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THE LEGAL REGULATION OF GENE EDITING AND DIGITAL BIOPIRACY: A JURIDICAL STUDY

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ABSTRACT

The paper investigates how genome editing practices create international biodiversity law problems, which currently exist as **"Biopiracy 2.0**." The shift of biotechnology research from physical biological materials to **Digital Sequence Information (DSI)** causes existing legal systems, which include the **Convention on Biological Diversity (CBD)** and the **Nagoya Protocol**, to face a "materiality trap." Modern gene-editing technologies such as CRISPR-Cas9 enable users to extract genetic data from its original biological source, which they can use to develop proprietary genetic materials that do not require Access and Benefit-Sharing (ABS) agreements.

The research examines how 20th-century environmental laws create a "forensic mismatch" that disrupts the synthetic biology innovations of 21st-century scientists. It explores how "Product-Based" exemptions for SDN-1 and SDN-2 edits facilitate regulatory arbitrage and digital colonialism, where the Global South's genomic wealth is extracted as open-access data and sold back as privatized intellectual property.

The research concludes by proposing a normative roadmap for **Informational Sovereignty**. It advocates for a shift from bilateral contract law to a "functional approach" to genetic resources, supported by the **WIPO Treaty (2024)** and cryptographic safeguards like blockchain-based "Smart-ABS" contracts. The paper demonstrates that international law needs to adopt "Lex Cryptographia" as its new standard for protecting digital blueprints of biodiversity, which establishes sovereign rights and bio-justice as permanent rights throughout the age of non-physical biological entities. The paper demonstrates that international law requires the adoption of "Lex Cryptographia" as its fundamental framework to secure digital biodiversity blueprints.

Keywords: Digital Sequence Information (DSI), Biopiracy 2.0, Informational Sovereignty, Regulatory Arbitrage, Nagoya Protocol

CHAPTER I: INTRODUCTION

Background of the Study: The Dematerialization of Biology

The traditional understanding of biopiracy was rooted in the physical misappropriation of biological resources—a "tangible" theft of plants or seeds. However, the rise of **CRISPR-Cas9** and high-throughput sequencing has ushered in a "digital turn" in biotechnology. Genetic information is no longer tied to its physical host; it is now stored, shared, and modified as **Digital Sequence Information (DSI)**.

This study explores the juridical crisis where the "genetic blueprint" is treated as an open-access data commodity, while the "genetic material" remains under sovereign protection. This creates a loophole where innovation in the Global North, powered by gene editing, can bypass the Nagoya Protocol's (2010) requirement for fair and equitable benefit-sharing.

Statement of the Problem: The Definitional Lacuna

The main issue lies in a **legal vacuum that is** created by a lag caused by the gap between technological advancement and statutory evolution.

- **The Materiality Trap:** The Convention on Biological Diversity (CBD), 1992, provides for a definition of genetic resources as "genetic material containing functional units of heredity." Current juridical interpretations continue to exclude DSI from regulatory scope.
- **The Gene Editing Paradox:** Technologies like CRISPR-Cas9 allow for SDN1 and SDN2 modifications that are indistinguishable from natural mutations. This makes it legally difficult to distinguish between an "invention" (patentable) and a "discovery" (non-patentable), leading to a surge in patents on genome editing technologies that may effectively privatize natural genetic traits.

Research Questions

1. **Redefining Sovereignty:** How does the digitization of genetic resources undermine the principle of "Sovereign Rights over Natural Resources" as enshrined in the CBD?
2. **IPR and In-Silico Access:** To what extent does the current Intellectual Property regime permit "Biopiracy 2.0" by ignoring the digital origin of gene-edited sequences?
3. **Regulatory Harmonization:** Is the ‘Cali Fund’ "Multilateral Mechanism" (as operationalized at COP16) more legally viable than the current bilateral "Prior Informed Consent" (PIC) model for DSI?

Hypothesis

This study operates on the hypothesis that the **juridical distinction between "material" and "information"** is a legal fiction that facilitates digital biopiracy. Unless international law adopts a "functional approach"—where the value is placed on the *information* rather than the *physical sample*—the Nagoya Protocol will become a dead letter in the age of synthetic biology.

