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# Bio-trade and Bioprospecting in India: A Critical Legal Analysis under the Biological Diversity Act, 2002

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### Abstract

India is one of the world's most biodiverse countries, possessing a vast range of biological resources and an equally rich repository of traditional knowledge held by indigenous and local communities. With the expansion of the global bio-economy, biological resources have increasingly become objects of commercial trade and scientific exploration, giving rise to complex legal and ethical concerns surrounding bio-trade and bioprospecting. In response to international commitments under the Convention on Biological Diversity, India enacted the Biological Diversity Act, 2002 to regulate access to biological resources and ensure fair and equitable benefit sharing. This paper undertakes a critical legal analysis of bio-trade and bioprospecting in India under the Biological Diversity Act, 2002, with particular emphasis on the contemporary regulatory framework and its practical implementation. Using a doctrinal research methodology, the study examines statutory provisions, institutional mechanisms, and recent Indian judicial decisions interpreting access, benefit sharing, and commercial utilisation of biological resources. The paper further analyses administrative orders of the National Biodiversity Authority and evolving regulatory practices in the post-2020 period. The study reveals that while the Act provides a comprehensive legal framework for regulating bio-trade and preventing biopiracy, significant challenges persist in terms of definitional ambiguities, procedural complexities, institutional capacity, and enforcement effectiveness. Judicial interventions have played a crucial role in clarifying statutory interpretation; however, inconsistencies in regulatory application continue to affect stakeholders, particularly local communities and small-scale enterprises. The paper concludes by proposing legal and policy reforms aimed at strengthening access and benefit-sharing mechanisms, improving institutional coordination, and promoting sustainable and community-centric bio-trade in India.

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### 1. Introduction

The growing global demand for biological resources has significantly expanded the scope of bio-trade and bioprospecting, positioning biodiversity as a strategic economic and scientific asset. Bio-trade refers to the collection, production, transformation, and commercialization of goods and services derived from native biodiversity, while bioprospecting involves the systematic exploration of biological resources for commercially valuable genetic and biochemical properties. Together, these activities form a crucial component of the modern bio-economy, particularly in

sectors such as pharmaceuticals, biotechnology, agriculture, cosmetics, and nutraceuticals. India occupies a unique position in this global landscape due to its exceptional biological diversity and long-standing traditions of indigenous and local knowledge systems. As one of the world's megadiverse countries, India hosts a wide range of ecosystems and species, many of which are closely linked to traditional medicinal practices and community-based resource management. However, the commercial exploitation of such resources has also raised serious legal and ethical concerns, particularly in relation to biopiracy, inequitable benefit

sharing, and the misappropriation of traditional knowledge. In response to these challenges, India enacted the Biological Diversity Act, 2002 to give effect to its obligations under the Convention on Biological Diversity.

The Act establishes a comprehensive regulatory framework governing access to biological resources, associated knowledge, and mechanisms for fair and equitable benefit sharing. Despite this statutory framework, persistent enforcement challenges, jurisdictional ambiguities, and evolving international norms especially under the Nagoya Protocol continue to test the effectiveness of India's biodiversity governance regime.

This research paper undertakes a critical legal analysis of bio-trade and bioprospecting in India within the framework of the Biological Diversity Act, 2002. It examines the conceptual foundations, regulatory mechanisms, and judicial interpretation of biodiversity law in India, with particular emphasis on Access and Benefit Sharing (ABS) and biopiracy-related disputes. By analysing key case studies and recent developments, the paper seeks to assess whether the existing legal framework adequately balances biodiversity conservation, community rights, and sustainable commercial utilisation, while also identifying areas for legal and policy reform.

## 2. Conceptual Framework

### 2.1 Bio-trade: Definition and Global Context

Bio-trade refers to commercial activities involving the sustainable use, production, and trade of biological resources and associated products derived from biodiversity. The term is commonly understood in the context of economic activities that depend on biological diversity, including plant and animal species, genetic materials, and ecosystem services, which are traded in domestic and international markets. Bio-trade goes beyond mere extraction; it encompasses value chains that link biological resources from producers (often local communities and smallholders) to markets while integrating environmental conservation and equitable socio-economic benefits.

