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DIGITAL SEQUENCE INFORMATION PATENTABILITY: WHEN GENOMIC DATA BECOMES PRIOR ART

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ABSTRACT

The fast development of genomics, bioinformatics, and digital sequencing technologies has led to the transformation of biological material into digitised genetic sequences, which have been termed Digital Sequence Information (DSI). This has resulted in a major shift in the architecture of biotech innovation since there has been a shift from the physical biological material used for innovations to digital genetic information. This paper explores the emerging legal and policy challenges associated with the patentability of inventions based on DSI and the growing recognition of genome databases as previous art. The author argues that the publicly accessible and technically feasible DSI ought to be considered as legally recognised previous art, particularly where the genetic sequences can be found in publicly available databases before applying for the patent. It has been stated that too stringent an approach towards previous art will undermine innovations in drugs, diagnostics, synthetic biology, and agricultural biotech.

This paper investigates the link between DSI and the three essential aspects of patenting, which are novelty, inventiveness, and disclosure. It takes note of the emerging clash between open science doctrines and the closed, proprietary patent system. This paper compares the U.S., the European Union, the United Kingdom, and India in respect to recognising DSI as an emerging trend in law. Notable are the differences between the jurisdictions regarding enabling claims, enablement, and contribution by technology. The major focus of the paper will be laid upon the biotechnology patenting system in India as provided for under Sections 3(c), 3(j), and 10(4) of the Patents Act 1970, together with its broader implications from Novartis AG vs. Union of India. The latest developments concerning the CBD and the WIPO treaty negotiations will also be evaluated, with particular regard to the fact that governance of DSI calls for an international regulatory regime.

I. INTRODUCTION

Recent advances in genomics, next-generation sequencing, and bioinformatics have transformed biological material into digitally accessible genetic information. Large-scale sequencing technologies and global data infrastructures now permit the rapid conversion, storage, and sharing of genetic sequence data in machine-readable forms. This transformation has shifted contemporary biotechnology innovation from dependence on physical biological material toward

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the increasing use of Digital Sequence Information ["**DSI**"].[1] DSI generally refers to digitised nucleotide and amino acid sequence data, together with associated structural, functional, or annotation-related information derived from biological resources..[2] Despite its growing importance in genomics, synthetic biology, vaccine development, and precision medicine, there remains no universally accepted legal definition of DSI in international law. Significantly, two important documents in international biodiversity governance, namely, the Convention on Biological Diversity and the Nagoya Protocol, do not contain a clear-cut definition of what DSI is.[3] The said documents were elaborated in a context where access to genetic resources was essentially about access to physical biological material.[4] The dematerialisation of genetic information has illustrated a conceptual and legal gap between the present international rules and advances in scientific technology.[5]

A major scientific significance of DSI is that it can be easily used, developed, and accessed. This is mainly due to the availability of sequencing projects that are government-funded. This ensures that the regulation concerning open access is standardised.[6] This model has substantially accelerated collaborative scientific research and innovation, particularly during the COVID-19 pandemic, when the rapid public release of the SARS-CoV-2 genome sequence enabled unprecedented speed in the development of vaccines and diagnostic technologies.[7]

At the same time, the openness of DSI has generated serious legal and distributive concerns. Biodiversity-rich nations have increasingly argued that unrestricted digital access to genetic information may permit the circumvention of existing access and benefit-sharing ["**ABS**"] frameworks established under the CBD and the Nagoya Protocol.[8] The ability to utilize genomic information without obtaining physical biological material has intensified concerns regarding bioprospecting, inequitable exploitation of genetic resources, and the erosion of sovereign control over biodiversity-derived innovation.[9]