CHAPTER II: LITERATURE REVIEW

Biology Without Borders: The Rise of the Sequence

The **Digital Sequence Information (DSI)** and the advent of high-rise sequencing provided for the paradigm shift from rudimentary stages of **Biopiracy 1.0** to a more evolved Biopiracy 2.0 form. In this contemporary phase, there is a shift toward biological utilization into the digital domain, where access occurs independently of territorial or physical interaction.

If a scientist in a laboratory in Europe downloads the genetic sequence of a drought-resistant plant from an Indian database and uses **CRISPR-Cas9** to replicate that trait in a local variety, this digital access may fall outside the scope of mandatory benefit-sharing. This represents a systemic failure of the "Physicalist" approach to international environmental law.[1]

Common Heritage or Stolen Wealth? The Legal Clash Over DNA

The evolution of biopiracy has polarized the legal discourse.

- **The Global South Perspective:** Nations argue that DSI is a functional extension of the physical resource. Treating it as "Open Access" data constitutes a modern form of **Digital Colonialism**, where the biological wealth of the South is extracted for the digital libraries of the North, fueling the multi-billion-dollar gene-editing industry while bypassing the Biological Diversity Act (2002).
- **The Global North Perspective:** Scientific organizations and developed states argue that "locking up" DSI behind paywalls or complex Access and Benefit Sharing (ABS) contracts would stifle global innovation. They cite the Common Heritage of Mankind

[1] B. Gates, "DIGITAL BIOPIRACY TO UNDERMINE INTERNATIONAL TREATIES THAT PROTECT BIODIVERSITY AND PREVENT BIOPIRACY," *COP13 - Convention on Biological Diversity*, [Online]. Available: https://navdanyainternational.org/wp-content/uploads/2020/10/SECTION-2-BIOPIRACY-BG-REPORT.pdf#:~:text=DSI%20facilitates%20%E2%80%9Cdigital%20biopiracy%E2%80%9D%20because%20it%20allows,from%20genetic%20information%20(metabolites)%20and%20even%20environmental.

doctrine, suggesting that genetic information should be a public good to facilitate rapid responses to climate change and pandemics.[2]

The literature identifies this clash as the "Great Bio-Justice Debate." The research gap identified here is that while we understand the *history* of physical biopiracy, the *legal architecture* for regulating the flow of digital sequences—and the subsequent gene-editing patents—remains fragmented and dangerously unenforceable.[3]

Breaking the Stalemate: The Multilateral Mechanism's Role in Bio-Justice

The **Multilateral Mechanism (MLM) has had its emergence traced within recent literature from the** 2024/2025 UN Biodiversity Summit.[4] This is a proposed legal "third way":

- **Decoupling Access from Benefit-Sharing:**[5] Instead of requiring a contract for *every* sequence downloaded (which is a logistical nightmare), the MLM suggests a global fund where companies using DSI (like those using CRISPR-Cas9) pay a percentage of their revenue.
- **The Juridical Challenge:** The gap in the literature remains: **Who decides the "fair" price?** And how does the law distinguish between a "purely scientific" edit and a "commercial" one? This research fills this gap by analyzing how the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge [GRATK] (2024)[6] might serve as an enforcement bridge by requiring disclosure of digital origin in patent applications.

The Product-Based Approach: The US and Indian "Exemption" Model

In contrast, the United States and, more recently, India have moved toward a **Product-Based**

[2]Sarath Babu Balijepalli, "Decoding sovereignty: The Global South's strategic stand over the 'source code' of future food," *Down to Earth*, Apr. 02, 2026. [Online]. Available: https://www.downtoearth.org.in/agriculture/decoding-sovereignty-the-global-souths-strategic-stand-over-the-source-code-of-future-food

[3]A. K. Soni, "Safeguarding Indigenous Knowledge in the Digital Age: A rights framework," *MaargX UPSC by SAARTHI IAS*, Apr. 05, 2026. https://iasaarthi.com/safeguarding-indigenous-knowledge-in-the-digital-age-a-rights-framework/#:~:text=The%20Biological%20Diversity%20Act%2C%202002,digitize%20and%20preserve%20cultural%20assets.

