



Intellectual Property Dimensions of Biodiversity Resources: From Evidence to Action

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The Indian law on protecting plant variety and biodiversity, along with its attendant rules and guidelines, tries to capture the biological inventions and evergreening. However, the techno-legal dimension of access and benefit-sharing falls beyond the pale and purview of the natural scientist's intense examination. The Supreme Court, High Court, and National Green Tribunal (NGT) frequently confront the legal interpretation of Normally Traded Commodities (NTCs), Value-Added Products (VAPs), and prospecting of biological resources. These vexed issues having a potential bearing on scientific research and innovations necessitate amicable resolution of complex biodiversity disputes to keep people and researchers' faith and other commercial entities in the judiciary intact. The paper attempts to subsume these concerns and highlight the repercussions of judicial interpretation and perception of biological resources on biotechnological research and discoveries in the Indian context.

Keywords: Biodiversity Resource, Commercial Utilization, Normally Traded Commodities, Value Added Product, Biological Diversity Act, 2002, Access and Benefit Sharing (ABS)

The Convention on Biological Diversity, 1992, Bonn Guideline, 2001, and the Nagoya Protocol, 2010 are the overarching regulatory mechanism for the sustainable use of biological resources and biotechnological innovation. The Biological Diversity Act, 2002, Biological Diversity Rule, 2003, and Access and Benefit Sharing (ABS) Guidelines, 2014, subscribe to the professed goals of intellectual property and sovereignty over natural resources in the Indian context. The international and national biodiversity law endeavours to fulfill these goals in the sustainability paradigm and biodiversity conservation. It enunciates that plants, animals, and micro-organisms are conserved and used for research and commercial purposes. However, it excludes the access and utilization of biological resources for commercial purposes by foreign and Indian companies.¹ In other words, the foreign and Indian companies and entities primarily seek Prior Informed Consent (PIC) and Mutually Agreed with Terms (MAT) before access and utilization of biodiversity by National Biodiversity Authority (NBA) and State Biodiversity Boards (SBB) and Biodiversity Management Committee (BMC).² The ABS with the grass root and indigenous entities is also a condition

precedent for fostering their intellectual property and innovation. Dalton's study of bio-prospecting of biodiversity constitutes the focal point of analysis in the present context.³ The legal appraisal supplemented Pethiyagoda's pragmatic note on the unintended effects of Biodiversity Laws at global and national levels.⁴ The erudite explanation of Paul M. Wood regarding the biological resources and values utilized under the present study.⁵ The paper constructs and codes the meaning of biodiversity resources culled out by the Indian courts in fostering potential research and innovation in India.

Indian Bio-diversity Governance

The teleological approach to biodiversity resources has a direct bearing on the Indian biodiversity governance regime. Sections 6⁶ and 19 of the Biodiversity Act, 2002, and Rule 18 of Biodiversity Rules, 2004,⁷ relate to PIC in access to biological resources. Section 19 (3) Biodiversity Act, 2002, and Rule 18 (5) of Biodiversity Rules, 2004 elaborate the MAT. Section 21 of Biodiversity Act, 2002,⁸ and Rule 20 of Biodiversity Rules, 2004⁹ specify the Access and Benefit-Sharing (ABS) principles, which require the NBA's approval for access to biological resources for researcher and commercial purposes. Sections 3, 4 & 6 of Biodiversity Act, 2002 and Rules 14-19 of the Biodiversity Rules, 2004 (Fig. 1).¹⁰

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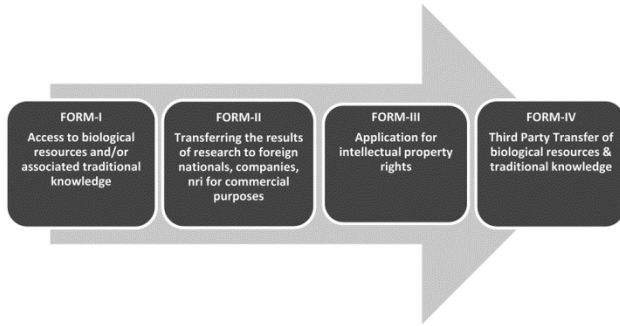


Fig. 1 — Procedure for the access and transfer of biological research in Indian Biodiversity Laws

The procedure and principles of access to biological resources are studied under four convenient forms. It collectively deals with the utilization and transfer of intellectual property rights. The gist of legislative compliance entails that the SBB is empowered to issue notices to Indian companies for ABS royalties in Section 7 of Biodiversity Act, 2002¹¹ and ABS Guidelines, 2014 (Fig. 2).