The United Nations Conference on Trade and Development (UNCTAD) has played a foundational role in defining the conceptual and operational framework for bio-trade. UNCTAD describes bio-trade as the "collection, production, transformation, and commercialization of goods and services derived from biological resources under sustainable and equitable conditions." According to the UNCTAD BioTrade Initiative, bio-trade includes products (such as natural ingredients, therapeutic plants, essential oils, natural cosmetics, extracts, and genetic resources) and services (such as ecotourism and ecosystem restoration) that contribute to livelihoods and biodiversity conservation.

UNCTAD's bio-trade framework is guided by a set of principles and criteria that aim to ensure that trade in biodiversity is environmentally sustainable, socially equitable, and economically viable.

The three fundamental components of this framework include:

i) **Sustainable Use of Biological Resources:** Bio-trade activities must be conducted in ways that maintain the long-term viability and productivity of biological resources and ecosystems. This implies the adoption of harvesting practices, cultivation systems, and supply chain processes that do not deplete populations, degrade habitats, or compromise ecological integrity. Sustainable use also incorporates adaptive management and

monitoring mechanisms to respond to environmental changes.

ii) **Environmental Conservation:** Beyond sustainable use, bio-trade should actively contribute to the conservation of biodiversity. This means that activities should support in situ and ex situ conservation efforts and align with broader biodiversity strategies and action plans. Conservation outcomes can include habitat protection, restoration initiatives, and incentive mechanisms that reward biodiversity stewardship.

iii) **Fair and Equitable Benefit Sharing:** Bio-trade must ensure that benefits arising from the utilization of biological resources and associated knowledge are shared equitably with communities and stakeholders who contribute to the conservation and sustainable use of biodiversity. This includes monetary benefits (such as royalties, premium pricing, profit-sharing) and non-monetary benefits (such as technology transfer, capacity building, employment opportunities, and community development). The principle of equitable benefit sharing is also a cornerstone of international instruments such as the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access and Benefit Sharing (ABS).

The global context of bio-trade has strengthened over time as countries seek to integrate biodiversity values into economic development strategies. Bio-trade illustrates the intersection of trade, environment, and sustainable development, bridging commercial interests with biodiversity goals. Global institutions, including UNCTAD, CBD Secretariat, United Nations Development Programme (UNDP), and Food and Agriculture Organization (FAO), have endorsed bio-trade as a vehicle for achieving national biodiversity strategies, promoting equitable market access for small producers, and enhancing rural livelihoods.

In summary, bio-trade is a multifaceted concept that encompasses the sustainable use and commercialization of biological resources, aligned with broader goals of biodiversity conservation and equitable sharing of benefits. The UNCTAD bio-trade framework provides internationally recognised guidance, which has influenced national regulatory regimes and socio-economic development policies worldwide.

### 2.2 Bioprospecting-Meaning and Scope

Bioprospecting refers to the systematic exploration, collection, and analysis of biological resources including plants, animals, microorganisms, and genetic material for the purpose of discovering commercially valuable biochemical compounds, genes, or biological processes. It is primarily undertaken in sectors such as pharmaceuticals, biotechnology, agriculture, cosmetics, nutraceuticals, and industrial enzymes. Unlike traditional extraction of natural resources, bioprospecting is knowledge-intensive and often relies on advanced scientific tools such as molecular biology, genomics, metabolomics, and bioinformatics.