[4]"UN Biodiversity Conference (CBD COP16) - Global donor platform for Rural development," *Global Donor Platform for Rural Development*, Nov. 11, 2024. https://www.donorplatform.org/event/partner/un-biodiversity-conference-cbd-cop16/#:~:text=The%2016th%20meeting%20of%20the%20Conference%20of,framework**%20*%20**Development%20of%20the%20monitoring%20framework**

[5]https://www.cbd.int/abs/dsi-views/2019/africangroup-dsi.pdf

[6]"WIPO Treaty on IP, GR and Associated TK," *Traditional-knowledge*. https://www.wipo.int/en/web/traditional-knowledge/wipo-treaty-on-ip-gr-and-associated-tk

or "Trait-Based" philosophy. This model argues that if a gene-edited plant does not contain foreign DNA (transgenes) and could have theoretically occurred through natural breeding or conventional mutagenesis, it should not be regulated as a GMO.

- **The Indian Shift (2022-2025):** A significant body of literature analyzes the Ministry of Environment, Forest, and Climate Change's 2022 notification, which exempted SDN-1 and SDN-2 categories of genome-edited plants from strict biosafety assessment.[7]
- **The Juridical "Blind Spot":** Scholars argue that this "product-based" deregulation creates a significant loophole for **Digital Biopiracy**. If an edited product is exempt from the Biological Diversity Act (2002) because it "looks natural," there is no formal mechanism to check if the digital blueprint for that "natural-looking" trait was pirated from a foreign genetic database. This creates a scenario where the law is "blind" to the digital origin of the invention.[8]

The Disclosure Deadlock: Redefining Provenance for the Digital Age

The **Mandatory Disclosure Requirement (MDR)** serves as a main topic of discussion in current IPR research.

- **The Nagoya Gap** shows that developed countries, including the USA, lack legal requirements to disclose digital sources of genetic data usage. [9]
- **The WIPO Treaty (2024)** requires all inventors to disclose their inventions that utilize genetic resources.[10] The final purported definition of 'Genetic Resources' does not include DSI, which creates a significant vulnerability that enables 'Biopiracy 2.0' to operate.

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[7]Bhavani, K. L., Singh, Y., Gigaulia, P., Likhitha, K., & Jha, S. (2026). Perspectives on Genome Editing Techniques.PLANT CELL BIOTECHNOLOGY AND MOLECULAR BIOLOGY, 27(1-2), 173–198.https://doi.org/10.56557/pcbmb/2026/v27i1-210301
(PDF) Perspectives on Genome Editing Techniques. Available from: https://www.researchgate.net/publication/401272738_Perspectives_on_Genome_Editing_Techniques [accessed Apr 23 2026]

[8]"Deregulation of gene edited organisms poses a serious threat to biosecurity « Biosafety Information Centre." https://biosafety-info.net/articles/biosafety-science/emerging-trends-techniques/deregulation-of-gene-edited-organisms-poses-a-serious-threat-to-biosecurity/#:~:text=Gene%20editing%20could%20lead%20to,Conclusions [accessed Apr 23 2026]

[9]C. M. Holman, "Should the United States join treaty mandating patent disclosure requirements for genetic resources?," *Biotechnology Law Report*, vol. 45, no. 1, pp. 7–20, Jan. 2026, doi: 10.1177/0730031x251414290.

[10]"WIPO member states adopt historic new Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge." https://www.wipo.int/pressroom/en/articles/2024/article_0007.html

Limitations of Existing Literature

The environmental law and the intellectual property systems face an institutional deadlock due to the fundamental conflict between their two systems. While biodiversity frameworks emphasize sovereignty and equitable benefit-sharing, patent systems prioritize innovation and exclusive rights. The two systems operate without coordination, which enables entities to exploit legal gaps that exist, especially in relation to digital genetic information.

The different standardized disclosure requirements that exist in various jurisdictions create compliance uncertainty. Inventors operating in jurisdictions without mandatory disclosure obligations are able to bypass benefit-sharing mechanisms entirely, which undermines the objectives of international agreements such as the CBD and the Nagoya Protocol.

The resolution to this conflict requires patent law reform as well as greater links between the legal institutions that control genetic resources and intellectual property rights.[11]

CHAPTER III: BEYOND THE SEED: MODERNIZING LAW FOR A DIGITAL WORLD

Defining the "Resource": The Materiality Flaw

The most critical part of the argument lies in **Article 2 of the CBD**[12]. The treaty defines "Genetic Resources" as "genetic material of actual or potential value." It further explains "genetic material" through the definition "any material of plant, animal, microbial, or other origin containing functional units of heredity."

