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Bio-Piracy: Corporate Hijacking of Indigenous Biowealth

PRAPTI CHATURVEDI*, NATASHA CHAUHAN**, AND ANANT SINGHAL***

ABSTRACT

Bio-piracy refers to the unauthorised appropriation of indigenous biological resources and traditional knowledge without prior informed consent or equitable benefit-sharing. This paper examines the phenomenon in India, a mega-biodiverse nation whose tribal communities hold extensive ethnobotanical knowledge, and traces its trajectory from colonial resource extraction to the contemporary patenting of genetic materials by corporations. Using the landmark Neem, Turmeric and Basmati disputes as reference points, the study evaluates India's legal and institutional response, including the Convention on Biological Diversity, the Biological Diversity Act 2002, the Patents Act 1970, the Nagoya Protocol and the Traditional Knowledge Digital Library. It analyses the Kani-Jeevani benefit-sharing model and the ruling in Divya Pharmacy v. Union of India, before assessing emerging challenges such as Digital Sequence Information. Drawing comparative lessons from South Africa, the European Union and Brazil, the paper argues that India must shift from formal compliance to substantive community participation, and recommends stronger prior-informed-consent mechanisms, standardised benefit-sharing, and user-side due diligence to protect indigenous bio-wealth.

Keywords: *bio-piracy, traditional knowledge, access and benefit-sharing, Biological Diversity Act 2002, indigenous communities, Digital Sequence Information*

I. INTRODUCTION

Bio-piracy is defined as the unauthorised and unethical seizure of indigenous biological resources and traditional knowledge by corporations or individuals without securing prior informed consent or ensuring fair benefit-sharing with the indigenous communities that are the rightful stewards of these resources.¹ This exploitation frequently entails the patenting, commercialisation, or monopolisation of genetic materials, medicinal plants, and traditional ecological knowledge, resulting in the marginalisation and dispossession of tribal populations.²

* Author is a Student at Delhi Metropolitan Education (affiliated to GGSIPU), Noida, Uttar Pradesh, India.

** Author is a Student at Delhi Metropolitan Education (affiliated to GGSIPU), Noida, Uttar Pradesh, India.

*** Author is an Assistant Professor at Delhi Metropolitan Education (affiliated to GGSIPU), Noida, Uttar Pradesh, India.

¹ IPR JOURNAL OF MAHARASHTRA NATIONAL LAW UNIVERSITY, NAGPUR 54.

² Yasodha Imran and others, *Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities*, SCI. WORLD J. (2021).

Beyond its legal implications, bio-piracy poses ethical and socio-environmental challenges that undermine core principles of justice, sustainability, and cultural preservation. Indigenous biological resources and traditional knowledge represent invaluable assets that have been cultivated and passed down through generations. These encompass medicinal plants, herbs, agricultural techniques, and ecological insights that support both biodiversity and cultural identity. Such knowledge is fundamental to indigenous healthcare, food security, and environmental stewardship.³ For tribal communities, these resources are not merely economic commodities but essential components of their social structure and survival, rendering their protection crucial for ecological equilibrium and sustainable development.

A. The issue in India with reference to tribal populations

India, which is home to more than 500 tribal groups making up nearly 19 per cent of its population, harbours an exceptional reservoir of traditional knowledge linked to biodiversity. Tribes such as the Gond and Kani possess profound expertise in the medicinal and ecological utilisation of natural resources.⁴ Nevertheless, corporate and institutional entities have increasingly taken advantage of this biological wealth, patenting indigenous knowledge or commercialising resources without proper acknowledgment, consent, or fair compensation. This unregulated appropriation not only jeopardises the socio-economic stability of tribal communities but also results in ecological degradation and cultural erosion. The issue is exacerbated by the lack of legal awareness among indigenous populations and the weak enforcement of protective measures.⁵ This research critically investigates the issue of bio-piracy in India, concentrating on the corporate exploitation of indigenous biological wealth and its repercussions for tribal rights, biodiversity conservation, and cultural integrity.

The study also considers constitutional aspects, emphasising that bio-piracy may violate the rights to life, livelihood, and a healthy environment as protected under Article 21.⁶ It proposes legal and policy reforms that foster participatory governance and safeguard the interests of indigenous communities. Moreover, the concentration of authority within entities such as the National Biodiversity Authority⁷ has, in the authors' assessment, curtailed community involvement in decision-making processes, relegating tribal communities to the role of passive

³ Janna Rose, *Biopiracy: When Indigenous Knowledge Is Patented for Profit*, THE CONVERSATION (Mar. 8, 2016), <https://theconversation.com/biopiracy-when-indigenous-knowledge-is-patented-for-profit-55589>.

⁴ Priya Priyadarshini & Purushothaman Chirakkuzhyil Abhilash, *Promoting Tribal Communities and Indigenous Knowledge as Potential Solutions for the Sustainable Development of India*, 32 ENV'T DEV. 100459 (2019).