The scope of bioprospecting has expanded significantly with advancements in biotechnology. Modern biotechnological techniques enable researchers to isolate, replicate, and modify genetic material, transforming raw biological inputs into high-value intellectual assets. As a result, bioprospecting has become closely intertwined with intellectual property rights (IPRs), particularly patents, plant variety protection, and trade secrets. Innovations derived from biological resources are frequently protected under patent regimes, provided they meet

criteria of novelty, inventive step, and industrial applicability. The linkage between bioprospecting and intellectual property law has generated both opportunities and concerns. On one hand, IPRs incentivise research and development by providing exclusive rights to innovators. On the other hand, when patents are granted over inventions derived from biological resources or traditional knowledge without the consent of source communities or countries, serious issues of equity and justice arise. This tension has led to international and domestic efforts to integrate access and benefit sharing (ABS) requirements into biodiversity and patent governance frameworks.

### 2.3 Biopiracy vs. Ethical Bioprospecting

A critical distinction must be drawn between biopiracy and ethical bioprospecting. Biopiracy refers to the unauthorised appropriation of biological resources or associated traditional knowledge, often followed by the acquisition of intellectual property rights without prior informed consent or benefit sharing with the rightful custodians. High-profile cases involving turmeric, neem, and basmati rice exemplify how traditional knowledge was historically patented abroad without acknowledgment or compensation to Indian communities.

Ethical bioprospecting, in contrast, operates within a legally regulated framework grounded in transparency, prior informed consent, and equitable benefit sharing. It requires compliance with national biodiversity laws, recognition of community rights, and adherence to international obligations under instruments such as the Convention on Biological Diversity and the Nagoya Protocol. Ethical bioprospecting seeks to align commercial innovation with conservation goals and social justice by ensuring that local and indigenous communities are recognised as stakeholders rather than mere resource providers.

Thus, the distinction between biopiracy and ethical bioprospecting lies not in the act of biological exploration itself, but in the process, legality, and equity governing access, use, and benefit distribution.

### 2.4 Growth of Bio-trade and Bioprospecting Globally

In recent decades, bio-trade and bioprospecting have emerged as critical components of the global bio-economy, driven by increased demand for natural products, genetic resources, and biologically derived innovations. Bio-trade broadly refers to the commercial production, transformation, and trade of goods and services derived from biodiversity, conducted in accordance with environmental, social, and economic sustainability criteria. Bioprospecting, as a subset of bio-trade, involves the systematic exploration of biological material for commercially valuable genetic and biochemical properties, particularly in pharmaceuticals, agriculture, cosmetics, and industrial biotechnology.

Technological advancements in molecular biology, genomics, and bioinformatics have significantly accelerated the pace of bioprospecting worldwide. Multinational corporations and research institutions increasingly rely on biological resources to develop novel drugs, enzymes, and crop varieties, many of which originate in biodiversity-rich regions of the Global South. Historically, several breakthrough pharmaceuticals including anti-cancer and anti-malarial compounds have been derived from plant and microbial sources, underscoring the economic importance of natural ecosystems in innovation processes.

However, the rapid commercialisation of biological resources has also exposed asymmetries between resource-providing countries and technology-owning entities. For much of the twentieth century, biological resources were treated as the “common heritage of mankind,” allowing unrestricted access without compensation to source countries or indigenous communities. This led to widespread instances of biopiracy, where biological materials and associated traditional knowledge were patented without consent or benefit sharing. The adoption of the Convention on Biological Diversity (CBD), 1992 marked a paradigm shift in global biodiversity governance. The CBD recognised the sovereign rights of states over their biological resources and introduced the principle of fair and equitable sharing of benefits arising from the utilisation of genetic resources. Subsequently, access and benefit-sharing (ABS) emerged as a core regulatory mechanism, seeking to balance innovation incentives with conservation and equity considerations. The Nagoya Protocol on Access and Benefit Sharing further strengthened this framework by providing detailed guidelines on prior informed consent and mutually agreed terms between resource providers and users.

As a result, bio-trade and bioprospecting have evolved from largely unregulated activities into legally structured economic processes governed by international agreements and domestic legislation. Countries rich in biodiversity have increasingly adopted national laws to regulate access to biological resources, reflecting a global consensus that sustainable use and equitable benefit sharing are essential to long-term biodiversity conservation.