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[1] SHEILA JASANOFF, THE ETHICS OF INVENTION: TECH. AND THE HUMAN FUTURE 87-90 (2016).
[2] *Convention on Biological Diversity*, Decision XV/9, Digital Sequence Information on Genetic Resources (2022).
[3] *Convention on Biological Diversity,* art. 2, June 5, 1992, 1760 U.N.T.S. 79.
[4] Frank Irikefe Akpoviri et al., *Digital Sequence Information and the Access and Benefit-Sharing Obligation of the Convention on Biological Diversity*, 17 NANOETHICS 1 (2023).
[5] Elisa Morgera, *Fair and Equitable Benefit-Sharing at the Crossroads of the Human Right to Science and International Biodiversity Law,* 4 LAWS 803, 810-12 (2015).
[6] Y. Nakamura et al., *The International Nucleotide Sequence Database Collaboration*, 30 NUCLEIC ACIDS RES. D21 (2012).
[7] Maria Deloria Knoll & Chizoba Wonodi, *Oxford-AstraZeneca COVID-19 Vaccine Efficacy*, 384 N. ENGL. J. MED. 1885 (2021).
[8] VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 49-52 (1997).
[9] Ruth L. Okediji, *Traditional Knowledge and the Public Domain*, 5 INDIAN J.L. & TECH. 1, 23-25 (2009).

Intellectual property law in general and patent law specifically have thus emerged as a significant area of contention in this scenario. Patent systems foster innovation by providing individuals with exclusive rights to new and non-obvious inventions, which are measured relative to pre-existing works. Conventionally, prior art consisted of patents, academic writings, and uses which provided others with access to technological information.[10] The advent of DSI complicates this scenario to some extent. Open-access genomic databases contain much sequence information developed before filings for patents.[11]

This is not only a technical problem but one that has great ramifications for distribution and policy. If DSI is considered prior art, then it can be used as a defence to circumscribe the authority of patent monopolies over genetic sequences or their derivatives. Simultaneously, patent examiners and applicants are in a quandary because neither party knows whether sequence data is evidential or enabling. Raw sequencing data may not indicate its utility or industrial applicability, but with the addition of standard bioinformatics tools, it may suggest future claims.[12] Thus, the question of when genetic data becomes legally useful information lies at the juncture of patent law, scientific epistemology, and digital infrastructure.

This article argues that DSI should be recognised as prior art where it is publicly accessible and technically enabling, but that such recognition must be applied carefully to avoid undermining legitimate biotechnology innovation. The article examines the scientific and legal ambiguities surrounding DSI, analyzes its implications for novelty, inventive step, and disclosure requirements, and evaluates comparative and international approaches toward the treatment of genomic information within patent law

II. Scientific and Legal Ambiguities of DSI

DSI occupies an uncertain position at the intersection of molecular biology, data science, and intellectual property law.[13] Scientifically, DSI refers to digitised nucleotide and amino acid sequence data together with associated annotations relating to biological structure or function. Such information forms the basis of contemporary genomics, synthetic biology, and computational biotechnology.

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[10] 35 U.S.C. § 102 (2018).

[11] Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1042-44 (1989).

[12] Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 UCLA L. REV. 691, 723-26 (2007).

[13] WORLD HEALTH ORGANIZATION, GENOMIC SEQUENCING OF SARS-COV-2: A GUIDE TO IMPLEMENTATION 4-6 (2021).

In scientific terms, the production of DSI is related to advances in the field of sequencing tools and techniques. The advent of high-throughput sequencing platforms has led to easier and faster deciphering of genomes, and currently, a massive amount of sequence information can be created at an unprecedented scale.[14] The sequences obtained are then organised and standardised, and they are stored either in the public domain or semi-public repositories. They are accompanied by details that make them more interpretable and reusable with greater ease. Digital sequencing technologies enable researchers to search a sequence database with algorithms, manipulate the sequences with computers, and prepare them as a template for other applications, such as gene manipulation and protein manipulation, or metabolic pathway development.[15]

The scientific worth of DSI is raised as it is able to interface with other systems effectively. Global database collaborations, for example, the International Nucleotide Sequence Database Collaboration, ensure that when sequence information is dispatched from a given location, it is swiftly replicated and made accessible to everyone globally.[16] Such a system has developed standards for open-access databases in genomics, and this reflects a basic scientific tenet that considers genetic sequence information as basic knowledge, and not intellectual property. The guiding ethical principle for this activity is that access improves cumulative innovation and prevents redundancy of efforts within scientific circles.[17] Nevertheless, the open science notion poses a challenge to patent law, which traditionally presupposes exclusivity and protection of intellectual property.

