiversity related activities without approval of the NBA, the results of research not to be transferred without approval of NBA, and application for IPR not to be made without permission of NBA respectively.		Imprisonment up to 5 years or fine up to Rs. 10 lakhs or both. When damage exceeds 10 lakhs, the penalty may be commensurate with the damage caused.
55(2)	Contravention of Section 7 of the BDA, related to prior intimation to State Biodiversity Board for obtaining biological resources.		Imprisonment up to 3 years or fine up to Rs. 5 lakhs or both.
56	Contravention of directions/ orders of the Central Government, State Government, NBA, and SBBs.		If no penalty is prescribed in any other provision of the Act, then Rs. 1 lakh for 1st default, Rs. 2 lakhs for 2nd default, and an additional 2 lakhs per day for continuous default.
57	For offenses committed by companies in contravention of the BDA.		Every person who was in charge or had the responsibility of the company at the time of the commission of the offense will be proceeded against and punished accordingly.

III. PATENTS AND FEBS

To proceed to grant patents, applications based on biodiversity components found in India must overcome specific additional compliances.

Before applying for any IPR in or outside India, linked to an invention based on biological material produced in India, compliance to acquire the prior approval of the NBA is mandated as per Section 6(1) of the BDA. However, approval of the NBA can be acquired after its filing or

acceptance, but before the sealing of the patent by the Patent Office. Furthermore, the NBA is required to act on any application for approval it receives within ninety days of receipt.

Additionally, Section 10 of the Patents Act, 1970 necessitates disclosure of the source and geographical origin of the biological material when used in an invention, in the specification. The provision requires a declaration and detailed information from the Applicant regarding any biological or biogenetic matter obtained from India.

One such case is ***NBA v. Sunev Pharma Solutions***[7], a classic example of inappropriate information and wrongful mention of the geographical source and origin of the biological resource. Section 25(2) of the Patents Act explicitly allows filing post-grant opposition on the grounds of wrongful disclosure of geographical source and origin of biological resource utilized in the invention. By virtue of the provision, NBA filed post-grant opposition before Indian Patent Office against Sunev Pharma Solutions (**Applicant**), who was granted patents on inventions using bio components viz. *Azadirachta indica, Berberis aristata or Berberis vulgaris, Glycyrrhiza glabra, Jasminum officinale, Picrorhiza kurroa, Pongamia pinnata, Rubia cordiflia, Saussurea lappa, Terminalia chebula, Capsicum abbreviata, Nymphea lotus, Curcuma longa; Tricosanthes diocia, Symplocos racemose, Ichnocarpus frutescens, Sesamum indicum oil, Ricinus communis oil, Cocos nucifera oil, Brassica juncea oil*.

NBA submitted that after it examined the said patent application, it was discovered that patents had already been awarded in countries namely Europe, South Africa, the United States of America, South Korea, and Mexico without prior permission, which is a breach of Section 6 of the BDA. NBA supported its argument stating that despite its rejection order passed because of the Applicant's wrongful disclosure of the source of biological components used in the invention, a patent was still awarded to the Applicant.

A search on the IPO database revealed that the patent was granted on 10 October 2018 with the patent number 302105. The IPO initially directed the Applicant to submit NBA approval in First Examination Report to which the Applicant responded on 10 October 2015, submitting that Applicant had applied for NBA's approval. Following that, on 04 January 2018, the Applicant amended their First Examination Report response to state that all biological resources were imported from China, except for *Sesamum indicum oil*, *Ricinus communis oil*, *Cocos nucifera oil*, and *Brassica juncea oil,* which were sourced from India and are exempted from NBA permission because they are notified as 'Normally Traded Commodities' in the NBA notification dated 07 April 2016.

[7] 2648/DEL/2006

To present, the abovementioned post-grant opposition/order is still pending considering the documents regarding the post-grant opposition proceeding/order are not available on the online records of the IPO. However, it would be interesting to watch how the IPO responds to the post-grant opposition in this matter. Not to mention, as per Section 64(1)(j) and or 64(1)(p) of the Patents Act, any false declaration made on behalf of the applicant will result in the revocation of a patent.

A) Persons who are mandated to acquire the NBA's Prior Approval before engaging in biodiversity-related activities

As per Section 3 of the BDA, without first obtaining NBA approval, certain persons are not permitted to engage in biodiversity-related activities or obtain any biological resource occurring in India or knowledge associated therewith for research, commercial exploitation, or bio-survey and bio-utilization, which include:

- a non-citizen of Indian citizen,
- a non-resident Indian citizen,
- a body corporate, association, or organization not incorporated or registered in India, and
- a body corporate, association, or organization incorporated or registered in India under any law in force that has any non-Indian participation in its share capital or management.