## 3. Biodiversity Law and Policy Framework

### 3.1 Convention on Biological Diversity, 1992

The Convention on Biological Diversity (CBD), 1992 represents a foundational international legal instrument governing biodiversity conservation and utilisation. It marked a significant departure from earlier approaches by recognising that states have sovereign rights over their biological resources.

The CBD establishes three core objectives:

1. Conservation of biological diversity;
2. Sustainable use of its components; and
3. Fair and equitable sharing of benefits arising from the utilisation of genetic resources.

Article 15 of the CBD introduced the principle that access to genetic resources is subject to prior informed consent of the provider country and must be based on mutually agreed terms, thereby laying the groundwork for access and benefit sharing regimes worldwide. The CBD also acknowledges the role of indigenous and local communities in conserving biodiversity and preserving traditional knowledge, urging states to respect, protect, and promote such knowledge systems.

### 3.2 Nagoya Protocol on Access and Benefit Sharing

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2010) was adopted to operationalise the ABS provisions of the CBD. It provides a more detailed and legally robust framework for regulating access to genetic resources and associated traditional knowledge.

India is a Party to the Nagoya Protocol, and its domestic biodiversity legislation largely aligns with the Protocol's objectives. The Protocol emphasises legal certainty, transparency, and compliance mechanisms, including



checkpoints to monitor utilisation of genetic resources and ensure benefit sharing. It also strengthens the rights of indigenous and local communities by explicitly recognising

their authority to grant access to traditional knowledge, subject to domestic law.

### 3.3 Indian Court Cases under the Biological Diversity Act, 2002

Table A

Case Name	Court	Year	Issue	Outcome	Legal Provision	Authorised Reference/URL
Divya Pharmacy v. Union of India	Uttarakhand High Court	2018	Whether Indian entities are liable to pay ABS under BD Act	ABS obligation upheld against Indian company	Sections 3, 7, 21 BD Act; ABS Guidelines 2014	<a href="https://www.mondaq.com/india/financial-services/785118">https://www.mondaq.com/india/financial-services/785118</a>
DCM Shriram Ltd. v. National Biodiversity Authority	Delhi High Court	2023	Determination of benefit sharing for past access	NBA empowered to levy benefit sharing	Sections 6, 21 BD Act	<a href="https://indiankanoon.org/doc/23877819/">https://indiankanoon.org/doc/23877819/</a>
State of Kerala v. Japanese Nationals	Kerala Sessions Court	2015	Illegal collection/export of biological resources	Conviction under BD Act	Section 3 BD Act	<a href="https://www.downtoearth.org.in/news/wildlife-biodiversity/japanese-nationals-convicted-under-biological-diversity-act-2002-50031">https://www.downtoearth.org.in/news/wildlife-biodiversity/japanese-nationals-convicted-under-biological-diversity-act-2002-50031</a>

### 3.4 Legal Framework under the Biological Diversity Act, 2002

The Biological Diversity Act, 2002 (Act) was enacted to fulfil India's obligations under the Convention on Biological Diversity (CBD) by providing a comprehensive domestic legal regime to conserve biological diversity, regulate access to biological resources, and ensure fair and equitable sharing of benefits arising from their utilisation. The Act establishes that no person shall obtain biological resources for commercial utilisation, research, or bio-survey without prior approval from relevant authorities.

The Act creates a three-tier institutional structure comprising the National Biodiversity Authority (NBA) at the central level, State Biodiversity Boards (SBBs), and Biodiversity Management Committees (BMCs) at the grassroots level. The NBA, constituted under Section 8, is empowered to grant approvals for access to biological resources and associated traditional knowledge, set conditions for benefit sharing, and adjudicate disputes related to non-compliance. SBBs, established under Section 22, handle applications for utilisation of biological resources from within the State and are responsible for enforcing benefit-sharing obligations.

