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Digital Sequence Information and Traditional Medicinal Knowledge: Bridging the Regulatory Gap in the Age of Dematerialisation

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The emergence of Digital Sequence Information as the primary medium through which genetic resources are accessed and exploited has exposed a structural gap in India's biodiversity governance framework. The central question addressed here is whether the Biological Diversity Act, 2002, as amended in 2023, adequately captures Digital Sequence Information within its access and benefit-sharing obligations, and if not, what doctrinal correction is needed. A strict textual reading of Section 2(c) of the Act excludes intangible genetic data from its scope a gap that the 2023 Amendment left intact despite being a clear legislative opportunity. The Biological Diversity Rules, 2024, and the National Biodiversity Authority Access and Benefit Sharing Regulations, 2025, attempt to fill this vacuum at the regulatory level, but sub-statutory instruments operating beyond the scope of the parent statute are vulnerable to constitutional challenge. Through a doctrinal analysis supplemented by a statutory comparison with Brazil's Law No. 13,123/2015, it is argued that India requires a targeted amendment to Section 2(c) to bring Digital Sequence Information explicitly within the national Access and Benefit Sharing framework.

Keywords: Digital Sequence Information, Traditional Knowledge, WIPO Treaty, 2024, Biological Diversity Act, 2023, Access and Benefit Sharing, Biopiracy, Brazil

Biotechnology has quietly outpaced the law. Today, a pharmaceutical researcher sitting in Boston or Berlin can retrieve the complete genetic sequence of an Indian medicinal plant from a public database, synthesise its active compound in a laboratory, and build a commercial product all without ever triggering a single obligation under India's biodiversity law. This is not a hypothetical abuse; it is the logical outcome of a legal framework designed for a world where the exploitation of biological resources required the physical movement of plant material across borders. That world no longer exists, at least not exclusively. The sequencing of biological material and the uploading of that sequence to databases like GenBank, European Nucleotide Archive (ENA), or DNA Data Bank of Japan (DDBJ) has produced a new form of access digital, borderless, and practically invisible to the access and benefit-sharing machinery constructed under the Convention on Biological Diversity and the Nagoya Protocol.[1] The phenomenon is commonly described as the dematerialisation of genetic resources.[2]When a plant's genome is digitised and placed in a freely accessible database, the informational value of the resource becomes detached from its physical substrate. A downstream user who retrieves the sequence data does not physically access anything. Under both the Nagoya Protocol and India's Biological Diversity Act, 2002, the trigger for Access and Benefit Sharing (ABS) obligations has consistently been interpreted as physical access to biological material. Once the sequence enters the digital commons, that trigger is bypassed.[3]The provider country India, in the case of its extraordinary repository of medicinal biodiversity has no mechanism under current statutory law to require prior informed consent, negotiate benefit-sharing, or ensure that the commercial gains from its genetic heritage flow back to the communities who stewarded it. The adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge in May 2024[4]was widely welcomed as a step toward remedying this imbalance.[5]By introducing a mandatory disclosure requirement in patent applications obligating applicants to reveal the country of origin of any genetic resource used in an invention the Treaty

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inserts a transparency mechanism into the patent system. Yet the Treaty's text contains a studied ambiguity regarding Digital Sequence Information (DSI). Whether inventions based on database-sourced genetic sequences trigger the disclosure obligation was a question the Diplomatic Conference deliberately deferred. The result is that the Treaty, for all its significance, places the burden of domestic regulatory action squarely on national legislatures. India's response to this burden has been inadequate. The Biological Diversity (Amendment) Act, 2023 the most significant revision to the country's biodiversity law since its enactment made no change to the definition of biological resources under Section 2(c) of the parent Act. DSI, genetic information, and digital sequence data remain entirely absent from the statutory text. The BD Rules, 2024, and the National Biodiversity Authority Regulations, 2025 have attempted to bridge this gap through subordinate legislation, but these instruments face a fundamental doctrinal problem: they may be extending the scope of the ABS regime beyond what Parliament has authorised.

