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Balancing Monopoly Rights and Social Responsibilities through Access and Benefit Sharing instrument under the Biological Diversity Act of India

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The interplay between the Indian Patent Act, 1970 and the Biological Diversity Act, 2002 (BD Act), now amended to the Biological Diversity (Amendment) Act, 2023, has an irrefutable direction regarding obligations and compliance from IPR applicants for access and benefit sharing (ABS). Compliance with both Acts is essential for obtaining intellectual property rights in India for any invention that utilises the country's biological resources. A fair and equitable sharing of benefits derived from the use of genetic resources, along with the sustainable use of biological diversity components, is a fundamental aspect of the Convention on Biological Diversity established in 1992.

In the present study, CSIR-National Botanical Research Institute (NBRI) has been taken as an example to give an overview of regulatory compliances under the Patent Law, the Biodiversity Act 2002, for R&D based on biological material. A sample of 25 patent applications of NBRI filed by the Council of Scientific and Industrial Research (CSIR) was taken, and the National Biodiversity Authority (NBA) executed the ABS agreement in compliance with the BD Act, 2002. Some of these applications were licensed to industrial partners with both financial and non-financial commitments. The article provides details of compliance with fulfilling the ABS agreement between CSIR and the NBA by allocating the agreed percentage of license fees, annual royalties, and other mandatory compliances to the National Biodiversity Fund (NBF) for all the cases mentioned herein. The present study provides an overview of the requisite regulatory requirements for domestic and international organisations seeking intellectual property rights for inventions wherein biological resources from India have been deployed. Further, the study also gives some insights into changes that have been brought in the BD Act with the amendment as enforced in 2023.

Keywords: Access and Benefit Sharing Agreement (ABS), Biological Diversity Act, 2002, Bio-Diversity, National Biodiversity Authority (NBA), Patent application, The Indian Patent Act, 1970

Biodiversity and Intellectual Property

India is recognized as one of the seventeen megadiverse countries in the world, featuring four distinct biodiversity hotspots.[1]This rich biodiversity is one of the key strengths that helped in the development of the country's economy. Agriculture, food, fisheries, forest produce, non-timber forest produce, drugs, enzymes, plant varieties, secondary metabolites used for medicine, fragrance, flavour, etc., are all products of biodiversity.[2] The rapidly changing environment affects biodiversity in several ways, with the highest loss and overexploitation of flora and fauna.[3] The overexploitation of flora & fauna is also associated with utilising biological resources for research and knowledge transfer.[4] Advancing and safeguarding this biological diversity can only be accomplished through sustainable practices and just, equitable distribution of benefits among all stakeholders, including government entities, non-profit organizations, researchers, conservationists, and individuals.[5,6]

Biological resources and associated knowledge are extensively used as research materials for developing innovative products through inventions, and intellectual property (IP) protection is sought in case the patentability criterion is met.[5, 7] Regulatory authorities such as the NBA play a vital role in establishing the legal framework that governs the granting of permission for the utilization of the nation's biological resources.[8,9] India has implemented almost 59 Acts, rules and regulations aimed at protecting biodiversity. These laws outline how to use and conserve biodiversity effectively.

The NBA was created after the Convention on Biological Diversity (CBD)[10]which is a multifaceted treaty that came into existence on December 29, 1993.

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The primary objective of this treaty is to develop national strategies aimed at the sustainable use and conservation of biological diversity. The Convention on Biological Diversity (CBD), which has garnered the commitment of 196 signatory nations, is fundamentally oriented towards three principal objectives: the sustainable utilization of biological resources, the conservation of biodiversity, and the equitable sharing of benefits that arise from the use of biodiversity.[11] The CBD includes two supplementary agreements: the Cartagena Protocol,[12] which aims to safeguard biodiversity from the risks associated with Genetically Modified Organisms (GMOs) and requires the labelling of genetically altered products, and the Nagoya Protocol,[13] which establishes a legal framework for access to genetic resources and ensures a fair and equitable share of benefits derived from their utilization. India ratified the CBD in 1994 and has been a party to the Cartagena and Nagoya Protocols since 2010 and 2014, respectively.