⁵ WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Using Traditional Knowledge to Revive the Body and a Community*, <https://www.wipo.int/en/web/ip-advantage/w/stories/using-traditional-knowledge-to-revive-the-body-and-a-community> (last visited Nov. 7, 2025).

⁶ INDIA CONST. art. 21.

⁷ The National Biodiversity Authority, constituted under the Biological Diversity Act, No. 18 of 2003, s. 8.

beneficiaries instead of active participants.⁸ Significant legal deficiencies include the lack of a compulsory framework for securing prior informed consent from indigenous communities and inadequately regulated corporate collaborations with tribal groups that may facilitate exploitation.

II. HISTORICAL DEVELOPMENT

The historical evolution of bio-piracy can be traced to the colonial period, during which the systematic exploitation of indigenous biological resources and traditional knowledge commenced. European colonial powers, driven by scientific inquiry and commercial interests, took advantage of the rich biodiversity found in their colonies without offering compensation or recognition to the indigenous communities who were the original stewards of this knowledge.⁹ For example, during the British colonial period in India, numerous medicinal plants and agricultural resources were appropriated and commercialised, often resulting in the commodification of knowledge possessed by tribal and rural communities. In the post-colonial era, bio-piracy became a more complex issue with the emergence of multinational corporations and advances in biotechnology.¹⁰ Corporations began to obtain patents on genetic materials and traditional remedies derived from indigenous knowledge, frequently circumventing the original knowledge holders. Prominent examples include the patenting of neem extracts, which have been utilised in India for centuries as a natural pesticide and medicinal treatment. The patent was initially awarded to a United States corporation, igniting global protests and legal disputes that ultimately resulted in the patent's revocation on the basis of prior traditional use.¹¹ Likewise, patents concerning turmeric¹² and basmati rice¹³ were contested owing to their deep-rooted cultural and agricultural importance to Indian communities.

These pivotal cases drew international focus to the ethical, legal, and socio-economic challenges associated with bio-piracy. Consequently, nations rich in biodiversity and indigenous populations, including India, began to advocate for legal mechanisms to safeguard their biological heritage. India ratified the Convention on Biological Diversity (CBD) in 1994, which

⁸ D.M. Prasad & S.C. Menon, *India: Implementing the Nagoya Protocol on Access and Benefit-Sharing: Emerging Legal Challenges*, 50 ENV'T POL'Y & L. 399 (2021).

⁹ Agrani Bhati & Aditya Singh, *Bio-Piracy: A Global Concern and Protection of Traditional Knowledge in India*, 3 NLUA J. INTELL. PROP. RTS. 91.

¹⁰ John Merson, *Bio-Prospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Colonial and Postcolonial Context*, 15 OSIRIS 282 (2000).

¹¹ *EPO Accepts Biopiracy Argument and Revokes Patent*, CORDIS (Mar. 11, 2005), <https://cordis.europa.eu/article/id/23505-epo-accepts-biopiracy-argument-and-revokes-patent>.

¹² U.S. Patent No. 5,401,504 (issued Mar. 28, 1995) (turmeric wound-healing patent, revoked on re-examination by the USPTO in 1997).

¹³ U.S. Patent No. 5,663,484 (issued Sept. 2, 1997) (RiceTec "Basmati rice lines and grains"; majority of claims struck down by the USPTO on re-examination in 2001).

underscored the sovereign rights of nations over their biological resources and mandated the equitable sharing of benefits arising from their commercial use.¹⁴ Following this, India enacted the Biological Diversity Act in 2002 to fulfil its CBD obligations domestically. This Act established authorities such as the National Biodiversity Authority and State Biodiversity Boards to regulate access to biological resources, ensure prior informed consent, and enforce benefit-sharing agreements. However, these institutions often face challenges such as insufficient awareness among indigenous communities and limited capacity to monitor corporate activities.

In conjunction with biodiversity legislation, India amended its Patents Act to include provisions that bar the patenting of traditional knowledge and to require that patent applicants disclose the origins of biological resources. The creation of the Traditional Knowledge Digital Library (TKDL) in 2001 has also played a vital role in documenting and preventing the wrongful patenting of traditional medicinal knowledge.¹⁵ Nevertheless, despite these advancements, bio-piracy continues to be a significant issue owing to enforcement loopholes and the adaptive strategies of corporations.

A. International frameworks on biodiversity and traditional knowledge protection

The international legal framework for safeguarding biological resources and traditional knowledge is fundamentally anchored in the CBD,¹⁶ adopted in 1992, which acknowledges the principle of national sovereignty over genetic resources and stipulates that access to these resources must be governed by fair and equitable access and benefit-sharing (ABS) with the countries and communities that provide them. This acknowledgement of sovereign rights over biological resources represented a significant shift from the previously prevailing concept of global commons, thereby establishing the foundation for national ABS frameworks, including India's Biological Diversity Act 2002.

