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Digital Sequence Information and India's ABS Framework: Legal Challenges and Opportunities

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ABSTRACT

Digital Sequence Information (DSI) has emerged as a pivotal issue in global biodiversity governance, reshaping the discourse on Access and Benefit Sharing under the Convention on Biological Diversity and its Nagoya Protocol. In India, the Biological Diversity Act, 2002, amended in 2023, along with the Biological Diversity Rules, 2024, and the newly notified Biological Diversity (Access to Biological Resources and Knowledge Associated thereto and Fair and Equitable Benefit Sharing) Regulations, 2025 (ABS Regulations, 2025), explicitly include DSI within the scope of ABS governance. This article explores the legal challenges and opportunities presented by integrating DSI into India's ABS framework. It examines the ambiguities surrounding DSI's definition, the implications of its regulation for Indigenous and Local Communities (ILCs), and the tension between equitable benefit sharing and commercial interests. Through an analysis of the ABS Regulations, 2025, and relevant case law, such as Divya Pharmacy v. Union of India and PepsiCo India, the article argues that while India's proactive inclusion of DSI offers opportunities to lead global ABS practices, significant challenges such as inadequate community participation, regulatory overreach, and enforcement gaps threaten to undermine its efficacy. The article proposes reforms to align India's framework with international obligations and ensure fair benefit sharing for ILCs.

I. INTRODUCTION

"*Genetic resources undoubtedly belong to the nation within whose borders they are found, yet they also, in a sense, belong to the indigenous and local communities who have nurtured and preserved them for generations.*"

\- Justice Sudhanshu Dhulia[2]

The rapid advancement of biotechnology and bioinformatics has transformed genetic resources into digital sequence information, comprising nucleotide sequences, protein data, and associated metadata stored in public or private databases. DSI enables researchers and

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[2] *Divya Pharmacy v Union of India and others*, 2018 SCC Online Utt. 1035

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industries to access and utilize genetic information without physical samples, posing novel challenges for Access and Benefit Sharing regimes globally. The Convention on Biological Diversity and its Nagoya Protocol, which govern ABS, have struggled to address DSI due to its intangible nature and cross-border accessibility. In India, a biodiversity-rich nation and a party to the CBD since 1994, the integration of DSI into the ABS framework marks a significant step toward modernizing biodiversity governance.

India's ABS framework, anchored by the Biological Diversity Act, 2002 (BD Act), has evolved through amendments in 2023, revised Biological Diversity Rules in 2024, and the ABS Regulations, 2025. These instruments explicitly regulate DSI, positioning India as a frontrunner in addressing this emerging issue. However, the inclusion of DSI raises complex legal questions: How should DSI be defined and regulated? What are the implications for Indigenous and Local Communities (ILCs) as custodians of traditional knowledge (TK)? How can India balance commercial innovation with equitable benefit sharing?

This article examines the legal challenges and opportunities of regulating DSI within India's ABS framework. Section II provides the international and domestic context of DSI and ABS. Section III analyzes the ABS Regulations, 2025, focusing on DSI provisions. Section IV discusses relevant case law, including *Divya Pharmacy v. Union of India*[3] and *PepsiCo India*[4], to highlight implementation gaps. Section V evaluates challenges, such as definitional ambiguity, community rights, and enforcement issues, and proposes opportunities for reform. Section VI concludes with recommendations to strengthen India's DSI governance.

II. BACKGROUND: DSI AND ABS IN GLOBAL AND INDIAN CONTEXTS

A. International Framework

The CBD, adopted in 1992, with the main aim to conserve and protect biodiversity with promoting sustainable use, and also ensure fair and equitable benefit sharing from genetic resources. The Nagoya Protocol (2010) elaborates on ABS, mandating Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) for accessing associated TK with genetic resources. However, neither instrument explicitly addresses DSI, which has sparked debates at CBD Conferences of Parties (COPs). Developing nations, including India, advocate for including DSI within ABS to prevent biopiracy, while developed nations favor open access to foster innovation.