The BD Act, 2002,[14] has now been amended to the BD (Amendment) Act, 2023.[15] The fundamental idea of the Act remains rooted in the principles of the United Nations Convention on Biological Diversity (UNCBD) from 1992, which governs the preservation of biodiversity and promotes the sustainable use of biological resources, delivering advantages to local communities.[16,17] The Act not only governs the sustainable utilization and preservation of biodiversity and related Traditional Knowledge (TK) but also establishes a framework for the submission and effective enforcement of Intellectual Property Rights (IPR) protections and the transfer of technology that utilizes biological resources from India.[9,18] Further, wherever intellectual property rights, particularly patents, are involved, the legal frameworks are provided under the Indian Patent Act, 1970[19] to regulate and promote research and development by giving rights to inventors/ applicants. Therefore, when filing a patent application or generating intellectual property using biological resources from India, the BD Act, 2002, and the Patent Act, 1970 have legal coordination and the fulfillment of specific requirements to protect the inventor's rights.

Compliance with Disclosure in the Indian Patent Act, 1970, as amended in 2005, and interplay with Obligations under the Biodiversity Act, 2002, as amended in 2023

The Indian Patent Act has a requirement under section 10 (ii) (u/s used thereafter) wherein the applicant(s) need to deposit biological resources used in any recognised repository. The key sections that provide the framework for regulating access, utilization, and equitable sharing of benefits arising from India's biological resources are Sections 3- 6, and 21 of the Biodiversity Act of 2002, which was recently amended in 2023.[20] In the BD Act, Section 3 restricted access to biological resources or related knowledge only to Indian citizens and entities without foreign control, while non-residents and foreign corporations required prior approval from the NBA. Additionally, prior notification to the relevant State Biodiversity Board (SBB) is required for accessing biological resources for bio-survey, bio-utilization, or commercial use, though this requirement does not apply to local communities, cultivators, and practitioners of traditional medicine, such as hakims and vaidyas. This provision enhances India's control over its biodiversity, ensuring equitable access and benefit-sharing mechanisms while curtailing exploitative practices by international entities. Section 4 further mandated NBA approval before transferring research results involving Indian biological resources to foreign persons or organizations. Collaborative research projects under Section 5 were exempted, provided they had Central Government approval and followed prescribed policy guidelines. A key provision, Section 6, prohibited applying for intellectual property rights based on Indian biological resources without prior NBA approval, ensuring benefit-sharing mechanisms were in place. Section 21 obligated the NBA to determine fair and equitable benefit-sharing among users, local bodies, and "benefit claimers," which included conservers, traditional knowledge holders, and local communities.

The 2023 Amendment Act introduced notable procedural simplifications and definitional clarifications. Under the amended Section 3, the scope of entities requiring NBA approval now explicitly includes those "controlled by a foreigner" as defined under the Companies Act, 2013. Section 4 continues to restrict the transfer of research results to such foreign-controlled entities but allows publication and further research under government guidelines without additional approval. Most significantly, Section 6(1A) now permits Indian nationals and entities under Section 7 to simply register with the NBA — rather than seek prior approval — before granted an IPR in India or abroad for inventions derived from Indian biological resources or related traditional knowledge,

including materials stored in foreign repositories. The new Section 6(1B) mandates NBA approval only at the stage of commercialization, thereby streamlining the IPR process while maintaining oversight.

In both versions, Section 21 remains central, requiring the NBA to ensure benefit-sharing through mutually agreed terms, including joint IPR ownership, technology transfer, or monetary compensation. The amendment reaffirms the NBA's duty to engage with local communities before granting access approvals, thus preserving indigenous rights even as administrative barriers are eased for domestic stakeholders. Notably, the 2023 amendment is not retrospective; therefore, patent applications filed prior to its enforcement continue to require prior NBA approval as per the 2002 Act. Although the reform expedites IPR filings, the NBA retains authority to impose benefit-sharing obligations upon commercialization to ensure compliance with India's sovereign biodiversity framework and commitments under the Convention on Biological Diversity and Nagoya Protocol (Table 1).