The precise research question examined here is whether India's current legal framework the Biological Diversity Act, 2002,(BDA) the 2023 Amendment, the BD Rules, 2024,[6] and the NBA Regulations, 2025 provides a legally secure basis for subjecting DSI to ABS obligations, and if not, what statutory intervention is required.[7] A comparison with Brazil's approach offers a clear answer, because Brazil has successfully resolved this precise question at the level of primary legislation, providing a workable model that India can adapt. The analysis proceeds through a doctrinal method. The central exercise is a textual and structural reading of the BDA, 2002 as amended in 2023, the BD Rules, 2024, and the NBA Regulations, 2025, alongside the relevant international instruments the Convention on Biological Diversity (CBD), 1992, the Nagoya Protocol (2010), and the WIPO Treaty (2024). Doctrinal analysis, as the dominant methodology in Indian legal scholarship, involves identifying the meaning of statutory provisions through established rules of interpretation, examining how those provisions interact with each other and with superior law, and assessing the consequences of different interpretive positions. The comparative element focuses exclusively on a statutory comparison between India and Brazil. Brazil was chosen because it is the only major megadiverse developing country whose primary biodiversity legislation explicitly covers DSI in information-based terms, making it directly relevant to the regulatory question under examination. The comparison is limited to legislative design and does not extend to compliance data or administrative practice, for which systematic records are not publicly available. This is acknowledged as a limitation, and is identified as a gap requiring separate empirical research.

Some legal clarity requires scientific grounding. DNA encodes the biological instructions of every living organism. When a sample a plant root, a soil microbe, a fungal extract is subjected to modern sequencing techniques, the result is a digital string of nucleotide characters representing the organism's genetic code. This string can be stored as a data file and transmitted anywhere in the world instantaneously. The explosion of next-generation sequencing technologies over the past two decades has dramatically reduced the cost of producing such sequences, resulting in what the CBD Secretariat's technical studies have described as a tsunami of genomic information being deposited into public databases. GenBank in the United States, ENA in Europe, and DDBJ in Japan operate under open-access policies. Any researcher in any country can retrieve any sequence free of charge, without registration, and without declaring the intended use. This infrastructure has undeniably accelerated scientific progress enabling rapid vaccine development, disease surveillance, crop improvement, and conservation monitoring. But it has also made the extraction of informational value from a country's biological resources structurally invisible to any legal mechanism premised on the tracking of physical movement. The economic dimension makes the problem acute: technical studies commissioned by the CBD Secretariat estimate that a sector-based levy of 0.1% to 1% on commercial revenues from DSI-derived products could generate between USD one billion and ten billion annually. Most of that commercial value is captured by entities in OECD countries, while a disproportionate share of the underlying biological diversity originates in tropical megadiverse nations like India, Brazil, and Indonesia.

The International Framework

The CBD's foundational premise is that states hold sovereign rights over their genetic resources and that access must be conditioned on prior informed consent and benefit-sharing on mutually agreed terms. The Nagoya Protocol operationalised this through a detailed ABS architecture.[8] Both instruments,