However, the status of DSI remains unclear in law. International law regarding biodiversity does not define DSI specifically, nor does it clearly define whether the digital form of genetic information falls under the term "genetic resources." The Convention on Biological Diversity defines "genetic resources" as "genetic material of actual or potential value." Genetic material is "any material of plant, animal, microbial, or other origin containing functional units of heredity."[18] Presently, no internationally accepted legal definition of DSI exists, which has led to much confusion regarding its legal standing and regulation. The concept applies the assumption of materiality, which can hardly be taken for granted under the circumstances, given the fact that

[14] Eric S. Lander et al., *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001).
[15] Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 450-52 (2005).
[16] *Supra* note 6, at 2.
[17] Robert Cook-Deegan & Stephen Heinemann, *The Public Domain of DNA*, 1 GENOME RES. 247, 249-51 (2000).
[18] *Convention on Biological Diversity*, art. 2, June 5, 1992, 1760 U.N.T.S. 79.

genetic information is severed from its material basis and begins flowing around digitally. The Nagoya Protocol does not cover the management of such genetic information either.[19]

This ambiguity in the definition has severe implications for regulation. For example, if DSI is considered genetic material, there would automatically be obligations regarding access and benefit-sharing in biodiversity conventions. However, if DSI is regarded as information or data, there would be no bindings in biodiversity conventions and would fall under open science and data regulation or intellectual property law. Since there is no consensus on the definition, various countries interpret and regulate DSI in their own manner. Some countries regulate DSI in their legislation in a manner that does not place any burden of access regulation on DSI, while others favour regulatory inclusion in the form of interpretation.[20]

The ambiguity concerning DSI is further complicated by the fact that it is a derivative of the original object. DSI comes from the process of extracting, sequencing, and analysing the biological material and thus leads to questions regarding whether it should be considered as a genetic resource or just knowledge derived from these resources.[21] According to the Nagoya Protocol, a "derivative" refers to a biochemical substance that occurs naturally and is produced as a consequence of the genetic expression or metabolism of biological resources. However, DSI cannot fit into this definition as it is mostly a collection of informational material and not a physical substance. This creates a great deal of ambiguity in the legal sense, particularly because the existing biodiversity regime was primarily developed for dealing with biological materials, whereas DSI represents intangible digital genetic information that can be reproduced infinitely.[22]

This ambiguity is most apparent in patent law and the realm of intellectual property in particular. The workings of patent law depend on being able to distinguish between discoveries that cannot be patented and discoveries that can be patented. Natural genetic sequences, if they exist in nature, have slowly been removed from patentability if they are only isolated, particularly with modifications to the law that emphasise the impossibility of patenting natural things.[23] However, digital forms of genetic sequences lie in the twilight zone as far as patentability is concerned. These

[19] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization,* art. 2, Oct. 29, 2010, 3008 U.N.T.S. 3.
[20] Elisa Morgera et al., *Study on Domestic Measures on Access and Benefit-Sharing* 45-47 (CBD Secretariat 2014).
[21] CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 192-94 (2000).
[22] *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. 2(e), Oct. 29, 2010, 3008 U.N.T.S. 1
[23] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590-94 (2013).

are neither physical nor non-physical entities, but the encoded use of information in technical applications, and if it is only the revelation of natural occurrences, then it only assists in the input of technology in innovative activity, in which the debate goes on and on.

The lack of stability in the concepts used by DSI also introduces evidentiary and interpretive difficulties. The nature of the sequence data differs from that in conventional scientific literature in that sometimes it lacks a story or deliberate functional explanation. It lacks an easy, written explanation in that the explanation emerges only through computational processing.[24] This contradicts legal constructs that rely on understandings based on disclosures that can be grasped by humans to assess how well information disseminates and can be anticipated. oath, DSI introduces a computationally generated scientific information into a legal milieu that previously depended on language-based argumentation.

Further clarification on the regulatory uncertainties related to digital genomic information can be drawn from ongoing global discourses about DSI. Current negotiations within the Convention on Biological Diversity demonstrate the understanding that the previous systems of governance were intended to govern tangible genetic resources, but not the circulating globally digital sequence data.[25] As a result, the states have been divided on the issue of whether DSI falls under the category of access and benefit-sharing obligations or whether free scientific access should regulate such data. The unresolved inconsistencies highlight the core problem of applying territorial laws to digital genomic information that may be copied, circulated, and used irrespective of the movement of biological samples.