Amendment in the Act has simplified requirement of compliance for domestic companies, organisationand Indian citizens. It will help them in

Table 1 — Comparison of the BD Act, 2002 and the Amended Act, 2023 related to IPR protection

Section	BD Act, 2002	BD Amendment Act, 2023
Section 3: Access to biological resources and knowledge related to such resources for research or for commercial utilization or for bio-survey and bio-utilisation.	Prohibited any *non-Indian citizen*, *non-resident Indian*, or *a body corporate, association or organization-not incorporated or registered in India;* from obtaining biological resources or related knowledge without prior approval of the NBA.	There is addition of: *a body corporate, association or organization incorporated or registered in India under any law for the time being in force, which is controlled by a foreigner within the meaning of clause (27) of Section 2 of the Companies Act, 2013.* (Section 3, sub-section (2), clause (c) of the Amended Act)
Section 4: Transfer of research resultsor traditional knowledge associated theretoto certain persons (as per Section 3, sub-section (2))	No person without NBA approval can transfer research results involving Indian biological resources to non-Indian persons or entities, excluding dissemination via publication or workshops/seminars as per the guidelines of the GoI.	The requirements have been largely maintained, with the addition of an entity, along with "person". It is important to note that if results have been used for further research, registration is required. However, for intellectual property and/or commercial purposes, permission/approval from the NBA is required, for use within or outside India
Section 5: Collaborative research	Exempted *Government-approved* collaborative projects under provisions of Sections 3 and 4, if consistent with official policy guidelines and Central Government approval.	It retains exemption, explicitly includes traditional knowledge in collaborative projects, and reaffirms central government approval requirements and conforms to the policy guidelines.
Section 6: Application for IPR	NBA approval is required before applying for any IPR (domestic or foreign) based on research or information from Indian biological resources.	Introduced *Section 6(1A)* — Indian nationals and entities under Section 7 need only register with NBA before IPR grant (no prior approval). *Section 6(1B)* — NBA approval required at the commercialization stage. A person or entity covered under sub-section (2) of section 3 applying for an intellectual property right has to obtain prior approval.
Section 21: Fair and equitable benefit sharing	NBA must ensure benefit-sharing agreements among users, local bodies, and benefit claimers; these agreements could involve royalties, technology transfer, joint IPRs, or monetary compensation.	Reaffirms NBA's role in fair and equitable benefit sharing; emphasizes *consultation with local communities* before approvals; strengthens *mutually agreed terms* as a compliance mechanism.
Process of NBA approval/ registration for IP protection or commercialization	The permission from the NBA was sought by a two-step process encompassing filing FORM-III with the NBA and subsequently executing the ABS agreement between the NBA and the applicant(s) of the Patent Application.	The BD (amendment) Act 2023 requires the completion of FORM-8 for registration with the NBA before an IPR can be granted. Subsequently, individuals covered under Section 7 of the Act must fill out FORM-9 to seek prior approval from the NBA in the event of commercialization post-registration.

research, development and commercialisation of innovations based on biological resources and traditional knowledge of India.[20]By introducing reference of companies act for foreign controlled Indian and foreign entities it has also introduced legal framework which will safeguard from any exploitation.[21]

Moreover, the People's Biodiversity Registers (PBRs), upheld by regional organizations, act as formal records of traditional knowledge, steering ABS negotiations and protecting against misappropriation. Failure to obtain NBA approval before accessing resources or filing patents constituted a legal offense under Section 55, with penalties ranging from fines to imprisonment for up to five years in the 2002 Act. Now it has been decriminalised and imprisonment aspect has been removed.[20]In the 2023 amended Act, the provision of imprisonment is now revoked, and only heavy fines are imposed. Sections 18 and 20 empower the NBA to revoke approvals, impose penalties, and initiate legal action against violators, including foreign entities attempting to bypass ABS requirements. Despite the amendments to the BD Act, many provisions of the BD Act, 2002 remain valid. The obligations established by the BD Act 2002 must still be met for all patent applications submitted prior to the implementation of the amended Act in April 2024.

The ABS[22] agreement is the primary element of adherence to the BD Act. It serves as the essential legal framework for the justifiable use and preservation of biological and genetic resources within and beyond national borders.[23,24] The requirement of the BD Act, 2002, entails that once the ABS agreement is signed, it shall remain in force from the effective date of this agreement till the subsistence of the IPR for which approval was granted.[25] The obligation of ABS involves notifying the NBA concerning technology transfer/commercialization as and when it happens, and submitting a status report to the NBA regarding all the applications.[24] Further, the applicant is responsible for proactively educating their staff, partners, and collaborators about the BD Act, 2002 provision, and organising awareness programmes within three months of the agreement's execution.[25] The applicant shall pay the percentage of the Licence fees and royalties received annually from the Licensee. However, while these legal frameworks are in place, their implementation faces several challenges. Despite explicit regulatory provisions, compliance with ABS obligations remains inconsistent, particularly in industries that rely on biological resources for pharmaceuticals, agriculture, and biotechnology.[27,28]