however, define genetic material as any material of plant, animal, microbial or other origin containing functional units of heredity. The word material is the crux of the interpretive dispute. Developed-country governments and user-industry stakeholders have consistently argued for a plain-text reading: material refers to physical matter, and once genetic information is disembodied into digital form, it falls outside ABS obligations. On this view, DSI is simply information, not a resource, and its inclusion in the public domain promotes innovation that all countries ultimately benefit from. This argument is not without legal credibility. The Vienna Convention on the Law of Treaties requires that treaty terms be given their ordinary meaning at the time of drafting.[9] In 1992, genetic material unambiguously referred to physical biological matter, and there is no negotiating record suggesting the parties contemplated digital data. To extend the term retroactively to information, through regulatory interpretation rather than treaty amendment, risks violating basic principles of legal certainty. Provider countries argue, however, that this textualist reading produces an outcome the CBD's drafters could not have intended: a comprehensive benefit-sharing regime made entirely redundant by a technological shift. The response lies in the principle of evolutionary interpretation, recognised by the International Court of Justice in *Dispute Regarding Navigational and Related Rights*[10] where the Court held that generic terms in treaties of continuing duration must be understood in light of evolving scientific knowledge. Applied to the CBD, genetic resources should encompass the informational content of biological material, because that content now represents the primary locus of economic value. This is the interpretation that a growing number of legal scholars support, and it is the position reflected in Brazil's domestic legislation. It was within this unresolved interpretive landscape that the WIPO Treaty was negotiated and adopted in May 2024.[11] The Treaty's central achievement is the mandatory disclosure requirement: patent applicants must now disclose the country of origin or source of genetic resources and associated traditional knowledge used in the claimed invention. For applications based on physical genetic resources, this creates a meaningful transparency obligation, allowing patent offices to verify ABS compliance and identify traditional knowledge prior art. What the Treaty did not achieve is equally significant.[12] The question of whether inventions based on DSI sequences retrieved from public databases trigger the disclosure obligation was a central battleground throughout the Diplomatic Conference. Delegations from the African Group and the Like-Minded Countries pressed for explicit DSI inclusion, arguing that any commercially valuable invention derived from the genetic information of a biological resource should disclose its country of origin regardless of whether the sequence was accessed physically or digitally. Delegations from Group B, led by the United States, Japan, and several EU members, resisted.[13] The United States maintained that imposing disclosure obligations on DSI users would create legal uncertainty, since the link between a database sequence and a specific national territory is often impossible to trace. Japan stressed that the patent system depends on predictability and that extending ABS obligations to intangible data would burden innovation in synthetic biology and computational drug discovery. The final treaty text reflects a compromise that satisfied neither side. Article 3 establishes the disclosure requirement for genetic resources without defining whether DSI falls within that term. This was not an accidental omission; it was a deliberate diplomatic mechanism to achieve consensus. A pharmaceutical company that develops a product using only database-sourced sequences may or may not be required to make a disclosure depending entirely on how the receiving patent office and domestic legislation interpret use of a genetic resource. That interpretive discretion is now exercised at the domestic level, which is precisely where India's framework is weakest.

India's Regulatory Framework

India's Biological Diversity Act, 2002 was forward-looking legislation at the time of its enactment. By establishing the National Biodiversity Authority, State Biodiversity Boards, and Biodiversity Management Committees, the Act created a three-tier governance structure that went further than most national ABS frameworks of the era.[14] Section 3 requires foreign entities to obtain NBA approval before accessing biological resources. Section 6 requires any person seeking an IPR over an invention that uses a biological resource obtained from India to seek prior NBA approval. These provisions, taken together, were designed to ensure that commercial exploitation of India's biodiversity was preceded by regulatory scrutiny and conditioned on benefit-sharing.[15] The problem lies in the foundational definition. Section 2(c) defines biological resources as

plants, animals, micro-organisms or parts thereof, their genetic material and by-products. Every category listed is physical and tangible. Parts thereof refers to physical subdivisions of organisms.[16] Genetic material is a physical substance the DNA, RNA, or other material found within cells. By-products are physical derivatives of biological processes. The Act contains no reference to information, sequences, data, or any digital representation of genetic content. A strict textual reading, applying the cardinal rule that words in a statute must be given their ordinary meaning unless context requires otherwise, leads to the conclusion that DSI is simply not a biological resource under the BDA. Section 2(p) compounds the problem. The Act exempts value-added products defined as products containing portions or extracts of plants or animals in unrecognisable and physically inseparable form from the definition of biological resources. Again, the language is entirely physical. A synthetic compound produced by a foreign laboratory using information retrieved from GenBank, functioning as a chemical equivalent of an active constituent of an Indian medicinal plant, likely falls outside the Act on both routes: it is not a biological resource as defined, and even if some physical connection could be argued, it may qualify as an exempt value-added product. The current statute offers no answer to this question.