Building on the CBD, the Nagoya Protocol on Access and Benefit-Sharing (2010) implements ABS through three interconnected pillars: access, benefit-sharing, and compliance. Parties to the Protocol are required to appoint competent national authorities, create standardised procedures for prior informed consent (PIC) and mutually agreed terms (MAT), and participate

¹⁴ Convention on Biological Diversity art. 8(j), June 5, 1992, 1760 U.N.T.S. 79.

¹⁵ R.A. Mani & R.D. Kumar, *An Analysis of the Issues and Challenges in the Protection of Indigenous Knowledge from Bio-Piracy in India*, 4 INDIAN J. INTEGRATED RSCH. L. 735.

¹⁶ Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79.

in the ABS Clearing-House, thereby improving transparency and the cross-border enforceability of obligations.¹⁷

B. Landmark Indian bio-piracy cases

Several significant disputes have revealed weaknesses in India's biodiversity protection framework and emphasised the necessity for comprehensive documentation of traditional knowledge. The Neem case became pivotal when the European Patent Office (EPO) annulled a patent concerning the fungicidal applications of neem seed extracts after a prolonged, decade-long dispute, acknowledging that the claimed invention was not novel owing to existing traditional uses in India. This ruling represented one of the earliest substantial annulments of a bio-pirated patent in Europe.¹⁸ Similarly, in the Turmeric case the United States Patent and Trademark Office (USPTO)¹⁹ invalidated a patent on the wound-healing properties of turmeric after the Council of Scientific and Industrial Research (CSIR)²⁰ presented prior art demonstrating that these uses were already embedded in Indian traditional knowledge. The Basmati rice controversy followed a comparable path, where the USPTO rejected the majority of claims in RiceTec's "Basmati rice lines and grains" patent upon re-examination, referencing overlaps with prior art and traditional farmer-bred varieties from India and Pakistan.²¹ Together, these cases exemplify how evidence of prior art and the documentation of traditional knowledge can function as potent defensive mechanisms against bio-piracy, although such remedies frequently occur after the fact.

The practical development of India's approach to bio-piracy can be most effectively understood through landmark cases and institutional initiatives that connect international obligations under the CBD-Nagoya framework with domestic implementation. The examples that follow, including the Kani-Jeevani benefit-sharing model, the Divya Pharmacy ruling, and the TKDL,²² underscore both the potential and the ongoing challenges of India's biodiversity governance systems. One of the earliest and most renowned instances of fair commercialisation of traditional knowledge in India is the Kani-Jeevani case. The Kani tribe of Kerala, who are the guardians of extensive ethnobotanical knowledge, shared their traditional understanding of the

¹⁷ 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, Oct. 29, 2010, 3008 U.N.T.S. (entered into force Oct. 12, 2014).

¹⁸ European Patent No. EP0436257 (neem fungicide patent, revoked by the EPO; revocation upheld on appeal, Mar. 8, 2005).

¹⁹ United States Patent and Trademark Office.

²⁰ Council of Scientific and Industrial Research.

²¹ *Basmati Rice Biopiracy: Patent Struck Down by U.S. Patent Office*, PUBLIC EYE (Jan. 31, 2024), <https://www.publiceye.ch/en/media-corner/press-releases/detail/basmati-rice-biopiracy-patent-struck-down-by-us-patent-office>.

²² Traditional Knowledge Digital Library.

Arogyapacha plant (*Trichopus zeylanicus*) with researchers at the Tropical Botanic Garden and Research Institute (TBGRI).²³ This partnership resulted in the creation of the herbal product "Jeevani," which is marketed for its restorative and anti-fatigue benefits. In 1997, TBGRI established one of India's pioneering formal benefit-sharing agreements, which included a Rs 5 lakh upfront licensing fee and a 2 per cent royalty payable to the Kerala Kani Samudaya Kshema Trust, an organisation formed to advance the community's interests.²⁴

The Kani-Jeevani model is widely acknowledged as a significant achievement in harmonising scientific innovation with indigenous rights. It illustrated that the concepts of prior informed consent (PIC) and mutually agreed terms (MAT) can function effectively when trust frameworks are established and communities are acknowledged as co-owners of knowledge. This model has been referenced by scholars and policymakers as a proactive and ethical alternative to bio-piracy, providing a structure for equitable benefit-sharing that respects indigenous stewardship. Nevertheless, subsequent assessments also highlight practical difficulties such as ensuring transparency, fair distribution of benefits within communities, and maintaining long-term institutional support, emphasising that even well-meaning models necessitate ongoing oversight and capacity development.²⁵

In *Divya Pharmacy v. Union of India* (2018),²⁶ the Uttarakhand High Court examined a significant uncertainty within India's benefit-sharing framework: the obligation of domestic entities to adhere to ABS requirements as stipulated by the Biological Diversity Act 2002. The Court held that Indian companies, including those involved in the manufacture of Ayurvedic, herbal, or cosmetic products, are obligated to follow fair and equitable benefit-sharing regulations.²⁷ This ruling directly challenged the common interpretation that ABS obligations applied solely to foreign entities.