India's rich biodiversity and traditional knowledge[29] have been vulnerable to exploitation by multinational corporations and foreign entities, often through patents filed in international jurisdictions without appropriate benefit-sharing mechanisms.[18,30] Numerous high-profile incidents of biopiracy have underscored the significance of ABS frameworks in safeguarding indigenous knowledge and ensuring equitable compensation for local communities. One notable example is the Turmeric Patent Case (1995), in which a patent was awarded in the United States for the wound-healing properties of turmeric, a remedy that has been well-documented in Indian traditional medicine. The Council of Scientific and Industrial Research (CSIR) successfully contested this patent by presenting evidence of prior art, ultimately leading to its revocation.[31,32] Similarly, the Neem Patent Case (1995) involved a U.S. company securing a European patent for neem-based fungicidal properties despite neem's medicinal applications being widely known and documented in Indian texts. After strong objections from Indian scientists and non-governmental organisations (NGOs), the patent was eventually revoked. Another controversial case involved Basmati Rice (1997), where a company in the U.S. secured a patent for a rice type derived from Indian Basmati, sparking worries about the exploitation of traditional agricultural wisdom. Following legal challenges, several claims under the patent were overturned, ensuring the protection of India's native rice varieties. Similar attempts have been made to patent medicinal plants such as Jamun, demonstrating the need for robust legal mechanisms to prevent the unauthorized exploitation of India's biological resources.[30] These cases underscore the significance of the BD Act 2002, which mandates compliance with ABS agreements for any commercial utilisation of Indian genetic resources (Banerjee, 2019; Sharma *et al*., 2018).

Several researchers and inventors have deliberated and analysed the principles of ABS[26,35-47]that provides a critical analysis of the doctrine of ABS, underlining that the present doctrine is substantially more complex in the international domain than in the national. Sara *et al*., 2022[48]emphasised that there is a

need for ABS recalibration, as it's an integral part of the sustainable use of biodiversity. However, even though monetary contributions are essential to benefit sharing, they should not be misconstrued as a primary financing mechanism. Sharma *et al*., 2022[49]also discussed in detail the tensions and collaborations between biodiversity and IPR, offering comprehensive information regarding the connection between traditional knowledge and the entitlements of traditional knowledge bearers both in India and around the world. Morrison *et al.* 2021 [50] also emphasised that ABS is a valuable economic tool in achieving the United Nations' (UN) Sustainable Development Goals (SDGs).

Till 2022, for accessing bioresources of the country, NBA has received about 5793 applications.[37]Nevertheless, there are enormous challenges for the ABS process in India, as stakeholders are unfamiliar with the ABS principles and their implications.[45] The recent NBA reports,[23] global case studies,[51] and critical analysis of ABS has been presented in the literature of CBD Case Studies & Publications (cbd.int), NBA Publication, and Main Publications (cbd.int) are good sources to understand and comply with ABS mechanisms. Many patent holders do not fully understand their responsibilities under the Act, and enforced mechanisms often struggle to ensure adherence to ABS agreements.[25]

The present study attempts to elaborate on the implementation of ABS agreement for the patent applications filed by CSIR for its constituent laboratory, NBRI, India, wherein the said applications used biological resources from India. The study focuses on showcasing the implementation of requisite procedures and the interplay of the BD Act, 2002, and the Indian Patent Act, 1970.

The Case Study

The Council of Scientific and Industrial Research (CSIR) is a premier research organization under the Ministry of Science & Technology, Government of India. With 38 constituent laboratories, CSIR ranks among the leading institutions in India for patent filings, boasting an extensive portfolio of patents in the Biological Sciences domain. These patents have been filed based on research and development utilizing Biological Resources sourced from India.

The National Botanical Research Institute (NBRI), located in Lucknow, which is part of the CSIR's group of laboratories, focuses on research related to plant sciences, the conservation of biodiversity, and innovations in biotechnology. Key achievements include developing novel herbal formulations, bioremediation technologies, and improved plant varieties. 25 patent applications were filed by CSIR-NBRI, and data depicted in Table 2 highlights the technologies developed, patented, and licensed at NBRI, wherein NBRI has fulfilled all requisite obligations and fulfilled necessary compliances under both the BD Act 2002 and the Indian Patent Act 1970. The ABS agreements have been signed for all applications having financial and non-financial outcomes.