Therefore, it is evident from the legislation that prior NBA permission is only required for those persons or entities that have any foreign ownership or management attached to them.

To access biological resources for doing research in India, Indian researchers do not require prior authorization from any agency, nor do they need to notify the State Biodiversity Board. Under Section 7 of the BDA, prior notification to the State Biodiversity Board is necessary if the study results are further used for commercialization.

One such case related to NBA approval and FEB is ***Divya Pharmacy v. Union of India & others***[8]**.** It was the case of the Divya Pharmacy **(Petitioner)** that the Uttarakhand State Biodiversity Board **(Respondents)** cannot issue a demand under the Head of FEBS because the Board lacks the authority and jurisdiction to do so. Secondly, since the Petitioner was an Indian company with no foreign ownership or management, cannot be forced to pay any amount in accordance with FEBS. The Petitioner's whole argument was based on a textual and legalistic interpretation, particularly on the FEBS definition clause.

[8] Divya Pharmacy v. Union of India, 2018 SCC OnLine Utt 1035

The High Court of Uttarakhand (**Court**) decided that the Respondents had jurisdiction to demand the benefit-sharing amount from the Petitioner, clarifying that domestic companies procuring biological resources are on par with foreign entities under Section 3(2) of the Access and Benefit Sharing Guidelines, 2014 when it comes to benefit-sharing obligations. The Court adopted a more expansive interpretation of the Nagoya Protocol, ruling that foreign and domestic enterprises must comply with FEBS and share their benefits with local and indigenous groups. Further, it opined that the FEBS should be interpreted with a broader canvass view, as it cannot be looked through the narrow contours of the definition clause alone. The FEBS concept is centered on benefits for local and indigenous communities. The Nagoya Protocol sees no difference between a foreign entity and a national entity in terms of their commitments to local and indigenous inhabitants. As a result, to bring out the actual meaning of FEBS, the "ambiguities" in the national statute must be viewed in light of the international treaties, namely Rio and Nagoya, and a purposive rather than a restricted or restricted or literal interpretation must be made.

B) BDA exempted activities and biological resources from approval

Besides the above compliances regarding bio-resources, certain exempted activities and resources do not need prior intimation approval from the NBA as stated under BDA. The exemptions are as follows:

- use of biological resources from India that are normally traded as commodities, such as Pulses, Oilseeds, Fiber Crops, and Forage Crops (for some species), and for no other reason,
- utilization of value-added products (implied from Section 2(c) of the BDA),
- traditional usage of Indian biological resources or usage in collaborative search initiatives between India and international universities, publication of research papers, and knowledge sharing in any seminar or workshop with compliance and necessary approval from the Central Government (Section 4 and 5 of the BDA),
- utilization and consumption of bio-resources including conventional breeding, traditional practices by the cultivators, framers, breeders, animal husbandry, poultry farming, live-stock keepers, beekeepers, and traditional healers such as *vaids*, *hakims* etc. (implied from Section 2(f) of the BDA), and
- Using entirely exhausted biological resources, i.e., bio-waste products.

There is a matter related to one such exemption raised in patent application **4228/KOLNP/2008,** before the Controller of patents. The use of plant-based oils and animal-derived eggshells was declared in the application by Romano Development Inc. As a result, the Controller instructed the Applicant to specify the source and its geographical origin and acquire approval from the NBA if biological components were obtained from India. The Applicant clarified in its response that the oil was from the United States, whereas regarding eggshells the Applicant submitted specific arguments.

The Applicant submitted that eggshell is a waste product with no practical application. Generating anything useful such as the compound of the present invention by utilizing waste is anyway a sincere contribution to the government's waste management efforts and can be considered a biological source that is otherwise depleted, hence its sustainable use is necessary, as stated in the objectives of the BDA. Eggshell waste is generated in enormous quantities every day; it will not result in any long-term reduction in biological diversity. Moreover, eggshell waste is not a biological resource whose depletion could be concerning. Because eggshell waste is animal waste, using it to isolate the compound of this invention will not degrade the nation's natural biological resources.

The Applicant further submitted that such eggshell waste could be compared to the use of domestic and livestock waste, all of which are entirely exhausted biological resources and exempted from BDA. In addition, the current inventors devised a method for isolating *aminoglycan* from garbage in a cost-effective manner and producing something valuable, such as cosmetics. Hence, the Applicant stated that the claims do not and cannot invoke the provisions of the BDA.

The Controller eventually approved the application in light of the above submissions, given that NBA approval was not required.