III. THE TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL): A DEFENSIVE SHIELD AGAINST BIO-PIRACY

In addition to these judicial and institutional initiatives, India established the Traditional Knowledge Digital Library (TKDL) in 2001 as a distinctive defensive strategy aimed at preventing the patenting of inventions rooted in traditional knowledge. The TKDL serves to

²³ Tropical Botanic Garden and Research Institute.

²⁴ R.V. Anuradha, *Sharing with the Kanis: A Case Study from Kerala, India*, CONVENTION ON BIOLOGICAL DIVERSITY 1, 5 (1998), <https://www.cbd.int/financial/bensharing/india-kanis.pdf>.

²⁵ *Access and Benefit Sharing from the Indigenous Peoples' Perspective: The TBGRI-Kani "Model,"* 3 LAW ENV'T & DEV. J. 1 (2007), <http://www.lead-journal.org/content/07001.pdf>.

²⁶ *Divya Pharmacy v. Union of India*, 2018 SCC OnLine Utt 1035.

²⁷ *India: Access and Benefit Sharing Under CBD and the Ayurveda Industry*, S.S. RANA & CO. (Aug. 22, 2018), <https://ssrana.in/articles/india-access-and-benefit-sharing-under-cbd-and-the-ayurveda-industry/>.

digitise and translate ancient medicinal knowledge from texts such as Ayurveda, Unani, Siddha, and Yoga into languages and formats that patent examiners can understand. This initiative has facilitated access for global patent offices to evidence of prior art, thus averting misappropriation during the examination process.²⁸

By 2014, interventions from the TKDL had resulted in the withdrawal, cancellation, or modification of more than 200 patent applications globally, stemming from over 1,100 challenges.²⁹ These challenges concerned products such as slimming agents, Ashwagandha-based anxiolytics, and various plant-derived therapeutic formulations. This digital archive has emerged as a fundamental element of India's defensive approach, significantly diminishing the need for expensive litigation while enhancing the international acknowledgment of Indian traditional knowledge. Consequently, the TKDL illustrates how the systematic documentation of traditional knowledge can advance the objectives of the CBD and Nagoya Protocol by proactively deterring bio-piracy rather than depending solely on post-grant opposition.

IV. RECENT ENFORCEMENT AND EMERGING CHALLENGES

Recent efforts by the National Biodiversity Authority (NBA)³⁰ have introduced online application systems, user categorisation, and turnover-based benefit-sharing mechanisms aimed at boosting transparency and improving administrative efficiency. The updated framework also emphasises the importance of properly documenting PIC, MAT, the disclosure of intellectual property rights, and Digital Sequence Information (DSI).³¹ However, hurdles remain, particularly regarding the effectiveness of Biodiversity Management Committees (BMCs),³² community awareness, and compliance monitoring. Additionally, inconsistencies at the state level in benefit-sharing continue to hinder fair outcomes for indigenous groups.

Insights from the Kani-Jeevani model, the Divya Pharmacy ruling, and the TKDL show that fair ABS can be realised when legal, institutional, and community frameworks work in harmony. The Kani initiative serves as a community-trust-based model for implementing PIC and MAT; the Divya Pharmacy decision extends ABS responsibilities to domestic entities; and the TKDL

²⁸ BENCY BABY T. & TIMMAKKONDU NARASIMMAN KUPPUSAMI SURIYAPRAKASH, *INTELLECTUAL PROPERTY RIGHTS: BIOPROSPECTING, BIOPIRACY AND PROTECTION OF TRADITIONAL KNOWLEDGE - AN INDIAN PERSPECTIVE* (2022).

²⁹ PRESS INFORMATION BUREAU, *Cabinet Approves Widening Access of the Traditional Knowledge Digital Library (TKDL) Database to Users, Besides Patent Offices* (Aug. 17, 2022), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1852528>.

³⁰ National Biodiversity Authority.

³¹ Digital Sequence Information.

³² Biodiversity Management Committees.

demonstrates how technology can help prevent bio-piracy.³³ To bolster these mechanisms, India should make community PIC mandatory, create standardised MAT templates with clear benefit thresholds, and enforce user due diligence throughout the value chain. Improved coordination between patent offices and biodiversity authorities, along with the integration of the TKDL with the ABS Clearing-House and capacity building for BMCs, can foster greater transparency and equity. These reforms could transform India's biodiversity governance from a reactive approach to a more participatory and preventive model, protecting bio-resources while honouring the cultural and intellectual heritage of local and tribal communities.³⁴

A. The dilemma of Digital Sequence Information

DSI has transformed the use, access, and exploitation of genetic resources. By allowing companies to work solely with representations of genetic code without ever physically handling the genetic material, DSI not only accelerates innovation but also creates a new frontier of bio-piracy, referred to as the digital bio-piracy or corporate appropriation of indigenous bio-wealth.³⁵