[3] Id. at 1

[4] Pratibha Brahmi, Vijaya Choudhary & Vandana Tyagi, *An Overview of Framework and Case Studies Related to ABS in Plant Genetic Resources*, 34(1) Indian J. Plant Genet. Resour. 25, 25–34 (2021), https://doi.org/10.5958/0976-1926.2021.00004.8.

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DSI's intangible nature complicates ABS enforcement. Unlike physical genetic resources, DSI can be shared instantly across borders, often bypassing national jurisdictions. The Kunming-Montreal Global Biodiversity Framework (KMGBF, 2022) acknowledges DSI's importance but leaves its regulation to national discretion, creating a patchwork of approaches.[5]

DSI, the digital representation of genetic sequences, is stored in over 1,700 global databases, with the International Nucleotide Sequence Database Collaboration (INSDC) receiving 23 million sequences annually.[6] Its accessibility through open-access platforms like the US GenBank or the European Bioinformatics Institute's ENA complicates the traditional ABS system under the Nagoya Protocol, which governs physical genetic resources through bilateral agreements. The digital nature of DSI makes it hard to track or enforce benefit-sharing, raising concerns about biopiracy, where genetic resources are exploited without compensating source countries or communities.

Two cases vividly illustrate these issues. In March 2020, the African Diversity Center, alongside NGOs Pelum and Andes, investigated a genetically modified (GM) potato developed by the International Potato Center in Peru for commercialization in Uganda and Rwanda. This potato, engineered for mildew resistance, incorporated three genes from Latin American varieties, two of which Rpi-vnt1.1 from Solanum venturii (Argentina) and Rpi-blb2 from Solanum bulbocastanum (Mexico) were synthesized using sequences from GenBank. Rpi-vnt1.1 was sequenced in the UK in 2010, and Rpi-blb2 in the Netherlands in 2005. Despite commercial claims by researchers backed by US and UK entities, there was little effort to share benefits with Latin American farmers, highlighting how DSI can bypass ABS obligations.

Similarly, during the 2014 Ebola outbreak in Guinea, the virus's genetic sequence, labeled C15, was sequenced by Germany's Nocht Institute and uploaded to GenBank, making it freely accessible. The US company Regeneron used this sequence to develop REGN-EB3, a monoclonal antibody treatment costing $10,000 per dose, funded by over $400 million from the US government.[7] No benefit-sharing agreement was made with Guinea, and the sequence was collected without patient consent, raising ethical concerns. These cases underscore the potential for DSI to undermine the CBD's principles of fairness and equity.

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[5] *Kunming-Montreal Global Biodiversity Framework*, adopted at the 15th Meeting of the Conference of the Parties to the Convention on Biological Diversity (Dec. 2022), https://www.unep.org/.

[6] **Centre for Sci. & Env't,** *The Issue of Digital Sequence Information on Genetic Resources, Factsheet*, **CSEINDIA (June 2025)**, https://www.cseindia.org

[7] Id. at. 6

The KMGBF, particularly Target 13, seeks to address these challenges by promoting benefit-sharing from DSI, genetic resources, and traditional knowledge by 2030 through legal, policy, and capacity-building measures. At COP15 in 2022, parties agreed to establish a multilateral mechanism for DSI benefit-sharing, moving beyond the Nagoya Protocol's bilateral approach. The Ad Hoc Open-ended Working Group on Benefit-sharing from DSI, formed post-COP15, has since met twice to develop this mechanism, proposing a global fund to which DSI users and philanthropies would contribute. At COP16, discussions focused on 29 modalities, including contribution amounts, sector involvement, and allocation methodologies to support biodiversity conservation and community development.