C) Provisions under the Patents Act, 1970 through which a third party can initiate proceedings against the grant of patent/granted patent using biological resources

Under the PA, the following actions can be taken:

- refuse to grant the patent: as per **Section 15 of the PA**, violations of provisions imbibed in BDA result in refusal to grant the patent.
- initiation of opposition proceedings: pre-grant opposition or post-grant opposition procedures can be filed under **Sections 25(1) and 25(2) of the PA** respectively, if the entire specification fails to disclose or wrongly mentions the source and geographical origin of biological material employed for the invention.
- revocation of patent: one of the grounds to procure patent revocation under the PA is non-disclosure or wrong mentioning of the source and geographical origin of biological material employed for the invention.

IV. THE BIOLOGICAL DIVERSITY (AMENDMENT) BILL, 2021

In December 2021, the Ministry of Environment, Forest, and Climate Change introduced the Biological Diversity (Amendment) Bill 2021 (**Amendment Bill)** in Parliament amending the

Biological Diversity Act 2002 (BDA). The Amendment Bill cites issues voiced by the medical, seed, and research sectors along with their appeal to the ministry to "simplify, streamline, and reduce compliance burden". Hence, in order to address the said issues and provide a conducive environment for resource exchange and research study, reduce the compliance burden along with simplified access to use bio-resources the Amendment Bill was proposed.

A) Main intent behind the Amendment Bill

The main reason behind introducing the Amendment Bill is to attain certain goals, all without imperiling the Nagoya Protocol's objectives. The goals are as follows:

- expand the scope of AYUSH (India's traditional medicine systems) researchers and practitioners by exempting the traditional healers from intimating biodiversity boards for gaining access to bio-resources/knowledge (*vaids and hakims*),
- attract more foreign investments in research and development of biodiversity,
- minimize the pressure on wild medicinal plants by fostering cultivation & framing of medicinal plants,
- fast-track and streamline the research patent application process including commercial utilization, expanding access, and sharing benefits with local communities.
- decriminalize and reclassify the violations of benefit-sharing law as civil offenses, because such laws are still recognized as criminal and non-bailable offenses.

The Amendment Bill authorizes State governments to establish district-level intermediate biodiversity management committees.

B) Reason behind the condemnation of the Amendment Bill

Aside from the concerns with the proposed legislation itself, the way Amendment Bill was introduced in Parliament gave scant regard to the legislative process. The Amendment Bill was proposed without soliciting public input or referring it to the appropriate Parliamentary Standing Committee (i.e., Parliamentary Standing Committee on Science and Technology, Environment and Climate Change). The Amendment Bill was being rushed through without much parliamentary scrutiny and public debate.

Secondly, the Amendment Bill contains vague provisions to safeguard, conserve, or increase local communities' stake in biodiversity conservation and sustainable use. The phrase 'bio-utilization' which is a key part of the Act, is not included in the Amendment Bill. Such a removal creates ambiguity over its regulation and would leave out a dozen commercially oriented operations like characterization, incentivization, and bioassay. Likewise, cultivated medicinal

plants are exempted by the Amendment Bill from the purview of the Act. However, it is nearly impossible to tell which plants are cultivated and which are wild.

Additionally, the proposed exemption to AYUSH practitioners and manufacturing companies and 'codified traditional knowledge only for Indians' including local communities from prior intimation clause could pave the way for bio-piracy allowing illegal commercial use of naturally existing genetic/biochemical material. To guarantee that no aberrations from international responsibilities occur, the extent of the terms 'codified traditional knowledge' and 'only for Indians' should be specified. Moreover, the meaning of Section 3 (2) has been expanded to encompass a 'foreign-controlled corporation' that is incorporated or registered in India. When compared to Section 2(42) of the Companies Act 2013, the proposed definition of 'foreign-controlled company' in the Bill causes dubiety. Because corporations that are not foreign-controlled are excused from prior intimation clause before utilizing biological resources. Therefore, the exemption could allow huge multinational and foreign corporations to escape from FEBS and avoid the need for prior approval.

Conclusively, the proposed Amendment Bill sabotages the primary goal of the BDA and the Nagoya Protocol of conserving biological resources. Certain loopholes in the proposed amendment could enable corporate or foreign organizations to exploit traditional biodiversity resources for economic gain without sharing the benefits with biodiversity conservationists. The environmental experts are of the opinion that the Amendment Bill will shatter the fundamental tenets of conservation and sustainable use if approved.

As of now, the Amendment Bill has been referred to a Joint Parliamentary Committee which is anticipated to submit a report by the 2022 budget session. According to reports, the submitted report will almost certainly be put up for public comment.

CONCLUSION

Consequently, for every innovator, researcher, and other business or non-business entity, it is paramount to realize and cognizantly comply with the requirements of BDA.