It applies to all international and native companies in compliance with Article 8 (j) of *CBD*, 1992 on PIC and MAT matters. The normative clarity of PIC, MAT, and ABS provisions in the *Divya Pharmacy* under the *Patanjali* brand offers sufficient evidence to action.

Legal Connotation of Biodiversity Resources

The biodiversity law defines biological resources to include ‘plants, animals and micro-organisms and genetic material’. It has by-products but excludes value-added products (Fig. 3). However, it does not contain human genetic material but contains genetic material and derivatives with actual or potential use or value for biodiversity.¹⁹

The purviews of the biological resources are subservient to two clauses, one dealing with the legal meaning of biodiversity and other access and benefit-sharing for the higher objectives of sustainable development and sovereign control over the bioresources. The definition of biodiversity spells out that ‘the variability among living organisms from all sources and the ecological complexes of species and eco-systems’.¹² The bio-survey, collection, and utilization covers species, subspecies, and genes of biodiversity. However, the components are inclusive of the characterization, incentivization, and biosafety.¹³

Judicial Interpretation of Biological Resource

The interpretation of biological resources has been on constant variation and divided judicial opinions.¹⁴

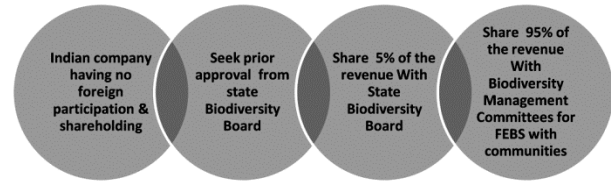


Fig. 2 — Access & Benefit-Sharing principles under Biodiversity Laws

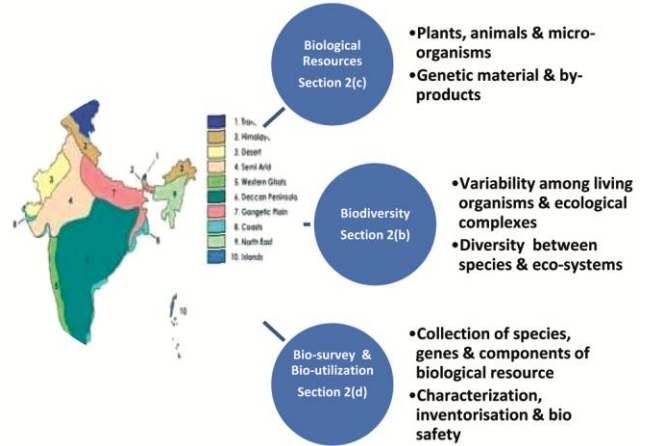


Fig. 3 — Geographic distribution of biodiversity resource zone in India

There is a catena of cases that enunciates that Indians entities not to inform but seek approval from the SBB to commercialize biological resources.¹⁵ The two sets of judicial opinions are subject to litigation in Bombay High Court to Uttarakhand High Court and the NGT. The legitimacy of the ABS Guidelines, 2014 called into question in *Central India AYUSH v State of Maharashtra*.¹⁶ *AYUSH* companies maintained that Section 7 of the Biodiversity Act, 2002 does not apply to Indian entities for accessing biological resources. The respondents’ state averred that the Bombay High Court does not have jurisdiction to hear this case, and only NGT being a specialized court, is a *forum convenient* to decide the matter (Fig. 4). The matter is still *sub judice*, and the decision waited in biodiversity and biotechnological entities in India and abroad.

It is pertinent to note that many crucial cases of *Vicco Laboratories*, *Aroma Herbal Private Limited*, and *Pathak Ayurvedic Pharmacy* are pending before different High Courts relating to the ABS of biological resources and biodiversity in India. The applicability of Section 7 of the Biodiversity Act, 2002 and ABS Guidelines, 2014, surfaced in *Vishwanath Paper and Boards Ltd. v State of Uttarakhand*.¹⁷ The critical issue in the case was whether used rice husk, waste paper, bagasse, and