Important definitions such as biological resource, associated traditional knowledge, commercial utilisation, and benefit sharing are contained in Section 2 and the Access and Benefit Sharing (ABS) Guidelines, 2014 framed under Section 21 of the Act. The Act also provides for the establishment of a National Biodiversity Fund to receive benefits where specific beneficiaries cannot be identified.

### 4. Access and Benefit Sharing (ABS) Mechanisms

Access and Benefit Sharing (ABS) is a central pillar of the Act and seeks to ensure that those who conserve and sustainably use biodiversity especially local and indigenous communities receive appropriate benefits when their resources or knowledge are utilised commercially. The legal procedure begins with obtaining prior approval of the NBA for accessing biological resources or associated traditional knowledge that may lead to commercial utilisation. The ABS Guidelines, 2014, further prescribe procedures for ABS agreements, methods to calculate monetary or non-monetary benefits, and criteria for equitable distribution.

Under the Act and ABS Framework, benefits can be shared in various forms, such as royalty payments, joint ventures, technology transfer, researchers' contributions to local development, and community empowerment initiatives.

Where benefit recipients cannot be identified, benefits may be routed to the National Biodiversity Fund, which supports conservation and sustainable use programs.

SBBs are tasked with monitoring compliance with ABS obligations for activities falling within their jurisdiction. For example, Section 7 requires that Indian entities intending to use biological resources for commercial purposes give prior intimation to the relevant SBB before accessing such resources, although exemptions exist for traditional users like vaidas (herbal practitioners) and cultivators.

### 5. Importance of India's Biodiversity and Traditional Knowledge

India occupies a unique position in the global bio-trade landscape due to its exceptional biological and cultural diversity. Despite covering only a small percentage of the world's land area, India is recognised as one of the world's mega-diverse countries, hosting nearly eight percent of known global species. Its varied ecosystems ranging from the Himalayas and Western Ghats to coastal and desert regions support a vast array of endemic flora and fauna. This biological richness forms the foundation of India's agricultural systems, traditional medicine, forest-based livelihoods, and emerging bio-economy sectors.

Equally significant is India's wealth of traditional knowledge, developed and preserved by indigenous and local communities over centuries. Traditional knowledge encompasses practices related to medicine, agriculture, biodiversity conservation, and sustainable resource management. Systems such as Ayurveda, Siddha, Unani, and folk medicine rely extensively on biological resources and represent sophisticated bodies of empirical knowledge. This traditional knowledge often provides the initial leads for modern bioprospecting by identifying species with therapeutic or functional properties, thereby reducing research costs and uncertainty for commercial entities.

However, the commercial value of India's biodiversity and traditional knowledge has historically made it vulnerable to misappropriation. High-profile cases involving turmeric, neem, and basmati rice revealed how traditional uses of biological resources were patented abroad without acknowledgement or compensation to Indian communities. These instances of biopiracy highlighted the inadequacy of conventional intellectual property regimes in recognising collective and inter-generational knowledge systems.

In response, India enacted the Biological Diversity Act, 2002, giving domestic legal effect to its international obligations under the CBD. The Act seeks to conserve biological diversity, promote sustainable use of its components, and ensure fair and equitable benefit sharing arising from the utilisation of biological resources and associated knowledge. It establishes a three-tier institutional framework comprising the National Biodiversity Authority, State Biodiversity Boards, and Biodiversity Management Committees, thereby linking national policy with local community participation. India's biodiversity and traditional knowledge thus represent not only ecological and cultural assets but also strategic economic resources. Effective governance of bio-trade and bioprospecting is essential to ensure that commercial utilisation contributes to conservation goals, respects community rights, and supports sustainable development. Strengthening legal safeguards, documentation mechanisms, and benefit-sharing frameworks remains central to preserving India's biological heritage while enabling responsible participation in the global bio-economy.