- **The Trap:** At the time of drafting in 1992, scientists had not yet advanced sequencing technology beyond its early development stage. Scientists and jurists considered genetic resources to be physical objects, which included leaves and seeds, and vials of blood.[13] The law established regulations to control the movement of atomic particles.
- **The Digital Disconnection:** This definitional limitation becomes critical in the context of DSI, where regulatory triggers tied to physical material are no longer activated.

[11]"Two Birds, Two Stones: Separating Biodiversity Conservation from Patent Law | Nebraska Law Review | Nebraska." https://lawreview.unl.edu/two-birds-two-stones-separating-biodiversity-conservation-patent-law/#:~:text=31%5D%20Contemporarily%2C%20corporate%20powers%20use,own%20environment/natural%20resources.%5B

[12]Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, art. 2.

[13]L. Glowka, "Implementing Article 15 of the CBD," 1997. [Online]. Available: https://www.cbd.int/doc/articles/2002-/A-00323.pdf

While the CBD text remains anchored in materiality, [14] the **establishment of the Cali Fund (2024)** represents a global attempt to bridge this gap by treating commercial DSI use as a trigger for benefit-sharing, effectively ending the era of 'free' digital access for large corporations.[15]

The CBD's definition system creates guidelines for biological resource control based on physical existence, which is no longer applicable due to developments in sequence-based scientific study.

The Bilateral Burden: PIC and MAT

At its foundation, the Nagoya Protocol rests on the principles of consent and equitable collaboration. It requires researchers to obtain prior informed consent from the provider state and to establish mutually agreed terms that ensure fair and equitable sharing of benefits arising from the use of genetic resources.[16]

- **The Juridical Requirement:** It requires researchers to obtain permission from the provider country (PIC) and sign a contract sharing future benefits (MAT) before they can access genetic resources.[17]
- **The DSI Loophole:** In the context of gene editing, the Nagoya Protocol only mandates these steps for "genetic resources" (physical material). [18]Digital access mechanisms bypass the procedural safeguards embedded within PIC and MAT frameworks. This creates a "jurisdictional bypass".[19]

This jurisdictional bypass becomes more apparent when examined in light of the scale at which Digital Sequence Information is accessed and utilized. Contemporary genetic databases, particularly those within the International Nucleotide Sequence Database Collaboration,

[14]R. Wynberg and S. A. Laird, "Fast science and sluggish policy: The herculean task of regulating biodiscovery," *Trends in Biotechnology*, vol. 36, no. 1, pp. 1–3, Sep. 2017, doi: 10.1016/j.tibtech.2017.09.002.
[15]"New fund to support Global Biodiversity Framework, Indigenous Peoples," *IISD SDG Knowledge Hub*, Feb. 26, 2025. https://sdg.iisd.org/news/new-fund-to-support-global-biodiversity-framework-indigenous-peoples/#:~:text=The%20Cali%20Fund%20was%20established,MoU)%20reflecting%20this%20institutional%20arrangement.
[16]Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, art. 5/6, Oct. 29, 2010, 3008 U.N.T.S.
[17]E. Morgera, E. Tsioumani, and M. Buck, *Unraveling the Nagoya Protocol: A commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity*. 2014. doi: 10.1163/9789004217188.
[18]UNDP-GEF PROJECT, *Access and benefit sharing in India*. [Online]. Available: http://nbaindia.org/uploaded/pdf/IDB_ABS.pdf
[19]A. H. Scholz *et al.*, "Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation," *Nature Communications*, vol. 13, no. 1, p. 1086, Feb. 2022, doi: 10.1038/s41467-022-28594-0.

contain over **228 million annotated sequences**, with approximately **1.5 billion sequence reads**, and are accessed through nearly **34 million downloads annually by an estimated 10–15 million users worldwide**.

In such a highly interconnected digital ecosystem, enforcing bilateral requirements such as prior informed consent and mutually agreed terms for each instance of access would be administratively unfeasible. Moreover, the value of genetic data is not derived from isolated use but from its integration within large datasets, where sequences are continuously reused, compared, and modified across jurisdictions. This makes it difficult to trace utilization back to a specific source or to operationalize traditional benefit-sharing mechanisms. As a result, the foundational structure of the Nagoya Protocol—designed for physical access—struggles to regulate the decentralized and iterative nature of digital genetic utilization.