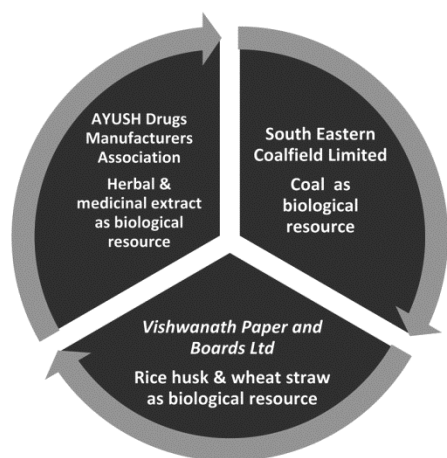


Fig. 4 — Interpretation of biological resources by Indian Courts and Green Tribunal

wheat straw qualify as biological resources within the meaning of Section 2(c) of the Biodiversity Act, 2002. The Uttarakhand High Court acquitted the company from the applicability of the impugned law and guideline.

Under this backdrop, the legal and judicial interpretations of the biological resources are imperative in some details. Natural resources deal with a variety of herbal, medicinal, paper, coal, NTCs. We are undertaking the five case studies to discern the nature and trend of environmental justice in the arena of biodiversity and biotechnology researches.¹⁸ These cases are studied in chronological order in lines to follow.¹⁹ In *Bio-Diversity Management Committee v Western Coalfields Ltd.*,²⁰ the BMC of Eklahara complained about the extraction of bioresources. It claimed ABS from South Eastern Coalfield Limited (SECL), Western Coalfields, and Northern Coalfields companies. According to MPSBB, the coal comes under the definition of a ‘bioresource’ under Section 2(c) of the Biodiversity Act, 2002. The company did not pay any royalty under FEBS. The coal companies denied the legal status of coal as biological resources. The NGT’s Central Zone Bench declared that coal is not a biological resource under Section 2(c) of the Biodiversity Act, 2002.²¹

Commercial Utilization of Biological Resources

A brief note on the law and its enforcement is in order under this section to lend appropriate credence to the subject. There are two major players in commercial utilization and research promotion of biological resources bio-utilization one ‘benefit claimers’ constituting of ‘the conservers of biological resources and holders of biological knowledge and

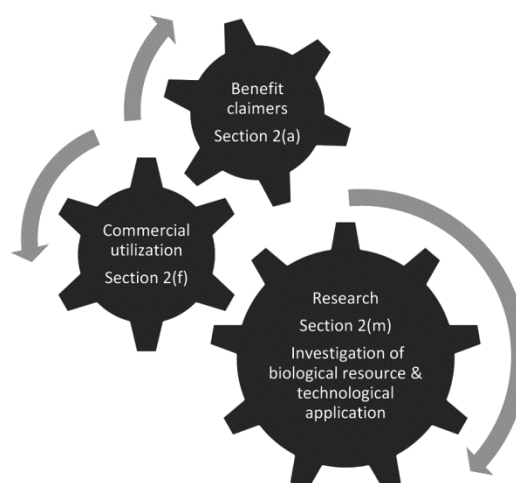


Fig. 5 — Commercial utilization and technological application of biological resources

innovations for application of biodiversity and biotechnology (Fig. 5).²² The multiple stakeholders for the commercial utilization of biological resources include end users encompassing drugs and cosmetics, enzymes, and genes. These natural resources are generally used for genetic intervention in agriculture, horticulture, animal husbandry, and beekeeping.²³ The net impact of the legal provision is to usher ‘research’ by systematic innovation study.²⁴ The access and utilization eventually lead to the ‘sustainable use’ intergenerational equity, environmental justice²⁷, and conducive and eco-system.²⁵

The Bangalore-based Environment Support Group (ESG)²⁶ filed a Public Interest Litigation (PIL) for judicial determination of the NTCs, VAP vis-à-vis the biological resources. The Ministry of Environment’s NTCs Notification, 2009 exempted 190 extinct plants under Section 40 of the *Biodiversity Act, 2002*.²⁷

The courts slipped into the controversial row over legal interpretation of NTCs and VAP.²⁸ Instead of subtle delineation of the biological resources, the Ministry, in consultation with NBA ushered more commercialization. The petitioner submitted that the NTCs Notification being *ultra vires* set aside to prevent bio-piracy (Fig. 6).²⁹ The ESG also prayed before the High Court of Karnataka for its legitimate consideration and not transferring the case to NGT jurisdiction in biodiversity matters.