One significant proposal involves creating a DSI database linked to the CBD's clearing-house system, which would mandate identifying the origin of sequences and verifying prior informed consent to align with ABS principles. Nations with limited resources to handle genetic data, particularly in the Global South, would gain assistance to engage fairly in this system. Yet, hurdles remain, such as ongoing disputes over how to fund the mechanism and doubts about organizations like the Global Environment Facility, often seen as prioritizing wealthier countries' interests. These issues will be revisited at COP18, providing an opportunity to refine the approach.

For India, a country teeming with biodiversity and guided by the Biological Diversity Act of 2002, DSI introduces regulatory challenges. The multilateral framework presents a chance to bolster India's ABS system by incorporating rules for DSI, like requiring source transparency in global databases to ensure fair benefit-sharing from its genetic wealth. Support for building technical expertise could lessen India's reliance on foreign data platforms. Safeguarding traditional knowledge through benefits like skill-sharing resonates with the global mechanism's goals. Still, India faces the task of aligning its existing bilateral ABS practices with this new international model while grappling with ethical dilemmas similar to those exposed in the Ebola case.

The global conversation around DSI, shaped by COP16 and the KMGBF, underscores the urgency of updating ABS frameworks for the digital age. DSI drives scientific breakthroughs, but without oversight, it risks deepening unfair practices, as evidenced by the potato and Ebola incidents. The multilateral system offers hope for a fairer future, with direct relevance for India's ABS policies. By actively participating in these worldwide discussions, India can protect its natural heritage and ensure its communities reap the rewards of their biodiversity, striking a careful balance between progress and fairness.

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B. India's ABS Framework

India's BD Act, enacted in 2002, establishes a three-tier ABS system: the National Biodiversity Authority (NBA) at the national level, State Biodiversity Boards (SBBs) at the state level, and Biodiversity Management Committees (BMCs). The Act requires non-Indian users to seek NBA approval for accessing biological resources, while Indian users must provide prior intimation for commercial use to SBBs. The ABS Regulations, 2014, introduced monetary benefit-sharing rates (0.1–0.5% of ex-factory sales), but faced criticism for bureaucratic delays and inadequate community involvement.[8]

The 2023 BD Act amendments and 2024 BD Rules revisions aimed to streamline ABS processes, particularly for the AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homeopathy) industry. The ABS Regulations, 2025, further clarify procedures, including DSI regulation, but reduce benefit-sharing ratios for ILCs (from 95% to 85–90%) and introduce exemptions for small businesses (turnover below ₹5 crore). These changes reflect a tension between economic growth and community rights, exacerbated by DSI's inclusion.

III. Analysis of ABS Regulations, 2025: DSI Provisions

The ABS Regulations, 2025, mark a bold attempt to regulate DSI, but their provisions reveal both progress and pitfalls.

A. Important DSI Provisions

Inclusion of DSI: Regulation 4 explicitly includes DSI within the scope of biological resources, aligning with India's advocacy at CBD COPs. This ensures that digital sequences derived from Indian genetic resource are subject to ABS obligations, regardless of physical access.

Benefit-Sharing Obligations: Users accessing DSI for commercial purposes must share benefits, with higher rates (25% above standard) for innovations based on TK-associated DSI. Exemptions apply to entities with turnovers below ₹5 crore, reducing the benefit-sharing pool for ILCs.[9]

Prior Intimation and Approval: Indian users must submit prior intimation to SBBs via Form B, with deemed approval after 15 days of inaction.[10] Non-Indian users require NBA approval,

[8] Raju Narayana Swamy & Kumari Saloni, *'Benefit Sharing' Regime in India Regarding the Use of Biological Resources – An Alternative Model*, 14 NUJS L. Rev. 1 (2021), https://nujslawreview.org/

[9] Biological Diversity (Access to Biological Resources and Knowledge Associated Thereto and Fair and Equitable Sharing of Benefits) Regulations, 2025, § 4.

[10] Biological Diversity (Access to Biological Resources and Knowledge Associated Thereto and Fair and Equitable Sharing of Benefits) Regulations, 2025, § 5.

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ensuring stricter oversight for DSI access.