The Biological Diversity (Amendment) Act, 2023, passed in the Monsoon Session of Parliament, introduced significant changes. The definition of persons requiring NBA approval under Section 3 was narrowed to cover only foreign-controlled companies registered under the Companies Act, 2013, while Indian-controlled entities with some foreign investment now require only prior intimation to the State Biodiversity Board. The amendment also expanded exemptions for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) practitioners operating within codified traditional knowledge systems, addressing a persistent complaint from the traditional medicine industry about disproportionate compliance burdens.[17] What the 2023 Amendment did not do is equally telling. The text of Section 2(c) was left untouched. The words digital sequence information, genetic information, or any equivalent phrase appear nowhere in the amended Act. The definitional gap that rendered DSI invisible to the ABS regime in 2002 survives intact in 2023. This was a significant missed opportunity, because the amendment process was the natural occasion for bringing the statute into alignment with both the scientific reality of how genetic resources are now exploited and the international policy direction signalled by the Kunming-Montreal Global Biodiversity Framework.

The NBA and the Ministry of Environment, Forest and Climate Change have not been passive in the face of this gap. Rule 16 of the BD Rules, 2024, mandates that entities applying for an IPR based on research using DSI accessed from India must obtain NBA approval before grant. The NBA Access and Benefit Sharing Regulations, 2025 operative from April 30, 2025 explicitly include DSI within the scope of biological resource for ABS purposes. A foreign entity commercialising a patent based on DSI from Indian species must apply for NBA approval in Form-7 and pay benefit-sharing at up to one percent of annual gross ex-factory sales, with an additional twenty-five percent if associated traditional knowledge was involved. These Regulations represent genuine regulatory progress. However, they face a doctrinal vulnerability the executive branch cannot resolve. The prevailing principle in Indian administrative law, articulated by the Supreme Court in *State of Tamil Nadu v. P. Krishnamurthy* [18], is that delegated legislation cannot travel beyond the scope of the enabling statute. If Section 2(c) does not cover DSI, the Rules and Regulations purporting to subject DSI to ABS obligations may be struck down on ultra vires grounds by a court reviewing any challenge from an entity disputing an NBA demand. The regulatory bridge, however well-intentioned, rests on constitutionally unstable ground.

The Counter-Argument and Why It Does Not Prevail

It would be intellectually dishonest to present the case for DSI inclusion without seriously engaging the opposing position. The argument against automatic DSI inclusion rests on three considerations worth examining on their merits. The textualist point has been noted: genetic material in the BDA, CBD, and Nagoya Protocol refers to physical matter, and courts generally resist extending statutory definitions through interpretive creativity when Parliament could have legislated directly. The 2023 Amendment's silence on DSI could itself be read as deliberate legislative inaction, which some interpretive traditions treat as implying no extension was intended. Beyond the textual argument, there is a genuine innovation concern. Research relying on public DSI databases

produces benefits that extend to developing countries, including India. A 2022 study in *Biodiversity and Conservation* documented the measurable contribution of open DSI access to pandemic preparedness efforts in low-income countries. Restricting this access in the name of benefit-sharing would impose costs disproportionate to the benefits if the compliance burden falls at the point of data retrieval, effectively taxing the scientific commons.[19] Third, there is a traceability difficulty: many sequences in public databases were uploaded years or decades ago by researchers operating under ABS frameworks that did not contemplate DSI, and holding current researchers accountable for the provenance of a sequence uploaded in 1995 raises legitimate questions of retroactive liability. These arguments do not justify the status quo, but they do counsel a specific design choice.[20] Benefit-sharing obligations should attach at the point of commercialisation not at the moment of data access. The academic researcher, the conservation biologist, the public health scientist should be able to query GenBank freely. Only the entity that converts DSI into a commercially valuable product and seeks intellectual property protection should face the benefit-sharing obligation. This is precisely the design Brazil has adopted[21], and it is the model that resolves the tension between open science and equitable benefit-sharing without sacrificing either value.