Meanwhile, NBA included ‘value-added products and by-products’³⁰ under 22 categories NTCs for exemption in July 2015, the MoEF&CC accordingly approved the commercialization of the in its Notification on 7 April 2016.³¹ Thus, instead of the judicial exposition of biological resources, the



Fig. 6 — Normative portrayal of NTCs & VAPs under NTCs Notification, 2009

controversy on VAP sparked in *Ayurvedic Drug Manufacturing Association Case*.³² Although Section 2 (c) Biodiversity Act, 2002, has categorically excluded the 'value-added product' from the purview of biological resources. The companies are flexing their strength to get it included in its ambit and scope of natural resources.

Bio-Diversity Researches and Bio-Piracy

The scientific community often remains distant to judicial interpretation and perception of biological resources, although it has a seminal bearing on the new biological innovation and discoveries. The judicial understanding of biodiversity is appreciated in the light of Sections 3³³ and 7 of the *Biodiversity Act*, 2002. However, its impact on intellectual property and biotechnological innovation remain a subject of examination. The NBA enjoys an omnibus power of grant of access to any biological resource to transfer research, commercial utilization, and patent and intellectual property protection. The NBA can approve access and use of natural resources after conducting inquiries and expert opinion. The grant will come under regulatory discipline and practicality of the public disclosure under Section 19 of the *Biodiversity Act*, 2002.³⁴ Legally speaking, Central Government, through its designated authority and benefits claimer, can initiate the complaint about FEBS and ABS.³⁵ The cognizance of biodiversity and biopiracy offences governed by Section 59 of the *Biodiversity Act*, 2002. The Central Government, designated authority and qualified officer are in charge of monitoring and compliance. They shall be a watchdog to any derogation of the rules in any other law, for the time being in force, relating to forests and wildlife and biodiversity.

The Czech Scientists Case, 2008,³⁶ case is a living indicator on the point. These scientists illegally entered into the Protected Area of Singhalila National Park, West Bengal, and collected 1500 endangered butterflies. Though the collection's purpose was for

bona fide research, they have not sought any PIC and approval from the NBA and SBB under the *Biodiversity Act*, 2002. Therefore the Chief Wildlife Warden of the West Bengal Forest Department clamped Sections 27 and 29 of the *Wildlife (Protection) Act*, 1972. Since the instant case pertains to 2009 and the *National Green Tribunal Act*, 2010 came to the statute book in 2010; therefore, the instant case was not possibly are filed in NGT. The SBB has also not approached the High Court against the biopiracy case against these scientists under Section 3 of the *Biodiversity Act*, 2002. As a natural sequel, the Chief Judicial Magistrate in Darjeeling convicted them under the *WLP Act*, 1972, on 8th September 2008. While one scientist fined ₹ 20,000/-, the other was sentenced to 3 years of imprisonment and fined ₹ 60,000/-. Later on, the Court released them on bail and bonded them with India's conditional residency until the Appellate Court's final disposal. They were arrested but finally released as the Court took relax on account of one of the scientists' international reputation.³⁷ The onset of biopiracy and scientific research has been aptly summarised by Kothamasi and Kiers in a published paper in the *Journal of Conservation Biology*.³⁸ This case discerns the flip side of the access for research and commercialization of biodiversity in the Indian context.

Bio-technological Innovations and Bio-piracy

The biodiversity jurisprudence has a natural connection to biotechnological researches. The other case has a significant bearing on biotechnological studies derives from biological resources. The collection of reptiles from the Athirappally forest in Kerala's Western Ghats biodiversity reserve by Japanese researchers in July 2015 represents another set of biotechnological innovations and biopiracy.³⁹ The case deals with the biotechnology laws and policies⁴⁰ in terms of Section 36 (4) (ii) of *Biodiversity Act*, 2002.⁴¹ It also regulates the risks associated with the adverse environmental impact on biological diversity⁴² and and living modified organisms. It will not be out of context to refer to the Supreme Court ruling in *Aruna Rodrigues v Union of India*⁴³ on India's legal position towards genetically modified crops and the bio-sustainability and bio-safety. The decision cast a legal duty of the Central Government to the Court speaking through Justice Swatanter Kumar, expressed concern over the environmental impact and bio-safety of genetically modified crops on human health. The petitioners

desired to adopt a bio-safety protocol and direction not to allow import, manufactures, or use any release of genetically modified organisms and crops in India.