The clarification of the scientific and legal nature of DSI is important with respect to the practical application of patent law because the way DSI is defined will affect the assessment of novelty, inventive step, and the scope of the biotechnology patent protection

III. DSI AND PATENTABILITY STANDARDS: NOVELTY, INVENTIVE STEP, AND DISCLOSURE

It is during the examination of the feasibility of patentability that the interplay between DSI and patents is most visible. In fact, and in general, any modern patenting regime has three core substantive criteria that must be satisfied before granting exclusive monopoly rights: novelty/originality, the presence of an innovative or non-obvious feature, and sufficiency of

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[24] *Supra* note 12, at 3.
[25] CBD Conference of the Parties, *Decision 15/9, Digital Sequence Information on Genetic Resources* (2022).

disclosure. It has long been challenging for the biotech industry in particular to adhere to these standards since lineages dividing discovery and invention are difficult to distinguish. Digital genomic information further obscures these standards since publicly available genomic information challenges established boundaries between prior art and the obviousness of knowledge for a person skilled in the area.

A. Novelty and DSI

Novelty can be considered as one of the oldest links between DSI and patent law. Under most patent statutes, an invention would lack novelty if it could be foreseen in antecedent work publicly available before the priority date of a patent application.[26] The existence of current accessible genomic databases with billions of nucleotide sequences would be impossible if a significant number of these sequences were not known before patent filings in the areas of pharmaceuticals, diagnostics, agriculture, or biotech. The defining question concerns whether anticipatory availability based on mere electronic accessibility to a DNA sequence meets the threshold of anticipatory disclosure. Deposited sequences have increasingly been treated as prior art if they disclose the same sequence that appears in a patent application, even if specified as having a certain industrial purpose in a database entry.[27] The Indian Patents Act of 1970, too, incorporates a broad definition of prior art in recognition of prior publication and public knowledge to disclaim any claim to innovation.[28]

This approach appears to represent a shift in doctrine from viewing sequence information abstractly, as mere knowledge, to viewing it more like a technical disclosure that could potentially bar novelty. A patent claim seeking to protect a specific nucleotide or amino acid sequence will be rendered not new if, in fact, a sequence appearing in a publicly available database is identical or highly similar.[29] The mere digital nature of this disclosure has no bearing on its legal status, but rather on how accessible it is for duplication. But this becomes complex in claims in which an assertion is made not only in terms of sequence information, but relative to specific functional uses that stem from those sequences. It appears novelty assessment would be required to ascertain if this useful information existed within the prior disclosure or if more creativity is required.[30]

[26] 35 U.S.C. § 102 (2018); *European Patent Convention* art. 54.
[27] EUROPEAN PATENT OFFICE, *Guidelines for Examination* pt. G-IV, 7 (2023).
[28] *Patents Act*, 1970, §§ 13, 29 (India).
[29] Christopher M. Holman, *Patent Eligibility of Isolated DNA Sequences*, 23 BERKELEY TECH. L.J. 1191, 1203-05 (2008).
[30] *In re Gleave*, 560 F.3d 1331, 1337-38 (Fed. Cir. 2009).

B. Inventive Step and DSI

The requirement of inventive step adds to the complexity in the legal assessment of DSI. An invention lacks inventive step if, in view of prior art, it would have been adjudged obvious to a person skilled in that art as of the date of filing. In biotech, it's generally assumed that the skilled person would have normal access to genome databases as well as to common bioinformatic tools.[31] Thus, publicly available DSI tends to be incorporated into common knowledge to decide obviousness. The question is no longer whether a skilled person would have access to sequence information. The question becomes whether experimental or algorithmic analysis would have required anything out of the ordinary to get from that information to a claimed invention.