Comparative Analysis: India and Brazil

Brazil's Law No. 13,123, enacted on 20 May 2015, is the most advanced primary ABS legislation in the world in terms of DSI coverage. Article 2, Item I defines genetic heritage (*patrimônio genético*) as the genetic information from plants, animals, microbial species, or any other species, including substances originating from the metabolism of these living organisms. The definition is explicitly information-based. It does not require physical matter; it reaches the genetic information contained within or originating from biological organisms, regardless of the form in which that information is accessed or stored. Decree No. 8,772/2016, which implements the Law, requires that when a researcher registers access in Brazil's national management system SisGen they must declare the country of origin of the genetic heritage, even if the sequence was obtained from an in silico source, meaning a database rather than a physical sample.[22]The benefit-sharing obligation is calibrated to the point of commercialisation. A researcher can freely access Brazilian genetic sequences from any database for research purposes. The obligation to register and share benefits arises only when research results are published, when an intellectual property application is filed, or when a product enters the market. This is not merely an administrative convenience; it is a principled statutory design that separates the scientific freedom to access data from the commercial obligation to share the benefits of exploiting it. The Law also establishes a National Benefit-Sharing Fund the Fundo Nacional para a Repartição de Benefícios (National Benefit-Sharing Fund of Brazil) (FNRB) to receive and distribute the payments generated by DSI commercialisation, providing an institutional channel that neither provider communities nor regulatory authorities need to monitor individually.[23]Two lessons emerge from this comparison. The decision to define genetic heritage as information rather than material is a small textual choice with large legal consequences. It makes DSI inclusion the natural and ordinary result of applying the statute, rather than a regulatory extension that strains against the statutory text. Second, Brazil's framework shows that it is possible to design a system where scientific access remains open and unconditioned, while commercial extraction is subject to a clear and proportionate benefit-sharing obligation. India's 2025 Regulations move in this direction, but they need the authority of primary legislation to be legally secure.

The Multilateral Benefit-Sharing Mechanism and India's Strategic Position

Domestic reform, necessary as it is, cannot by itself solve the global dimension of the DSI problem. DSI is accessed from databases maintained in the United States, Europe, and Japan, by researchers operating in dozens of jurisdictions. Even a well-drafted amendment to the BDA cannot compel a German biotech company to comply with NBA approval requirements if it never physically enters India. For the benefit-sharing obligation to reach those who are actually exploiting Indian biodiversity through digital channels, a global mechanism is essential.

At COP-15 (Conference of the Parties)in Montreal in December 2022, the parties to the CBD agreed for the first time to include DSI in the benefit-sharing architecture of the Post-2020 Global Biodiversity Framework. Target 13 of the Kunming-Montreal Framework specifically addresses the equitable sharing of benefits from DSI, and a Working Group

was established to design a Multilateral Mechanism for this purpose. The preferred design in most technical studies is a sector-based levy on commercial revenues from DSI-derived products in pharmaceuticals, cosmetics, and agricultural biotechnology, with proceeds flowing into a Global Fund for biodiversity conservation and benefit-sharing. The rationale for a sector levy rather than a transaction-by-transaction bilateral model is practical: tracing every database query to a specific country of origin is technically impossible in many cases, while a levy on sectors that systematically benefit from DSI achieves a rough justice that is both feasible and proportionate. India should advocate for an MLM governance structure where megadiverse developing countries hold proportionate representation and where disbursements reach local Biodiversity Management Committees established under the BDA the institutions closest to the communities whose stewardship created the biological diversity being commercially exploited.

Generative Biology and the Data Governance Deficit

The legal urgency of the DSI gap is compounded by a technological development that moves faster than any legislature. Generative biology the use of artificial intelligence and machine learning to design new genetic sequences has reached a stage where a pharmaceutical company can train a model on millions of existing sequences from public databases and use that model to generate novel bioactive compounds without reference to any specific sequence. This creates a second-order regulatory problem. Even if DSI is included in the BDA through a statutory amendment, a product developed through generative AI may be sufficiently distant from any specific Indian sequence that the disclosure obligation under the WIPO Treaty and the benefit-sharing obligation under the BDA cannot be practically enforced. The legal category of derivative, already contested in the physical-resource context, becomes almost impossibly difficult to apply when the productive input is a statistical model trained on millions of sequences from hundreds of countries.[24]A partial response lies not in restricting data access but in improving data governance. Global Biodiversity Framework (Kunming-Montreal, 2022) (GenBank) , ENA, and DDBJ currently do not require researchers to declare the country of origin of the biological material from which an uploaded sequence was derived, nor to certify compliance with the ABS law of the source country. This means provider countries cannot monitor what happens to their sovereign genetic heritage once it enters the international database system. A metadata protocol requiring country-of-origin declaration and ABS compliance certification as a condition of sequence submission aligned with the FAIR principles (Findable, Accessible, Interoperable, Reusable) and the CARE principles (Collective Benefit, Authority to Control, Responsibility, Ethics) would not restrict research access to sequences but would create a traceability record that becomes relevant when commercial exploitation occurs. India should support the adoption of such a protocol internationally while, in the interim, requiring under the amended BDA that researchers accessing Indian biological resources for sequencing register the resulting sequences with the NBA, as the 2025 Regulations partially contemplate.