Three dynamics are at play:

Dematerialisation of genetic resources: the genetic code of plants, animals, micro-organisms, and even humans is freely uploaded into open-access global repositories such as the International Nucleotide Sequence Database Collaboration (INSDC) and can be freely downloaded by anyone across the globe.³⁶

Bypassing access and benefit-sharing: since ABS agreements such as the CBD, the Nagoya Protocol, and national laws in various countries have traditionally been based on the principle of physical access to resources, it becomes possible for DSI to be obtained online by companies without the need to enter into ABS agreements.³⁷

³³ S. Balasubramanian et al., *Traditional Knowledge and Biopiracy in Basmati Rice: Using Patent Information for Defensive Protection*, 27 BIOTECH. L. REP. (2020), <https://journals.sagepub.com/doi/10.1089/blr.2020.29161.zmn>.

³⁴ INDIAN INSTITUTE OF MANAGEMENT AHMEDABAD, *Value Addition to Local Kani Tribal Knowledge: Patenting, Licensing and Benefit Sharing* (2021), <https://www.iima.ac.in/publication/value-addition-local-kani-tribal-knowledge-patenting-licensing-and-benefit-sharing>.

³⁵ Ajay Gautam, *Biopiracy 2.0: Will the Proposed Multilateral Benefit-Sharing Mechanism Legitimise Another Great Gene Plunder?*, DOWN TO EARTH (Mar. 9, 2023), <https://www.downtoearth.org.in/wildlife-biodiversity/biopiracy-20-will-the-proposed-multilateral-benefit-sharing-mechanism-legitimise-another-great-gene-plunder>.

³⁶ RIGHT TO FOOD AND NUTRITION WATCH, *Dematerialization of Plant Genetic Resources*, <https://www.righttofoodandnutrition.org/publication/dematerialization-plant-genetic-resources/>.

³⁷ WIPO INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE, *Working Document: DSI* (May 21, 2024), https://www.twn.my/announcement/WIPO%20IGC%20-%20DSI%20%20working%20document_21052024.pdf.

Corporate enclosure through intellectual property and platforms: through DSI, companies may apply for patents over genetic sequences, traits, and products, and package them in proprietary seeds, medicines, and platforms. This may result in monopoly control over genetic traits and traditional knowledge that originally derived from indigenous lands and farming systems.³⁸

In this regard, DSI has the potential to enable another, more hidden wave of corporate appropriation of indigenous biological wealth, namely its extraction, digitalisation, and privatisation without any form of consent, control, or benefit-sharing from the communities that have fostered and nurtured this wealth throughout history.

B. Persistent gaps and the need for stronger compliance

In practice, the enforcement of ABS obligations is weak, especially with respect to monitoring after access, ensuring compliance with cross-border MAT,³⁹ and providing legal remedies. The lack of coordination between biodiversity authorities makes it even more difficult to properly scrutinise patent applications that involve traditional knowledge. To strengthen this framework, it is necessary to implement thorough due diligence protocols, create standardised MAT templates, establish clear procedures for community-level PIC, and integrate traditional knowledge databases such as the TKDL into the patent examination process. While the international frameworks lay a solid groundwork, their effectiveness hinges on how well they are implemented at the national level and on the degree of international collaboration. India's experience shows that documented traditional knowledge can help prevent bio-piracy, but it also highlights the gaps that exist when community consent and proper documentation are missing.

V. ANALYSIS OF LEGAL PROTECTION OF INDIGENOUS BIO-WEALTH IN INDIA

India, recognised as a mega-biodiverse nation, is home to more than 7,500 plant species utilised in traditional medicinal and agricultural practices, supporting nearly two-thirds of its population who depend on indigenous knowledge systems for their health and livelihoods.⁴⁰

A. Violation of fundamental rights and lack of community control

The Gond and Kani tribes have experienced systematic dispossession of their biological resources and traditional knowledge without PIC or fair benefit-sharing. Of the traditional crop varieties registered, fewer than 55 per cent are formally owned or managed by farmers or

³⁸ GLOBAL 2000, *Report on New Genetic Engineering and Patents* (Oct. 19, 2022), https://www.global2000.at/sites/global/files/GLOBAL2000_NeueGentechnik_Patente_Report_20221019.pdf.

³⁹ Material Transfer Agreements.