Enforcement Failures and the "Traceability Gap"

The Protocol relies on **Compliance Checkpoints** (like patent offices[20]). However, most patent offices in the Global North do not recognize the lack of a CBD-compliant Mutually Agreed Terms as a valid reason to reject a biotechnology patent.[21]

- **The Juridical Outcome:** This creates a disconnect where a product can be "legal" under Patent Law but "pirated" under Environmental Law.[22] The research argues that the Nagoya Protocol is a **"De-linked" system**: it creates duties for researchers but provides no real "teeth" for the provider nations to enforce them once the sequence has been digitized and edited.[23]

From Biological "Samples" to Digital "Blueprints"

In the 1990s, utilizing a genetic resource required a physical sample—a leaf, a seed, or a vial. Today, synthetic biology allows for the "decoupling" of information from the material.

[20]Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity art. 17, Oct. 29, 2010, U.N. Doc. UNEP/CBD/COP/DEC/X/1.
[21]G. Dutfield, QUNO, and Quaker International Affairs Programme, "Thinking aloud on disclosure of origin," Oct. 2005. [Online]. Available: https://www.iprsonline.org/unctadictsd/docs/Disclosure_Dutfield.pdf
[22]J. D. Sarnoff and C. M. Correa, "Analysis of options for implementing disclosure of origin requirements in intellectual property Applications - a contribution to UNCTAD's response to the invitation of the Seventh Conference of the Parties of the Convention on Biological Diversity," *SSRN Electronic Journal*, Jan. 2006, doi: 10.2139/ssrn.2278629.
[23]D. on E. and L. Studies, B. on L. Sciences, B. on C. S. A. Technology, and C. on S. for I. and A. P. B. V. P. by S. Biology, "Biotechnology in the age of synthetic biology," *Biodefense in the Age of Synthetic Biology - NCBI Bookshelf*, Jun. 19, 2018. https://www.ncbi.nlm.nih.gov/books/NBK535871/

- **The Juridical Break:** This process involves no physical "access" to the source country. Consequently, the legal "trigger" for benefit-sharing—which is based on physical access—is never pulled. This confirms the **Hypothesis** that the law's "physical bias" renders it obsolete in the face of synthetic biology. This transition from physical access to data-driven utilization disrupts the foundational assumptions of existing regulatory frameworks.

CRISPR-Cas9 and the "Natural Variant" Legal Defense

The status of **SDN-1 and SDN-2** modifications presents a complex legal challenge that emerges from gene editing technology.

- **The SDN Distinction:** CRISPR enables scientists to create minute genetic changes that produce results that researchers cannot differentiate from natural genetic variations. [24]
- **The Regulatory Loophole:** The scientific distinction allows corporations to claim their products do not require stringent regulation under the Biological Diversity Act (2002). If a product is "natural-like," it bypasses the "biopiracy" checkpoints, even if the blueprint for that "natural" trait was obtained digitally from a sovereign state's biodiversity.

CHAPTER IV: THE JURIDICAL MECHANICS OF GENE EDITING AND INTELLECTUAL PROPERTY

The Technical-Legal Interface: "Invention" vs. "Discovery"

The foundational tension in biotechnology patents lies in the **Product of Nature** doctrine. [25]Under Section 3(c) of the Indian Patents Act, 1970, "mere discoveries" of naturally occurring substances are non-patentable.[26] However, the emergence of high-precision gene editing disrupts this binary by allowing for modifications that are functionally identical to natural processes.

The Jurisdictional Bypass of "In-Silico" Access

The traditional MDR framework was designed to track the movement of physical and biological material across borders.[27]

[24]"EC study on new genomic techniques," *Food Safety*. https://food.ec.europa.eu/plants/genetically-modified-organisms/new-developments-biotechnology/ec-study-new-genomic-techniques_en
[25]*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)
[26]Indian Patents Act,1970 §3(c)
[27]S. A. Laird, R. P. Wynberg, People and Plants International, University of Cape Town, A. Iranzadeh, and A. S. Kooser, "FACT-FINDING AND SCOPING STUDY ON DIGITAL SEQUENCE INFORMATION ON

- **The Disclosure Loophole:** When a researcher utilizes **CRISPR-Cas9** to edit a plant based on a sequence downloaded from a database like GenBank, they frequently claim a "laboratory-synthesized" origin for the genetic material.
- **Legal Decoupling:** This results in a functional disconnection between access mechanisms and regulatory oversight.