Recommendations for Legal Reform

The most important reform India needs is a direct amendment to Section 2(c) of the BDA. The definition of biological resources should be expanded to add an explicit sub-clause to the effect that it includes Digital Sequence Information, meaning the digitised representation of the genetic or biochemical composition of any plant, animal, or micro-organism originating from India, regardless of the medium or source through which such information is accessed. This single amendment would give the BD Rules 2024 and the NBA Regulations 2025 the statutory authority they currently lack, resolving the ultra vires vulnerability without disrupting the broader architecture of the Act. Alongside this definitional amendment, the value-added product exemption in Section 2(p) needs clarification. A targeted proviso should make clear that compounds or products generated through the digital exploitation of Indian genetic information where those products function as substitutes for naturally occurring biological active compounds do not qualify as exempt VAPs. Without this, the synthetic biology loophole remains open even after a DSI amendment to Section 2(c). On enforcement, the 2023 Amendment's decriminalisation deserves reconsideration in the specific context of DSI misappropriation by foreign commercial entities. The policy rationale for decriminalisation protecting AYUSH practitioners and small domestic businesses from disproportionate criminal exposure does not apply to large

pharmaceutical companies deliberately circumventing ABS obligations to commercialise products derived from Indian genetic heritage. The NBA should be empowered to seek invalidation of IPRs granted on the basis of DSI accessed from India without compliance, both before the Indian Patent Office and, pursuant to the WIPO Treaty's disclosure framework, before foreign patent offices. Finally, India's Traditional Knowledge Digital Library should be expanded to include associated genetic sequence data for the medicinal species documented within Ayurveda, Unani, Siddha, and Yoga systems, as well as oral traditional knowledge gathered under appropriate community consent protocols. An expanded Traditional Knowledge Digital Library, cross-referenced with international patent databases, would function as a systematic prior art resource for patent examinations conducted under the WIPO Treaty's disclosure mechanism, identifying DSI-based patent claims that lack novelty or inventive step in light of India's traditional medicinal knowledge.

Conclusion

The governance of Digital Sequence Information represents one of the most technically and politically complex challenges in contemporary intellectual property and biodiversity law. India has a direct and urgent stake in resolving it, because its biodiversity and traditional medicinal knowledge constitute a national resource that is, under existing legal arrangements, being commercially exploited without adequate legal recourse. What the analysis reveals is that the problem is not fundamentally one of regulatory will the NBA's attempt to extend ABS obligations to DSI through the 2025 Regulations shows that the institutional instinct is correct. The problem is one of statutory authority. The Biological Diversity (Amendment) Act, 2023 missed the opportunity to provide it. The WIPO Treaty, for all its value as a patent disclosure mechanism, has left the DSI question to domestic implementation. Brazil's Law No. 13,123/2015 demonstrates, with commendable clarity, that a legislature can resolve this question in primary legislation using information-based definitional language that encompasses DSI without impeding scientific access.A targeted amendment to Section 2(c) of the BDA, modelled on Brazil's approach and informed by the commercialisation-stage benefit-sharing mechanism already reflected in India's 2025 Regulations, would bring India's domestic framework into alignment with both scientific reality and international policy direction. This is not a complex or expensive reform. It requires political will and legislative precision rather than institutional overhaul. The communities and ecosystems of India's megadiverse landscapes have, for generations, sustained the biological heritage that is now being sequenced, digitised, and commercially exploited. Giving them the legal protection they are owed is a question of both doctrinal coherence and fundamental fairness.

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