⁴⁰ Achyuth B. Nandan & Narendran Thiruthy, *Transforming Biodiversity Governance Through Patent Information Linkage*, 16 QUEEN MARY J. INTELL. PROP. 77 (2024), <https://tind.wipo.int/record/60275>.

indigenous communities, primarily owing to gaps in procedure and awareness, which undermines their right to benefit from these resources. The legal safeguarding of indigenous biological wealth in India embodies a complex interplay of environmental conservation, intellectual property rights, and human rights law. The biodiversity of India, intricately linked to the traditional knowledge of its tribal and local communities, constitutes a vital aspect of both its ecological and cultural heritage. However, the increasing incidence of bio-piracy, where corporations exploit indigenous biological resources and the associated traditional knowledge without consent or equitable compensation, has revealed significant shortcomings in the nation's regulatory and legal systems. Corporations have on occasion secured patents on bio-resources long utilised by tribal communities, as evidenced by the Neem, Turmeric, and Basmati disputes. These conflicts have highlighted how the absence of systematic documentation and inadequate legal acknowledgment of oral traditions have facilitated ongoing misappropriation under the pretext of innovation.

Judicial and policy evaluations further indicate that inadequate enforcement of biodiversity regulations can lead to breaches of Articles 14 and 21 of the Constitution, which ensure equality under the law and the right to life and livelihood. Bio-piracy poses a direct threat to the existence of indigenous communities by denying them access to their ecological resources and undermining their cultural autonomy. Insufficient regulation of corporate access to these resources also engages the doctrine of public trust, which requires the state to safeguard natural wealth for the benefit of all.

Judicial actions, such as in *Divya Pharmacy v. Union of India* (2018),⁴¹ have begun to acknowledge that even domestic firms are subject to benefit-sharing responsibilities, thereby extending accountability beyond foreign entities. Similarly, the Kani-Jeevani benefit-sharing model serves as a prime example of how equitable partnerships, founded on consent, negotiated royalties, and community trusts, can transform traditional knowledge into a means of empowerment rather than exploitation. Concurrently, preventive measures such as the Traditional Knowledge Digital Library (TKDL) have illustrated that systematic documentation can act as a robust defence against bio-piracy at the patent-office level, thereby diminishing the need for expensive litigation.

In conclusion, safeguarding indigenous bio-wealth in India necessitates a comprehensive approach that encompasses legislative reform, institutional transparency, and community

⁴¹ *Divya Pharmacy*, *supra* note 26, at 7.

involvement. The objective is not solely to criminalise bio-piracy but to acknowledge indigenous knowledge as a living heritage that merits both legal and moral respect.

VI. COMPARATIVE ANALYSIS OF LEGAL PROTECTION OF INDIGENOUS BIO-WEALTH: LESSONS FOR INDIA FROM SOUTH AFRICA, THE EUROPEAN UNION, AND BRAZIL

India and South Africa: the enforcement of ABS obligations remains weak, especially with respect to monitoring after access, ensuring compliance with cross-border MAT, and providing legal remedies. The lack of coordination between biodiversity authorities makes it even more difficult to properly scrutinise patent applications that involve traditional knowledge. To strengthen this framework, it is necessary to implement thorough due diligence protocols, create standardised MAT templates, establish clear procedures for community-level PIC, and integrate traditional knowledge databases such as the TKDL into the patent examination process.⁴²

While the international frameworks provide the groundwork, their effectiveness hinges on how well they are implemented at the national level and on the degree of international collaboration. India's experience with cases involving Neem, Turmeric, and Basmati shows that documented traditional knowledge can help prevent bio-piracy, but it also highlights the gaps that exist when community consent and proper documentation are missing.

India and the European Union: user-side compliance and cross-border enforcement. India adopts a provider-focused stance, emphasising control over access to genetic resources within the country through permits, approvals, and patent-disclosure requirements. However, this approach falls short in addressing the needs of downstream users engaged in research, development, and commercialisation, especially when resources or traditional knowledge extend beyond India's borders. By contrast, the European Union's Regulation (EU) No 511/2014,⁴³ which operates under the Nagoya Protocol, adopts a user-compliance framework. It places due diligence responsibilities on all users throughout the research and development process. Users must provide proof of lawful access, adhere to mutually agreed terms (MAT), keep detailed records, and submit due diligence declarations at specific checkpoints.⁴⁴

⁴² Krish Kaushal, *From Biopiracy to Benefit-Sharing: A Techno-Legal Analysis of the WIPO Treaty's Framework for Protecting Indigenous Rights and Traditional Knowledge in India Within a Global Context*, CSRI PR BLOG (June 26, 2025), <https://csriprnusr1.wordpress.com/2025/06/26/from-biopiracy-to-benefit-sharing-a-techno-legal-analysis-of-the-wipo-treatys-framework-for-protecting-indigenous-rights-and-traditional-knowledge-in-india-within-a-global-context/>.

⁴³ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization in the Union, 2014 O.J. (L 150) 59.

Competent authorities are tasked with conducting audits and enforcing penalties⁴⁵ through a risk-based assessment system, ensuring that accountability is maintained throughout the entire value chain.