In all the 25 applications, biological resources were used from India, and as per obligations under the Patent Act 1970, CSIR-NBRI has deposited voucher specimens in national repositories to seek permission from NBA for filing patent applications in India and abroad by filing Form III and thereafter executing an ABS Agreement with NBA. Additionally, the NBA was informed about the approval and commercialization of the patent application on an individual basis whenever applicable. NBRI ensured adherence to the distribution of financial gains from the commercialized patent applications and kept thorough records of these transactions.

For compliance with the ABS agreements signed with the NBA for the patent applications filed by CSIR-NBRI, the following steps have been undertaken:

a) Information about biological material: Under Annexure A of the ABS agreement, details of biological material used in the invention were disclosed to NBA, which included:

(i) Common Name of biological resource
(ii) Scientific Name of Biological Resources
(iii) Nature of Biological Resources
(iv) Part of Biological resources
(v) Geographical location

b) Sharing of License fee and royalty: As agreed in the ABS agreement, the license fees and royalty were shared for patent applications.For application number 201811044361 (patent under examination), as per clauses 3.1 & 4.1 and Schedule A of the ABS, if the applicant Licenses know-how to a third party, it must share 4% of the Licence fee and royalty received by it.Application number 201811044361 was licensed to M/S Marc Laboratories, New Delhi,in 2022 for the

Table 2 — A brief description of all patent applications filed and the compliances met under the BD Act, 2002 and the Patent Act, 1970

Title of Invention	Granted/ Application Patent Number	Signed ABS FY	Technology transferred Y/N
A Cost-Effective Method of Producing High-Density *Trichoderma*-Based Formulation	406461	2022-23	N
A Synergistic Herbal Formulation Useful for Urolithiasis And Nephrolithiasis	201811044361 (under examination)	2021-22	Y
A Bioinoculant Composition Comprising *Trichoderma* Protoplast fusant Useful for Enhancing Nutritional Value and Growth of Plants	326937	2021-22	N
A Process for Preparation of a Novel Insecticidal Chitinase Toxic Against Whiteflies, Its Encoding Nucleotides and Application There Off	415132	2020-21	N
A Synergistic Herbal Composition Useful for The Management Of Diabetes	354536	2020-21	Y
TrimethoxyTetrahydrobenzoDioxoloIsochromene Compound and Pharmaceutical Composition Comprising Same for Management of Inflammation	408571	2020-21	N
A Nicotine Free Synergistic Polyherbal Masticatory Formulation and A Process for The Preparation Thereof	348376	2020-21	N
A Synergistic Pharmaceutical Composition for Gastrointestinal Disorders	359877	2020-21	N
Natural Hair Dye and Its Applications	376653	2020-21	N
A Novel Ready to Use Formulation Useful Against Soil Pathogens and A Process for The Preparation Thereof	201911012429 (under examination)	2020-21	N
Functional Aphrodisiac Rolled Herbal Bidis, And Cigarettes	244788	2020-21	N
An Essential Oil Composition and Herbal Emulsion Based Formulation of The Same and A Process for Preparation Thereof	542828	2020-21	N
A Herbal Emulsion Based Formulation Useful For Vulvovaginal Candidiasis And A Process For The Preparation Thereof	538652	2020-21	N
A Wound Inducible Expression Construct And A Method Of Its Preparation	415119	2020-21	N
A Primer Sequence For The Preparation Of Insecticidal Protein From *MicrosoriumScolopendriurn*	507326	2020-21	N
Novel Reversible Expression System For Transgene Expression In Plants	493540	2020-21	N
A Novel Formulation For Improving The Yield And Quality Of Fiber In Cotton Plants	458874	2020-21	N
A Synergistic Antipyretic Formulation.	239346	2020-21	
A Herbal Insecticidal Composition For Controlling Insect Pests And Process Of Preparation Thereof	253066	2019-20	N
A Novel Soil Improving Synergistic Composition Of Useful For The Reclamation Of Degraded Land/Soil.	284657	2019-20	N
Artificial Bidirectional Promoter For Activation Of Gene Expression.	236110	2019-20	N
Development Of Herbal Nutritious Chocklate And Its Processing.	248784	2019-20	N
Novel Health Promoting Functional Foods Fortified With Herbs.	415113	2019-20	Y
A Novel Anti-Diabetic Herbal Formulation.	240358	2019-20	N
A Herbal Insecticidal Composition For Controlling Stored Grain Insect Pests And A Process For The Preparation Thereof.	404656	2018-19	N

c) invention "A Synergistic Herbal Formulation Useful for Urolithiasis and Nephrolithiasis".