## 6. Indian Constitutional and Statutory Approach

India's biodiversity governance framework draws legitimacy not only from international commitments but also from constitutional principles. Article 48A of the Directive Principles of State Policy mandates the State to protect and improve the environment and safeguard forests and wildlife. Article 51A(g) imposes a fundamental duty on citizens to protect the natural environment, reflecting constitutional recognition of ecological stewardship.

Statutorily, the Biological Diversity Act, 2002 serves as the primary legislation implementing India's obligations under the CBD and Nagoya Protocol. The Act establishes a structured regulatory mechanism to control access to biological resources, protect traditional knowledge, and ensure equitable benefit sharing. Through institutions such as the National Biodiversity Authority, State Biodiversity Boards, and Biodiversity Management Committees, the Act integrates conservation goals with decentralised governance and community participation.

India's biodiversity law thus represents a hybrid framework combining international environmental principles, constitutional mandates, and domestic regulatory mechanisms. This integrated approach positions India as a leading jurisdiction in addressing the legal, ethical, and economic dimensions of bioprospecting and bio-trade.

## 7. Indian Judicial Interpretation and Recent Cases

Judicial interpretation has played a significant role in clarifying the application of the Act, especially around ABS obligations for both domestic and foreign entities and the authority of biodiversity boards.

- i) **Divya Pharmacy v. Union of India (Uttarakhand High Court, 2018):** In a landmark ruling, the Uttarakhand High Court held that Indian companies using biological resources for commercial purposes are obligated to obtain prior approval and share benefits with indigenous and local communities under the Act and ABS Guidelines. The court rejected the petitioner's argument that ABS requirements apply only to foreign entities, emphasising that equitable benefit sharing is a core objective of the statute. This decision extended ABS obligations to all users irrespective of nationality and strengthened the regulatory reach of SBBs.
- ii) **DCM Shriram Limited v. National Biodiversity Authority (2023):** In this case, the National Biodiversity

Authority fixed benefit-sharing terms for past unauthorised access to biological resources by the appellant. The authority, backed by expert committee recommendations, required upfront payments and higher rates for commercial use. The High Court upheld the NBA's powers to fix ABS terms and clarified that unauthorised access remains a violation subject to enforcement under the Act.

- iii) **BT Brinjal Biopiracy Allegation (NBA/Karnataka Biodiversity Board vs. Mahyco et al.):** One of India's earliest enforcement actions involved allegations against Mahyco and collaborators for transferring brinjal germplasm lacking prior approvals, raising complex questions about commercial utilisation and penalties under Section 3. Although the matter involved procedural challenges, it marked an important assertion of biodiversity regulators' powers to investigate biopiracy.
- iv) **Japanese Nationals' Case (Kerala Forest Division):** An enforcement action led to the conviction of two Japanese scientists for unauthorised collection and attempted export of endangered insects without NBA approval, emphasising strict compliance requirements under the Act for non-Indian nationals.

These cases collectively demonstrate the judiciary's proactive role in interpreting the ABS regime, resolving jurisdictional ambiguities, and enforcing compliance, thereby reinforcing the Act's purpose to protect biodiversity and community interests.

## 8. Biopiracy and Judicial Responses: Indian Experience

Biopiracy refers to the unauthorised appropriation, patenting, or commercial exploitation of biological resources and associated traditional knowledge without obtaining prior informed consent or ensuring equitable benefit sharing with the source country or indigenous communities. India's experience with biopiracy has played a pivotal role in shaping global discourse on access to genetic resources and the protection of traditional knowledge. Prior to the enactment of the Biological Diversity Act, 2002, several instances of misappropriation of Indian biological resources exposed critical gaps in international intellectual property regimes and highlighted the vulnerability of traditional knowledge systems.