India and Brazil: governance innovation and national benefit-sharing funds. Brazil's Law No 13.123/2015⁴⁶ offers a well-rounded approach to benefit-sharing, blending both monetary and non-monetary aspects through clear governance structures. Unlike India's somewhat fragmented and negotiable system, Brazil ties benefit-sharing directly to the commercial use of products or reproductive materials derived from genetic resources or traditional knowledge (TK) of non-identifiable origin. Typically, a standardised contribution of about 1 per cent of annual net revenue goes into the National Benefit-Sharing Fund,⁴⁷ with small businesses and traditional farmers enjoying certain exemptions. The law draws a clear distinction between identifiable and diffuse TK: where it is identifiable, obtaining PIC and establishing MAT is mandatory; where it is not, the proceeds are channelled into the Fund, which is overseen by a board comprising equal representation from indigenous and local communities. This structure ensures that benefits are distributed fairly across the nation, even where it is difficult to pinpoint community contributions.

By contrast, owing to India's decentralised approach to benefit-sharing,⁴⁸ certain regional variances exist in the implementation process across different states, alongside challenges stemming from weak BMCs. While tools such as the TKDL serve as crucial safeguards against bio-piracy, translating these defensive measures into tangible benefits for communities remains an area of active policy development. Brazil's centralised fund and consolidated governance model offer an alternative framework for optimising the management of unidentifiable TK and enhancing collective benefit-sharing in a more efficient and transparent manner.

⁴⁴ *Compliance with Rules on Access and Benefit-Sharing Arising from the Use of Genetic Resources and Associated Traditional Knowledge*, EUR-LEX (Nov. 20, 2020), <https://eur-lex.europa.eu/EN/legal-content/summary/compliance-with-rules-on-access-and-benefit-sharing-arising-from-the-use-of-genetic-resources-and-associated-traditional-knowledge.html>.

⁴⁵ Bernard Vanheusden & Griet Van den Berghe, *The Implementation of "Access and Benefit-Sharing" in Five EU Member States: The Achievements and Deficiencies of the Nagoya Protocol and the EU Regulation 511/2014*, 14 J. EUR. ENVTL. & PLAN. L. 7 (2017).

⁴⁶ Lei No. 13.123, de 20 de Maio de 2015, Diário Oficial da União [D.O.U.] de 21.5.2015 (Braz.) (regulating access to genetic heritage and associated traditional knowledge and benefit-sharing).

⁴⁷ MINISTRY OF THE ENVIRONMENT OF BRAZIL, *Genetic Heritage, Associated Traditional Knowledge and Benefit Sharing: Law 13,123, of May 20, 2015; Decree 8,772, of May 11, 2016* (2d ed. 2022), https://www.gov.br/mma/pt-br/assuntos/bioeconomia/patrimonio-genetico/publicacoes/cartilha_cta_2edio_ingls_final1.pdf.

⁴⁸ NATIONAL BIODIVERSITY AUTHORITY, *Access and Benefit Sharing Experiences from India* (2012), http://nbaindia.org/uploaded/pdf/ABS_Factsheets_1.pdf.

VII. FUTURE TRENDS IN PROTECTION OF INDIGENOUS BIO-WEALTH AND BIODIVERSITY

A. National Red List Roadmap 2025-2030

In October 2025, India unveiled the National Red List Roadmap and Vision 2025-2030 at the IUCN World Conservation Congress.⁴⁹ This initiative is a significant step towards implementing evidence-based biodiversity governance.

The aim is to evaluate the extinction risk of around 11,000 species by 2030 using the IUCN Red List criteria. This will help create a detailed database of both endemic and threatened plants and animals, which will serve as a guide for focused conservation and sustainable management efforts.⁵⁰ The roadmap places a strong emphasis on transparency, scientific integrity, and collaboration among researchers, policymakers, and local communities. It also aims to integrate traditional knowledge into biodiversity documentation. By strengthening baseline data on species and the threats they face, the plan will enhance conservation strategies, resource allocation, and the protection of ecosystems that are vital for indigenous livelihoods. Future policy directions will focus on inclusive governance, empowering BMCs, ensuring representation of Indigenous Peoples and Local Communities (IPLCs)⁵¹ in decision-making processes, and formalising Free, Prior and Informed Consent (FPIC) in line with customary laws. Moreover, integrating digital traditional knowledge repositories with REDD+, species databases, and ABS monitoring platforms will improve the traceability of genetic resources and promote fair benefit-sharing. Alignment with the Nagoya Protocol⁵² and the Kunming-Montreal Global Biodiversity Framework⁵³ will further strengthen India's international commitments to combat biodiversity loss. Enhanced intellectual property and patent review mechanisms, improved user-compliance standards, and cross-border due diligence modelled on the EU framework are anticipated to bridge regulatory gaps and foster accountability in bio-prospecting. Recognising DSI as part of genetic resource governance presents new policy challenges in balancing open data sharing with equitable benefits for IPLCs.

⁴⁹ MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE, *Union MoS Shri Kirti Vardhan Singh Leads Indian Delegation at the IUCN World Conservation Congress in Abu Dhabi and Launches India's National Red List Roadmap*, PRESS INFORMATION BUREAU (Oct. 9, 2025), <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2176948>.