Regarding patent number 354536, in accordance with clause 4.1 and Schedule A of the ABS, the institute distributed 3% of the licensing fee and 2% of the royalties that were granted to M/S Aimil Pharmaceuticals Ltd in New Delhi in 2014 for the invention titled "A synergistic herbal composition useful for the management of diabetes." This invention provided a valuable synergistic herbal

Table 3— Details of awareness programs organized by CSIR-NBRI and Innovation Protection Unit, CSIR HQ, for all employees across CSIR Laboratories

Program Details	Date	Organisers
Webinar on International Day for Biological Diversity	22 May 2021	IPU, CSIR-HQ
IPR Protection & Access and Benefit Sharing under the Biodiversity Act, 2002	02 August 2021	CSIR-NBRI
Webinar on International Day for Biological Diversity	22 May 2022	IPU, CSIR-HQ
Panel Discussion on International Day for Biological Diversity	22 May 2023	IPU, CSIR-HQ
Panel Discussion on International Day for Biological Diversity	24 May 2024	IPU, CSIR-HQ

formulation for reducing elevated blood glucose levels by combining various plant extracts.

In a separate case concerning patent number 415113, 2% of the licensing fee and royalties have been allocated to the NBA under clause 5.1, applicable to third-party commercialization. This patent was licensed to M/S Herbal Ayurveda and Research Centre in Noida in 2017 for the invention titled "Novel Health-Promoting Functional Foods Fortified with Herbs." This invention features an innovative herbal composition that supports various pharmacological activities, demonstrating notable antioxidant, anti-stress, and adaptogenic properties.

Additionally, CSIR-NBRI will maintain its practice of sharing the negotiated license fees and royalty rates for patent applications on a case-by-case basis, in accordance with the stipulations of the ABS agreement.

d) Reports submission: While the ABS is in effect, the applicant is required to file a status report annually for each jurisdiction using the specified format outlined in the ABS agreement for every invention. Failing to submit these status reports on time may result in penalties. The status report must include the Applicant's name, Application number, Agreement signing date, Title of the patent, reporting period, Country of filing, Patent application number, Status of the patent application, Method of commercialization, Annual Gross ex-factory sales of the patented invention, assignment details, and a summary of total fees received, royalties received, and total ABS fees paid or owed for each financial year. As of the 2022-2023 period, CSIR-NBRI has submitted 72 status reports, and in 2023-24, 46 reports have been filed for every patent or patent application each year across various jurisdictions under ABS. All these certificates were certified by a chartered accountant as required. Under ABS, the patent applicant must submit a copy of Form 27 of the Indian Patent Rules, 2015, disclosing the information regarding the commercial working of the patent in India with NBA within one month of filing the same at the Indian Patent Office. CSIR-NBRI has submitted a copy of Form 27 every year with the NBA to Date.

e) Awareness programme: CSIR-NBRI organised awareness programs on biological diversity and related matters for the benefit of students, scientists, and staff under compliance with the BD Act, 2002 and submitted a detailed report about the same to NBA. Further, the Innovation Protection Unit, under CSIR-HQ, organised four awareness programs during 2021- 2024 on the Biological Diversity Day (Table 3).

The relationship between IPR and ABS is conflicting, as IPR believes in monopoly, while ABS is a regulatory requirement of an ideological nature. Intellectual Property associated with bio-resources, particularly in the pharmaceutical, agricultural, and cosmetics sectors, poses a significant obstacle to implementing the ABS mechanism in India. The challenge lies in reconciling IP, which is individual-oriented, with ABS, which is community-oriented.[52] This complex harmonisation requires addressing various issues, such as managing IP rights in non-commercial and commercial ABS agreements, including addressing issues in licensing, ownership, and transferring IP rights to third parties.