The Patent Office as a "Laundering" Station

A central thesis of this study is that without explicit digital disclosure mandates, the patent office inadvertently facilitates **Digital Biopiracy**.

- **Administrative Silence:** Currently, most international patent forms do not include a specific field for **"Digital Origin"** or **"DSI Metadata."** This administrative oversight permits "Juridical Laundering" to occur because uncompensated genetic data becomes transformed into legally protected commercial property.
- **The Burden of Proof:** Nehring 2022 shows that the provider state must prove all cases of misappropriation which must be proven. This shifts the burden of proof onto provider states, often beyond their technical and institutional capacity.

The Patent vs. Regulation Paradox

The research demonstrates that biotechnology companies exhibit a fundamental inconsistency when they present their SDN-1 and SDN-2 gene-edited products to various legal platforms.:

- **The "Natural" Defense for Biosafety:** Corporations present CRISPR-edited crops as "substantially equivalent" natural variants in environmental and biosafety forums because their genetically modified organisms lack foreign DNA. The Indian authorities used this reasoning to create an exemption from strict GMO regulations for particular plant species in their 2022 notification.
- **The "Novel" Claim for IPR:** Conversely, in patent offices, the same firms must argue that the product is "novel" and "non-obvious" to secure a 20-year monopoly.
- **Juridical Critique:** This creates a **"Double-Standard"** in the law. A product is "natural enough" to avoid the benefit-sharing and biosafety duties of the Biological Diversity Act (2002), yet "innovative enough" to be privatized under the Patents Act (1970).

GENETIC RESOURCES IN THE CONTEXT OF THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE NAGOYA PROTOCOL," Jan. 2018. [Online]. Available: https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf

The "DSI Ambiguity": A Fatal Flaw?

A critical analytical finding of this study is the treaty's silence regarding **Digital Sequence Information (DSI)**.

- **The Definitional Constraint:** While the treaty covers "genetic resources," it does not explicitly define them to include digital data. If interpreted narrowly (material-only), the treaty will fail to regulate **Biopiracy 2.0**, where the genetic resource is accessed via a database rather than a physical forest.
- **The "Based On" Test:** It could be argued that the phrase "based on" must be interpreted to include digital blueprints. If a CRISPR-edited plant is "based on" a sequence from India, the disclosure duty should be triggered regardless of the medium (atom vs. bit).

CHAPTER V: THE GLOBAL FAULT LINES: A COMPARATIVE STUDY OF BIO-REGULATORY PHILOSOPHIES

Guarding the Biological Front Door: The EU's Precautionary Paradigm

The European Union is quite evident in its approach, maintaining a cautious outlook to biotechnology research, which is different from the fast-paced methods of international technology development. The EU employs the Precautionary Principle, which serves as its testament to its commitment toward safeguarding environmental resources despite incomplete scientific knowledge.[28]

The Indian "SDN-Exemption" and its Juridical Aftermath

The 2022-2024 timeline provides for an era that showcased significant changes for Indian bio-law with the implementation of novel regulatory systems. It is important to analyse Article 21 of the Indian Constitution along with the Public Trust Doctrine that serves as a framework for analysing this initiative. The state creates a paradox, SDN-1 and SDN-2 category exemption from the Environmental Protection Act (1986), even as it seeks advances in the scientific front. This, therefore, undermines its capacity to protect its sovereign genetic resources.