Monetary vs. Non-Monetary Benefits: The Regulations emphasize monetary benefits (e.g., royalties, license fees) but provide limited guidance on non-monetary benefits (e.g., technology transfer), listed only in Form F.[11]

B. Strengths

Global Leadership: By regulating DSI, India sets a precedent for biodiversity-rich nations, reinforcing its stance against digital biopiracy.

Clarity for Users: The distinction between prior approval (NBA) and prior intimation (SBBs), coupled with deemed approval timelines, reduces procedural ambiguity for commercial users.

TK Protection: Higher benefit-sharing rates for TK-associated DSI acknowledge ILCs' contributions, deterring misappropriation.

C. Weaknesses

Definitional Ambiguity: The Regulations use DSI as a placeholder term without defining its scope, creating uncertainty about what constitutes regulable DSI (e.g., nucleotide sequences vs. metadata).

Reduced Community Benefits: The 85–90% benefit-sharing ratio, down from 95%, and exemptions for small businesses diminish ILCs' entitlements, violating Section 21(3) of the BD Act, which mandates direct payment to identified providers.

Lack of PIC and MAT: The Regulations are silent on obtaining PIC and negotiating MAT for DSI access, undermining Nagoya Protocol obligations.

Opaque Process: The absence of public consultation during the Regulations' drafting erodes transparency, particularly for ILCs.

IV. Relevant Case Law: Lessons from Implementation

Case law under India's ABS framework highlights systemic challenges that DSI regulation must address.

A. Divya Pharmacy v. Union of India

In Divya Pharmacy v. Union of India[12], the Uttarakhand High Court upheld SBBs' authority to impose benefit-sharing obligations on Indian users, despite the BD Act's literal

[11] Biological Diversity (Access to Biological Resources and Knowledge Associated Thereto and Fair and Equitable Sharing of Benefits) Regulations, 2025, § 11.
[12] Id. at 1

interpretation limiting such powers to the NBA for non-Indian users. Divya Pharmacy, an AYUSH manufacturer, challenged a 2% revenue-sharing notice, arguing that Section 2(g) of the BD Act defines benefit sharing as determined by the NBA. The Court adopted a purposive interpretation, citing India's CBD and Nagoya Protocol obligations, and validated the ABS Regulations, 2014.

Implications for DSI: The ruling expands SBBs' regulatory scope, potentially applying to DSI access by Indian users. However, it exacerbates bureaucratic overreach, as SBBs lack the expertise to evaluate DSI's technical complexity. The Court's disregard for the BD Act's clear text sets a precedent for regulatory ambiguity, which could complicate DSI enforcement. This case highlights the need for legislative clarity to prevent judicial overreach in DSI governance.

B. PepsiCo India

The PepsiCo India case[13] involved NBA agreements for commercial access and third-party transfer of Kappaphycus alvarezii seaweed from Tamil Nadu. Despite collecting benefit-sharing funds, the NBA failed to distribute them to 754 benefit claimers across four districts until 2010, due to the absence of BMCs. The case revealed inefficiencies in benefit distribution and a focus on commodities rather than genetic resources.

Implications for DSI: DSI's intangible nature amplifies distribution challenges, as tracing its use across digital platforms is complex. Without robust BMCs, DSI benefits may not reach ILCs. The case highlights the risk of prioritizing commercial interests (e.g., exports) over community development, a concern with DSI exemptions for small businesses. It underscores the need for transparent mechanisms to identify benefit claimers in DSI contexts.

C. Bio India Biologicals

In the Bio India Biologicals case,[14] the NBA collected royalties for exporting 2000 kg of neem to Japan but transferred only a portion to Amarchinta village's biodiversity body for planting saplings. Critics argued that this minimal benefit sharing failed to reflect neem's genetic value or ILCs' TK contributions.