Strengthening the connection between India's ABS implementation and global biodiversity conservation efforts is essential. While India has taken significant steps in ABS compliance, many challenges, such as enforcement gaps, benefit-sharing delays, and industry engagement issues, mirror those observed in mega-diverse countries like Brazil, South Africa, and Indonesia.[28] Systemic weaknesses in ABS implementation are not apparent due to a lack of data and critical evaluation on enforcement gaps, inefficiencies in benefit-sharing, industry challenges, and the global relevance of India's ABS framework. The absence of a uniform compliance mechanism across states further exacerbates enforcement

challenges, allowing unauthorised access and use of biological resources.[53]The most significant issue in ABS implementation is the delay in benefit-sharing distribution. Further, the funds collected under the National Biodiversity Fund, consequential to ABS compliance, do not always reach local and indigenous communities on time. These delays undermine the core objective of the ABS mechanism, which is to ensure fair and equitable sharing of benefits.[54]In this regard, the Biological Diversity (Amendment) Act of 2023 attempted to streamline processes. The provisions of exemption of AYUSH practitioners from benefit-sharing obligations have the potential to reduce benefit sharing with traditional knowledge holders and have created loopholes that may lead to biopiracy and exploitation of biological resources, which are the subject matter of Traditional Knowledge.For keeping standards of the CBD and Nagoya Protocol, a tracking mechanism should be introduced to avoid this exemption getting converted into commercial angle.[21]

Discussion

Since joining CBD in 1994, India has taken a firm stand on biodiversity-related matters. It has taken a lead on establishing legislative, administrative, and policy frameworks to promote the fair and equitable sharing of benefits derived from using biological resources and related knowledge Since the adoption of the BD Act and its later amendments the central issue has been accessing biological resources and sharing their benefits for conservation of biological diversity and upliftment of communities which are instrument to its conservation. The government's new guidelines on access and benefit sharing, introduced in 2014, have only slightly added to the provisions outlined in the Act and its rules. While many patent applications utilise India's biological resources, not all are licensed, which means that even if ABS agreements are in place, there are no actual benefits to be passed to the stakeholders. As in the aforementioned cases, out of 25 applications, only three have been commercialised. Accordingly, the new BD (Amendment) Act, 2023 has changed the procedure for ABS agreement, which will come into force subject to the realisation of the commercial valuation of such patent applications.

ABS is a complex issue influenced by legal, institutional, and ethical factors. Legal complexities arise due to varying national laws, jurisdictional disputes, and enforcement challenges. Stakeholder conflicts often emerge between indigenous communities and governments over ownership rights, researchers and regulators over bureaucratic barriers, and companies resisting strict ABS obligations, while conservationists advocate for fair benefit-sharing. Disputes exist over monetary versus non-monetary benefits, unequal bargaining power, and determining rightful beneficiaries.[55]Biopiracy remains a concern, with cases of unauthorised use and controversial patents on biological resources. Emerging challenges include digital sequence information (DSI),[56] synthetic biology, and biodiversity loss, which complicate traditional ABS frameworks. Key debates revolve around whether digital genetic data should be included in ABS, how to simplify regulations without hindering research, and ensuring benefits reach local communities. The private sector faces significant hurdles primarily because of the vast complexity posed by nearly 200 distinct national ABS frameworks, along with additional variations at provincial and local levels. These challenges are further compounded by the non-linear nature of product development, the intricacies of commercial value chains, and the inconsistent implementation of the Nagoya Protocol. As a result, businesses find it difficult to track legislative changes and even more so to ensure compliance with the diverse ABS regulations. Many companies rely on hundreds or even thousands of raw materials linked to, or derived from, genetic resources for both research and commercial use. For each of these materials, firms typically source from multiple suppliers, each with differing levels of awareness regarding ABS requirements, and supplier choices often evolve over time.[57]

The cases from CSIR-NBRI involved Indian biological resources, and the applications have been granted and licensed with both economic and nonmonetary outcomes. As a result, CSIR-NBRI has complied with ABS agreements by paying the agreed percentage of license fees and annual royalties to the National Biodiversity Fund. However, the amount of license fees and royalties contributing to conservation is small due to the limited number of such applications. Additionally, there are debates about exemptions and definitions of value-added products under the Act. If a patent application is withdrawn before or after the grant, especially those filed internationally, closing the case with the NBA can be

lengthy. CSIR has addressed these issues for over a decade and significantly streamlined the process. From our perspective, the amount of effort required to address compliance matters is often far greater than the actual benefits that ABS agreements could yield and distribute. The CSIR-NBRI has demonstrated a commendable record in applying the ABS mechanism alongside IPR, which serves to promote both the conservation and sustainable use of biological resources. Sharing such experiences and related data in a transparent manner at the national level can offer meaningful guidance for shaping a reformed approach to ABS—one that operates more efficiently while effectively achieving its intended goals.