One of the most significant biopiracy disputes involved the grant of a United States patent on the wound-healing properties of turmeric (*Curcuma longa*). The patent attempted to claim exclusive rights over a use that had been part of Indian traditional medicine for centuries. The Council of Scientific and Industrial Research (CSIR), representing India, successfully challenged the patent by producing documentary evidence of prior traditional use, leading to its revocation by the United States Patent and Trademark Office. This case demonstrated that traditional knowledge, though often undocumented in formal scientific literature, constitutes valid prior art and must be recognised within patent examination processes.

A similar challenge arose in the case of neem (*Azadirachta indica*), where a European patent was granted for the fungicidal properties of neem oil. Indian authorities and civil society organisations opposed the patent before the European Patent Office, arguing that the claimed invention lacked novelty and inventive step due to long-standing traditional usage in India. The eventual revocation of the patent reinforced the principle that indigenous knowledge systems

cannot be monopolised through intellectual property rights merely by repackaging existing traditional practices.

The basmati rice controversy further illustrated the complexities of protecting agricultural biodiversity and traditional knowledge in a globalised market. A U.S.-based company obtained patent protection for certain rice varieties and characteristics closely resembling traditional basmati strains cultivated in the Indian subcontinent. Following objections by the Government of India, several patent claims were either withdrawn or significantly narrowed. This dispute underscored the intersection between biopiracy, geographical

indications, and farmers' rights, and influenced India's subsequent legal and policy approach to protecting region-specific biological resources.

Collectively, these cases exposed systemic deficiencies in international patent systems and underscored the need for domestic biodiversity legislation. The enactment of the Biological Diversity Act, 2002 marked a legislative response aimed at preventing future misappropriation by regulating access to biological resources, mandating benefit sharing, and linking biodiversity governance with intellectual property regimes.

### 8.1 Biopiracy Case Law Table (India)

Case	Authority/Court	Biological Resource	Issue Involved	Decision/Outcome	Legal Significance
CSIR v. University of Mississippi (Turmeric Case, 1997)	USPTO (USA)	Turmeric ( <i>Curcuma longa</i> )	Patent granted for wound-healing property based on traditional knowledge	Patent revoked for lack of novelty and prior art	Established traditional knowledge as valid prior art; triggered TKDL creation
Neem Patent Case (W.R. Grace v. EPO, 2000/2005)	European Patent Office	Neem ( <i>Azadirachta indica</i> )	Patent on neem-based fungicide process	Patent revoked for lack of inventive step	Highlighted biopiracy risks; strengthened CBD-based advocacy
RiceTec Inc. Basmati Case (1997)	USPTO (USA)	Basmati Rice	Patent over basmati rice lines and traits	Claims narrowed after India's challenge	Led to GI protection focus and farmers' rights recognition

### 8.2 Comparative Biopiracy Case Studies (India vs. Foreign Jurisdictions)

Table B

Case Name	Jurisdiction	Resource	Issue	Outcome	Legal Impact	Authorised Reference/URL
Turmeric Patent Case	USA	Turmeric ( <i>Curcuma longa</i> )	Patent on traditional wound-healing use	Patent revoked	Traditional knowledge recognised as prior art	<a href="https://www.wipo.int/tk/en/case_studies/turmeric.html">https://www.wipo.int/tk/en/case_studies/turmeric.html</a>
Neem Patent Case	European Union	Neem ( <i>Azadirachta indica</i> )	Patent on fungicidal process	Patent revoked	Reinforced CBD principles against biopiracy	<a href="https://www.epo.org/law-practice/case-law-appeals/recent/technical.html">https://www.epo.org/law-practice/case-law-appeals/recent/technical.html</a>
Basmati Rice Case (RiceTec)	USA	Basmati Rice	Patent over basmati rice varieties	Claims narrowed	Strengthened GI protection regime	<a href="https://www.wipo.int/ipadvantage/en/details.jsp?id=2593">https://www.wipo.int/ipadvantage/en/details.jsp?id=2593</a>

### 9. Data and Statistics on Bio-trade and Access & Benefit Sharing in India

India's bio-trade potential is intrinsically linked to its status as a mega-diverse country, hosting nearly eight percent of global species diversity despite occupying a relatively small share of the world's land area. This biodiversity forms the backbone of India's medicinal plant sector, agricultural exports, and nature-based industries.