The Court vides its order dated 1 May 2006, directed for techno-legal auditing environmental health and bio-safety compliance. The Court constituted a Technical Expert Committee to review and recommend the biological sequencing and associated risk assessment on environmental health and safety studies. To examine the feasibility of validated protocols and functional testing for contamination, the Committee will keep the environment, health, and bio-safety into consideration. The Court desired an in-depth examination of the ban and field test protocols for the implementation of GMOs. Thus, the National and State biodiversity authorities, Genetic Engineering Approval Committee, Ministries of environment and technology can codify guidelines and advisories.⁴⁴ Despite the current scenario, there is a sense of optimism that eventually, biodiversity jurisprudence will chart out a specific bio-prospecting and biodiversity conservation course.

Biodiversity Laboratory and Community

Although, its total land area is only 2.4 percent of the world's total geographical area, the country accounts for eight percent of the total global biodiversity with an estimated 49000 species of plants, of which 4900 are endemic.⁴⁵ The industrial exploitation of biodiversity resources requires a radical shift from the laboratory to land and local communities to promote the human right to the environment and ecological balance.⁴⁶ The country's biodiversity resources earnings from the pharmaceutical plants earn an annual income of rupees 55 crores. The Maradavally State Forest case study reveals that the primary beneficiaries of biological resources are contractors and intermediaries. These entities are primarily driven by commercial motives ignoring the short and long-term environmental impacts.⁴⁷ India remains one of the 12 biodiversity-rich countries globally; the victimization syndrome of over-exploitation breeds a sustainability crisis. The 15,000 species of flora are getting extinct. The gradual shrinkage reflected in the Indian Agricultural Research Institute reports documented that out of 30,000 paddy varieties, only 50 combinations will be available at the end of the century. There is a need for a coherent system by identifying the strength, weaknesses, opportunities, and threats (SWOT) to biodiversity conservation.⁴⁸

The communitarian and diversity-related approach under the intellectual property rights and biodiversity laws necessitate due harnessing of human resources.⁴⁹

The national and international markets enjoin for the systemic development of Small and Medium Business Enterprises (SME's), predominantly indigenous and local cultivators.

Influx of ABS Law

The international and national biodiversity laws proactively engage researchers to advance biodiversity science and biotechnological innovations by following PIC, ABS, provision for approval by NBA and SBB. Therefore, it is imperative to understand the right-based approach to environment and biodiversity conservation in the biological resources' operational ambit. It is equally significant to look at the benefit claimers' purview, commercial utilization, and researchers provided under Section 2 of the Biological Diversity Act, 2002. The judicial approach underwent a metamorphosis in *Divya Pharmacy v Union of India*⁵⁰ by Uttarakhand High Court. It delineated that Indian biodiversity does not distinguish between Indian and foreign entities in ABS and share its profit and revenue from 0.5% to 5% to Uttarakhand Biodiversity Board. The judicial variance reconciled in *Divya Pharmacy* by Uttarakhand High Court to the effect that any application for ABS on Indian biological resources irrespective of whether Indians or non-Indians entities virtually submit to the discipline of PIC and approval of the NBA.⁵¹ The judgment laid down legitimate enforcement of international and Indian biodiversity laws and set at rest the distinction between an Indian commercial use and non-Indian commercial use in the exploitation of biological resources in biodiversity stewardship. Third-world countries, including indigenous Indian populations, demand ABS, whereas the commercial entities expect to harness maximum profits.⁵² The influx of ABS is cardinal to the intellectual property enforcement and compliance of Indian and international biodiversity laws.

Conclusion

The impact of biodiversity jurisprudence needs an erudite explanation and careful examination under current discourse and diametric. The legal and judicial attitude deduced from the case study of five prominent Indian cases unequivocally suggests the Court's relaxed approach in delineating the techno-legal import of the biological resources. It is a quantum leap for the equitable benefit sharing of

natural resources for Indian and foreign entities. The confusion is compounded by the fact that Indian biodiversity is at a threatening stage and rampant biopiracy. Instead of settling the natural resources' legal connotations, the Court was trapped with the interpretation of NTCs and VAPs in Section 40 of the Biodiversity Act, 2002. There is a feeling gaining ground now that Convention on Biological Diversity, 1992, Bonn Guideline, 2001, and the Nagoya Protocol, 2010 fraught with unintended consequences of rampant commercial use of genetic resources and curtailed biodiversity research. The bureaucratic biodiversity regime is working as an impediment to a facilitator to discoveries. This syndrome finds an erudite explanation under many scientific and legal studies and necessitates the shreds of evidence to bring into action biodiversity conservation. India's courts will delineate biological resources from a myopic perspective to a broad horizon of biodiversity jurisprudence.

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