Various principles of justice, including commutative, distributive, global, procedural, and compensatory, influence the idea of benefit sharing in international research and bioprospecting.[58] The ABS mechanism serves as a tool for distributive justice.[59] A comprehensive benefit-sharing framework should integrate all these principles, but further empirical studies are needed to understand their practical implications.[60] However, weak enforcement, lack of will, and insufficient awareness among the beneficiaries have hindered the distribution of benefits to relevant stakeholders. Several companies in the industry dedicate substantial efforts to ensuring compliance with ABS regulations. These efforts include internal education and alignment with stakeholders across value chains, continuous monitoring and assessment of regulatory developments, and establishing best practices. Additionally, significant resources are invested in negotiating ABS agreements and qualifying suppliers.[57]To genuinely implement the goal of CBD, it is essential to strengthen the administrative and legal systems, address existing gaps, and educate stakeholders about their rights and responsibilities.[61,62]

Although the CBD has been in effect for nearly three decades, uncertainty still surrounds the realization of fair and equitable benefit-sharing, and researchers continue to criticize the added obstacles posed by ABS.[54] Streamlined benefit-sharing mechanism, expedited permit issuance, and reduced transaction costs will collectively expedite the unlocking of commercial potential and encourage the increased utilization of genetic resources[63] and traditional knowledge for the advantage of all stakeholders. Policies should focus on strengthening legal frameworks, facilitating access procedures, ensuring equitable benefit-sharing, and enhancing capacity-building initiatives. Comprehensive national legislation should be aligned with international agreements such as the CBD and the Nagoya Protocol, featuring clear definitions of genetic resources and benefits to avoid ambiguity.[64-66] Transparent, non-arbitrary access procedures should include Prior Informed Consent (PIC) and standardised Material Transfer Agreements (MATs) to clearly define terms. Benefit-sharing arrangements should be based on mutually agreed terms, ensuring fair financial and non-financial benefits such as technology transfer, capacity building, and access to research outcomes.[25] Effective monitoring and enforcement mechanisms should be established to ensure compliance. Additional capacity-building initiatives, technical assistance, and knowledge-sharing programs will support the implementation of ABS frameworks. Engaging stakeholders, including indigenous and local communities, researchers, and industry representatives, is essential to creating inclusive policies that balance innovation with fairness in genetic resource utilisation. [67]

The BD Act 2002 faced significant opposition from industrial lobbyists, as it covered everything associated with plants, animals, and microbes (i.e., living beings) within its scope. Further, the regulatory mechanism and penal clauses were very stringent. Thus, the amendment of the Act was a very welcome step. However, once the new Act came into force, the hardliners started finding faults with it. All being said, and despite some very noteworthy amendments, the BD (Amendment) Act of 2023 has also faced criticism, as it weakens the safeguards for benefit sharing. A significant change to the Principal Act of 2002 has stirred up quite a conversation: it exempts “AYUSH practitioners and traditional knowledge holders” from paying Access and Benefit Sharing (ABS) fees. Typically, these fees are paid to tribal and other communities that have historically gathered, protected, and utilized vital herbs and medicinal plants critical to the AYUSH sector. This move raises important questions about the balance between traditional knowledge and environmental stewardship. With less than two years in implementation, the new Biodiversity Amendment Act has faced challenges in its armour. This goes towards strengthening the importance of the subject matter.

Steps still need to be implemented to enhance the effectiveness of enforcing the Act's provisions. The areas for capacity-building include not only the regulatory aspects of ABS but also compliance related to maintaining the books of records of commercial exploitation by the applicants, be it public or private, and also on the regulatory bodies like the NBA. Transparency in the utilisation of resources generated by regulatory agencies and their utilisation in biodiversity conservation and upliftment of communities will go a long way in voluntary compliance by conscientious citizens.

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