Following the operationalization of Access and Benefit Sharing (ABS) mechanisms under the Biological Diversity Act, the National Biodiversity Authority (NBA) has emerged as the central institution regulating commercial utilisation of biological resources. Recent data indicate that cumulative ABS collections in India have crossed ₹260 crore, reflecting increasing regulatory enforcement and corporate compliance. A significant portion of these funds has been channeled towards state biodiversity boards and local stakeholders, demonstrating a gradual shift toward community-centric benefit sharing.

Medicinal plants constitute a major component of India's bio-trade economy. Global demand for medicinal plant-based products is estimated to exceed USD 14 billion annually, with India contributing approximately USD 1 billion through domestic use and exports. The export of herbal products and plant-based formulations has shown consistent growth, driven by increased demand for traditional medicine systems and natural health products.

The basmati rice sector represents another economically significant dimension of bio-trade linked to traditional agricultural knowledge. India remains one of the world's largest exporters of basmati rice, with export values running into several billion dollars annually. This economic success, however, also increases the risk of misappropriation and underscores the need for robust legal protection of traditional crop varieties and geographical identities.

While these figures highlight India's growing bio-trade economy, they also reveal structural challenges in translating economic gains into equitable outcomes for indigenous and local communities. Strengthening ABS enforcement, improving transparency in benefit distribution, and enhancing documentation of traditional knowledge remain essential for achieving the objectives of the Biological Diversity Act, 2002.

### 10. Legal Gaps in the Biological Diversity Act, 2002

Despite its comprehensive objectives, the Biological Diversity Act, 2002 exhibits certain structural and operational gaps. Key statutory terms such as "commercial utilisation" and "associated traditional knowledge" are broadly framed, resulting in interpretational ambiguities that complicate regulatory enforcement.

Institutional coordination among the National Biodiversity Authority, State Biodiversity Boards, and Biodiversity Management Committees remains uneven. While the NBA

has made progress in collecting ABS payments, local-level institutions often lack the technical and financial capacity to document traditional knowledge or negotiate equitable benefit-sharing agreements.

Another critical gap lies in the interface between biodiversity law and intellectual property regimes. Although the Act requires prior approval for seeking intellectual property rights based on Indian biological resources, enforcement remains inconsistent, and reliance on external mechanisms such as the Traditional Knowledge Digital Library continues to compensate for domestic documentation deficiencies.

Addressing these gaps is essential to ensure that the Act functions not merely as a regulatory statute but as an effective instrument for biodiversity conservation, community empowerment, and sustainable bio-trade governance.

## 11. Policy Recommendations

Based on legal and data analysis, the following recommendations aim to strengthen Bio-trade, Bioprospecting regime and biodiversity governance in India:

- i) **Clarify Statutory Definitions:** The Act's definitions of "commercial utilisation," "associated traditional knowledge," and "biological resources" should be refined through legislative amendments or detailed rules to reduce ambiguity and enhance predictability for regulators and users.
- ii) **Strengthen Institutional Capacities:** State Biodiversity Boards and BMCs should be equipped with technical resources and training to document traditional knowledge and negotiate benefit-sharing agreements effectively. This includes digital repositories for PBRs and TK records.
- iii) **Enhance Transparency and Data Reporting:** A centralised online portal for ABS applications, approvals, and benefit distribution data can promote transparency and facilitate academic and policy research. Annual reports should feature disaggregated details on beneficiaries, ABS amounts, and compliance trends.
- iv) **Harmonise with Intellectual Property Regimes:** A clear procedural link between NBA approvals and intellectual property filings should be established, ensuring that patent applications derived from Indian resources or traditional knowledge comply with ABS requirements.

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