Implications for DSI: DSI derived from neem or similar resources could be misappropriated without clear valuation methods, as the Regulations' flat-rate approach (0.1–0.5%) ignores resource-specific value. The case emphasizes the need for non-monetary benefits (e.g., capacity building) in DSI agreements to empower ILCs. It highlights enforcement gaps, as DSI's global accessibility requires international cooperation beyond India's jurisdiction.

[13] Id. at 2
[14] Id. at 2

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V. LEGAL CHALLENGES AND OPPORTUNITIES

A. Challenges

Definitional Ambiguity: The lack of a precise DSI definition in the ABS Regulations, 2025, creates enforcement uncertainty. For instance, does DSI include synthetic sequences derived from Indian genetic resources? This ambiguity risks loopholes for biopiracy.

Solution: India should adopt a broad yet clear definition, encompassing nucleotide sequences, protein data, and metadata, aligned with ongoing CBD discussions.

Dilution of Community Rights: The reduced benefit-sharing ratio (85–90%) and exemptions for entities with turnovers below ₹5 crore violate Section 21(3) of the BD Act and the Nagoya Protocol's PIC and MAT requirements. Regulation 5.7's extension to non-cultivated medicinal plants is ultra vires, as it exceeds the BD Act's scope (*Naresh Chandra Agrawal v. ICAI.*[15])

Solution: Reinstate the 95% benefit-sharing ratio and mandate PIC and MAT for DSI access, involving BMCs directly.

Bureaucratic Overreach: The Divya Pharmacy ruling and ABS Regulations, 2025, empower SBBs beyond the BD Act's intent, risking arbitrary enforcement. SBBs lack the technical capacity to regulate DSI, leading to delays and corruption risks.

Solution: Establish a specialized DSI task force under the NBA to handle technical evaluations, with SBBs focusing on community engagement.

Enforcement Gaps: DSI's global accessibility undermines India's jurisdiction, as seen in cases like Bio India Biologicals. Monitoring DSI use requires international cooperation, which the Regulations do not address.

Solution: Advocate for a multilateral DSI benefit-sharing mechanism at CBD COPs, integrating India's framework with global databases.

B. Opportunities

Global Leadership: India's proactive DSI regulation positions it as a model for biodiversity-rich nations. By refining its framework, India can influence CBD negotiations, advocating for equitable DSI governance.

Action: Host international workshops to share India's ABS experience, emphasizing DSI's role.

[15] *Naresh Chandra Agrawal v. ICAI,* [2024] 2 S.C.R. 194.

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Strengthening TK Protection: Higher benefit-sharing rates for TK-associated DSI offer an opportunity to safeguard ILCs' knowledge. The Traditional Knowledge Digital Library (TKDL) can be expanded to include DSI, preventing misappropriation.

Action: Integrate TKDL with DSI databases, ensuring ILCs' consent for access.

Promoting Innovation: Streamlined ABS processes, such as deemed approvals, can incentivize biotechnology research using DSI, particularly for AYUSH and pharmaceutical industries.

Action: Develop sector-specific DSI guidelines, balancing innovation with benefit sharing.

Community Empowerment: Robust BMCs and transparent benefit distribution can empower ILCs, as seen in the Kani case. Non-monetary benefits, like technology transfer, can enhance community resilience.

Action: Mandate BMC training programs and allocate DSI benefits for capacity building.

VI. CONCLUSION

India's inclusion of DSI in its ABS framework through the ABS Regulations, 2025, is a commendable step toward addressing digital biopiracy and aligning with global biodiversity goals. However, challenges such as definitional ambiguity, diluted community rights, bureaucratic overreach, and enforcement gaps threaten its effectiveness. Case law, including Divya Pharmacy and PepsiCo India, underscores the need for transparent and equitable benefit distribution, particularly for ILCs. By adopting a clear DSI definition, reinstating robust community protections, and fostering international cooperation, India can transform these challenges into opportunities. A reformed ABS framework, centered on ILCs' rights and global leadership, will not only fulfil India's CBD and Nagoya Protocol obligations but also set a benchmark for sustainable biodiversity governance in the digital age.

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