⁵⁰ BOTANICAL SURVEY OF INDIA, *National Red List Assessment of Indian Flora and Fauna: Vision 2025-2030* (May 30, 2025), https://bsi.gov.in/uploads/documents/publications/e-publications/english/IUCN_Vision_2025-2030_published.pdf.

⁵¹ Indigenous Peoples and Local Communities.

⁵² 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, Oct. 29, 2010, 3008 U.N.T.S. 49303.

⁵³ Conference of the Parties to the Convention on Biological Diversity, *Kunming-Montreal Global Biodiversity Framework*, U.N. Doc. CBD/COP/DEC/15/4 (2022).

VIII. SYNTHESIS AND POLICY LESSONS FOR INDIA

Comparative analyses from South Africa, the European Union, and Brazil indicate that India's biodiversity governance could be considerably enhanced through focused legal and institutional reforms. India can adopt explicit community-level PIC procedures from South Africa, which would require written resolutions from communities and the establishment of dedicated ABS trust funds to manage and oversee benefit distributions. The European Union offers insights into the importance of user-compliance mechanisms, including due diligence obligations, audit checkpoints, and documentation requirements throughout the product lifecycle, thereby ensuring accountability that extends beyond the access phase. Brazil provides a model for India to create a National Benefit-Sharing Fund with indigenous co-governance, facilitating a transparent approach to the equitable distribution of benefits where TK ownership is diffuse or shared among various communities. Collectively, these comparative frameworks demonstrate that the effective safeguarding of indigenous bio-wealth necessitates a transition from mere formal compliance to genuine substantive participation. Future reforms in India must transcend administrative oversight and focus on empowering indigenous peoples as proactive stakeholders in the governance of biodiversity. By integrating community consent, ongoing due diligence, and fair benefit distribution into a cohesive legal framework, India would not only meet its international commitments under the CBD and Nagoya Protocol but also fulfil the constitutional promise of justice, equality, and environmental stewardship for its indigenous populations.

India's advancements in the protection of indigenous bio-wealth and biodiversity have been marked by significant accomplishments such as the National Red List Roadmap 2025-2030.⁵⁴ The legal and institutional frameworks in India establish a strong statutory basis for ABS and the safeguarding of traditional knowledge. However, the implementation process remains inconsistent and fragmented. The benefit-sharing mechanisms encounter substantial delays owing to institutional obstacles and limited operational capacity. Enforcement lacks uniformity across different states, resulting in indigenous and local communities having minimal authority over decisions related to resource access.

IX. RECOMMENDATIONS

Strengthen institutional capacity: enhance the effectiveness of BMCs and State Biodiversity Boards (SBBs) through better staffing, funding, and community representation. Institutionalise

⁵⁴ *Supra* note 50, at 13.

FPIC⁵⁵ and ensure participatory monitoring to make biodiversity governance inclusive and accountable.

Ensure transparent benefit-sharing: establish standardised benefit-sharing rates, royalty frameworks, and timelines. Create central and state-level trust funds under the NBA to ensure fair and traceable benefit distribution to TK holders.

Improve TK documentation and patent coordination: expand the TKDL, link it with Patent Office databases and Biodiversity Registries, and train examiners in TK systems, prior-art identification, and disclosure of biological origins to curb bio-piracy.

Adopt user-side due diligence: introduce due diligence declarations, audits, and compliance mechanisms modelled on Regulation (EU) No 511/2014, and strengthen cross-border cooperation to enforce PIC and MAT obligations internationally.

Clarify laws and build judicial capacity: define ambiguous ABS provisions, especially for domestic users, and train judicial officers, administrators, and indigenous leaders in biodiversity law. Establish specialised biodiversity benches or mediation forums for effective dispute resolution.

Integrate science and community efforts: align initiatives such as the National Red List Roadmap with community-based conservation and TK documentation. Promote joint biodiversity monitoring and public-private partnerships in sustainable bio-prospecting with strong ethical and benefit-sharing standards.

X. CONCLUSION

India's path towards safeguarding its indigenous biological wealth and addressing bio-piracy has been both ambitious and instructive. India's efforts reflect both progress and persistent challenges. The Biological Diversity Act, the Patents Act, and initiatives such as the Kani-Jeevani agreement, the TKDL, and the National Red List Roadmap 2025-2030 demonstrate a strong commitment to equitable and evidence-based biodiversity governance.

However, uneven implementation, institutional gaps, and inconsistent interpretation of ABS provisions continue to limit the realisation of indigenous rights. Strengthening PIC mechanisms, standardising benefit-sharing, enhancing inter-agency coordination, and ensuring cross-border due diligence are essential for more inclusive governance. Going forward, India must integrate community participation, scientific rigour, and international collaboration to ensure that its

⁵⁵ Free, Prior, and Informed Consent.

biological heritage is both sustainably managed and justly shared with its indigenous custodians.