To ensure complete mitigation of institutional weakness, it is important to consider the National Biodiversity Authority (NBA). The NBA's enforcement mechanisms are designed for the "physical" collection of herbs and biological samples. When a gene-edited product is exempted

[28] D. Bourguignon and European Parliamentary Research Service, "The precautionary principle," report PE 573.876, Dec. 2015. doi: 10.2861/821468.

from biosafety oversight, it effectively slips through the NBA's benefit-sharing net. For example, if a domestic lab uses DSI from a drought-resistant indigenous millet variety to "edit" a commercial crop, the lack of a "physical trigger" means the NBA is never notified. This creates an Internal Regulatory Gap where India's attempt to promote innovation erodes the very "Sovereign Rights" it championed in the 2002 Act.[29]

The United States and the Absence of Access and Benefit-Sharing Obligations

The United States represents a distinct "Deregulated Model" that serves as the primary foil to the EU's Precautionary Paradigm. 196 nations are signatories to the **Convention on Biological Diversity (CBD)** as well as the **Nagoya Protocol; the United States is not part of either**. This creates a conflict regarding Access and Benefit-Sharing (ABS) obligations that cannot be legally overseen.

In the American jurisdiction, the "Open Science" model dominates, viewing genetic resources as common heritage or raw data for innovation. From a juridical standpoint, US law prioritizes the **Patent System** over sovereign resource rights. Under the current framework, there are no federal domestic requirements for researchers to obtain Prior Informed Consent (PIC) or establish Mutually Agreed Terms (MAT) when accessing genetic sequences, provided the material is not obtained through theft. This absence of ABS obligations creates a "Safe Harbor" for biotech firms to utilize DSI harvested from the Global South without any legal mandate to share profits. This study posits that the US position acts as a global "sink" for digital biopiracy, where the informational value of sovereign resources is converted into private intellectual property through the "Myriad Shadow" of synthetic cDNA.

Synthesis: The Emergence of "Regulatory Arbitrage" in the Digital Era

The divergence between the EU's "Process-Based" caution and the "Product-Based" exemptions seen in India and the US creates a fragmented global landscape. This lack of unity acts as a catalyst for Regulatory Arbitrage, where genetic research and commercialization migrate to permissive jurisdictions to bypass benefit-sharing obligations.

The Re-characterization of Genetic Data: This study posits that digital sequences are effectively re-characterized through jurisdictional shifts. A sequence originating in a high-protection

[29]Department of Biotechnology, Ministry of Science & Technology, Government of India, "Standard Operating Procedures for Regulatory Review of Genome Edited Plants under SDN-1 and SDN-2 Categories," 2022. [Online]. Available: https://www.iari.res.in/files/Latest-News/Standard_Operating_Procedures_SDN1_and_SDN2_07102022.pdf

regime can be digitally transferred and synthesized in a deregulated environment, emerging as a "new" product that is legally severed from its sovereign origins.

The Limits of Bilateralism: The Nagoya Protocol's bilateral model is increasingly inadequate in addressing DSI-driven exchanges. As digital sequence information becomes the primary medium of utilization, traditional access-based regulatory frameworks lose their effectiveness, while digital modes of access remain largely unregulated and susceptible to exploitation. For India, this results in a dual vulnerability—both as a source of genetic data and as a jurisdiction attempting to balance innovation with bio-sovereignty.

Towards a Harmonized Legal Framework for Digital Genetic Resources

The preceding analysis demonstrates that the fragmentation of global regulatory approaches has created systemic vulnerabilities in the governance of genetic resources. The examination of Digital Sequence Information (DSI) shows how this governance system becomes vulnerable to its regulatory patches that depend on specific jurisdictional frameworks. The existing challenges need a complete solution, which requires international legal systems to develop unified regulations that match current gene editing and digital biopiracy technologies.

CHAPTER VI: THE JURISPRUDENTIAL FRONTIER – A COMPARATIVE STUDY OF NATIONAL DIVERGENCE

The Indian Model: Statutory Obsolescence and the Egalitarian Crisis

The Indian approach to human genome editing and biotechnology is a study in **Bio-Regulatory Dissonance**. On one hand, India is a fierce advocate for "Sovereign Rights" over biological resources; on the other, its domestic regulatory infrastructure remains anchored in 20th-century paradigms that fail to recognize the digital reality of modern genetics. As analyzed, India's primary challenge is a profound **Statutory Obsolescence**, where the laws intended to protect the environment are being stretched to govern the most intimate building blocks of human life.

CHAPTER VII: THE FORENSIC MISMATCH: ASSESSING THE EFFICACY OF 20TH-CENTURY ENVIRONMENTAL LAW IN THE AGE OF CRISPR

The Dematerialized Native: Reconfiguring National Authority over Genomic Assets

The historic basis of supranational bio-law, which originates from Article 15 of the Convention on Biological Diversity (CBD), depends on a 20th-century geopolitical framework that

establishes Territorial Sovereignty as its foundation. This legal paradigm assumes that a state's authority over its genetic resources is an extension of its physical land rights. However, the transition from tangible biological matter to Digital Sequence Information (DSI) has fractured this geographical link, creating a crisis of jurisdiction. The utility of genetic resources has undergone a "Phase Shift"—the economic and scientific value is no longer stored in the physical mass of a seed or a tissue sample, but in the computational potential of its decrypted code.[30]

The Collapse of Traditional Legal Categories: The Category Error of 20th-Century Law

The global regulatory crisis is fundamentally a Category Error. Modern bio-law is currently paralyzed by three primary binary collapses: GMO vs. Natural, Product vs. Process, and Material vs. Informational. These distinctions were forged in an era of "transgenic" biology (moving DNA from one species to another), but they are functionally useless in the era of Site-Directed Nucleases (SDN-1 and SDN-2).

Digital Biopiracy as a New Form of Colonialism: Data Extraction and Value Capture

This section theorizes Digital Biopiracy as Data Colonialism. While 19th-century colonialism involved the physical extraction of land, ivory, and labor, 21st-century colonialism involves the computational extraction of genomic value. The Global South remains the "Biodiversity Source," providing the raw genomic data, while the Global North functions as the "IP Owner," utilizing advanced computational tools to lock that data behind a "Paywall" of Intellectual Property Rights.[31]

Towards a New Legal Paradigm: The 2026 "Living Statute."

The section develops a global bio-law framework through its implementation of policy recommendations, which Chapter VI established, so that it can develop new bio-law systems. To rectify the failures identified in the Indian, Russian, and Korean models, this research proposes a Normative Architecture that moves beyond the failed bilateralism of the Nagoya Protocol. The 2024 WIPO Treaty, together with the CODATA findings from 2025, establishes the foundation for this new paradigm.

[30]M. Arita, "Data Sovereignty and Open Sharing: Reconceiving Benefit-Sharing and Governance of Digital Sequence information," *Data Science Journal*, vol. 24, Jan. 2025, doi: 10.5334/dsj-2025-009.
[31]K. R. Srinivas, "Ikechi Mgbeoji: Global biopiracy: patents, plants and indigenous knowledge," *Agriculture and Human Values*, vol. 26, no. 4, pp. 401–402, Jul. 2009, doi: 10.1007/s10460-009-9227-4.

Conclusion: The Way Forward

The process of digitalizing genetic resources brings forth a crucial legal conflict that exists within international law frameworks. The current legal frameworks continue to define biological resources through physical assets because biotechnology now permits scientists to handle and use genetic materials. The existing regulatory systems face operational challenges because the current situation has created fundamental structural problems that lead to their ineffective operation.

The legal systems that prioritize material evidence continue to exist because digital genetic information has become essential to legal systems that govern genetic research. The combined effect of fragmented regulatory systems and incomplete statutory structures enables companies to extract genetic resources while they transform and sell these resources without proper acknowledgment of their source. This situation results in a situation where economic advantages become unequally distributed, which leads to greater economic hardship for areas that contain rich biodiversity.

The shift from biological sovereignty to informational sovereignty requires a legal transformation that goes beyond technical modifications. The governance frameworks for genetic resources need to develop new methods that can handle digital genetic materials. The traditional understanding of sovereignty will become ineffective because of technological advancements unless these two elements are brought together through technological advancements.

The future of bio-law requires authorities to create regulatory systems that can adapt to current challenges while protecting fundamental rights through comprehensive systems. The legal system needs to establish digital genetic resource rights, develop better tracing systems, and create global partnerships to achieve equitable and sustainable distribution of biotechnology benefits.

The essential issue exists between two questions that require separate answers. The question requires an answer about whether legal systems can adapt to technological progress while maintaining the essential legal concepts of sovereignty, accountability, and justice. The governance systems of genetic resources need to develop new legal frameworks that will enable them to function effectively in the digital age.[32]

[32]Secretariat of the Convention on Biological Diversity, “Kunming-Montreal Global Biodiversity Framework.” https://www.cbd.int/gbf