Traditionally, biotech patents were known to exploit the fact that determining and naming genetic sequences was riddled with scientific uncertainty.[32] However, with advances in sequence detection methods and computational biology, much of this has been overcome. Henceforth, biotech innovations which only rely on identifying existing genetic sequences will become clearer unless there is a demonstration of genuine technical advancement or novel use. India's patent law has been conservative in the matter of patents based on naturally occurring biological discoveries through the exception provided under Sections 3(c) and 3(j) of the Patents Act, 1970.[33]

C. Disclosure Requirements and DSI

The requirement of disclosure of information is the third key manner in which DSI alters the perception of patentability. For a patent to be granted, the applicant must present their invention in a manner that would be easily understandable and detailed enough so that a person knowledgeable in that particular area would be able to reproduce the invention. In biotechnology, this would normally include sequence listing, biological materials deposited, or full experimental directions. It raises a question about whether relying on publicly accessible sequence databases meets or violates this requirement due to the presence of DSI. Some inventors would argue that since existing sequences are used, there is no need to provide much information. The patent authorities have been making it clear that biotechnology patents have to show significant technological advancement instead of mere identification of natural genetic sequences. Indeed, Indian patent law, in Section 10(4) of the Patents Act, 1970, states that "*the complete specification shall*

[31] Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 UCLA L. REV. 691, 718-20 (2007).
[32] Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1044-46 (1989).
[33] *Patents Act*, 1970, § 3(c), 3(j) (India).

fully and particularly describe the invention and its operation or use."[34] Similarly, European patent law requires adequate disclosure enabling a person of skill in the art to recreate the invention without unduly burdening him or her.[35]

The relationship between disclosure and DSI also poses broader questions about justice and transparency. In the context of patent applicants employing DSI in regions with much biodiversity, the question arises whether the quality of disclosure ought to concern itself not only with technical merit but also the origin of the genetic material or, alternatively, the origin of the genetic data. The traditional patent regime had held that access and benefit-sharing considerations ought not to be included in the rules for patentability, although current international circumstances signal impending shifts in these assumptions.[36] Regulations regarding the genetic resources, particularly digital forms, aim to enhance transparency and compliance without affecting the patentability's relationship to the agreements on benefit-sharing.

From an evidentiary basis, the integration of DSI in patent examination can be problematic in practical terms. This is because the patent office requires improvements in its technical expertise to be able to screen and analyse massive genomic information, assess similarity in DNA sequences, and determine their relevance to the matter at hand. There is increased reliance on computerised similarity analysis and prior art searches using algorithms, but these can be problematic in terms of their reliability and consistency.[37] The increased role of computer tools in patent examination refers to an evolving nature of patent examination in the digital era and the need to adapt to this reality by institutions.

It appears from the interaction between the parameters of DSI and patentability that biotechnology patents are gradually evolving. The novelty screening criterion comes to acknowledge digital sequences within prior anticipatory prior art; novelty screening takes into account routine access to genomic information within the skill level of a person; and disclosure restrictions call for a meaningful technical contribution rather than any kind of data appropriators. The development illustrates how a DSI actually serves both functions of limiting overly broad patents and increasingly higher standards for novelty in genome-wide innovation.

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[34] *Patents Act*, 1970, § 10(4) (India).
[35] EUROPEAN PATENT OFFICE, *Guidelines for Examination* pt. F-III, 1 (2023).
[36] WIPO, *Intellectual Property, Genetic Resources and Associated Traditional Knowledge* 41-44 (2020).
[37] CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 195-97 (2d ed. 2020).

IV. DSI AS PRIOR ART IN COMPARATIVE JURISPRUDENCE

The approach to DSI as prior art shows significant contrast between different countries, revealing a wide variety of national IP regimes, their capabilities, and agendas as well. Though national IP regimes agree on novelty and inventive step requirements set through patent law, there's considerable divergence on what "publicly available" means, as well as on how digital genetic data should be treated, from jurisdiction to jurisdiction. The branches of comparative jurisdiction demonstrate convergence/divergence on how national patent offices have handled DSI as a key ingredient in determining what to consider as "prior art."

A. United States

In the USA, patent regulation is increasingly addressing the issue of whether published digital works, such as data relating to genetics, may be regarded as prior art in the development of innovative technology. The framework used in patent regulation under the America Invents Act accepts a broad meaning of prior art, which incorporates "otherwise accessible to the public."[38] In US patent trials, such wording has been interpreted to extend to online data resources, subject to those resources having been sufficiently accessible. In biotech infringement claims, data stored in a public database relating to sequences has been accepted as "anticipatory prior art" when that data reveals an identical structure which is claimed in a patent application.[39]

Federal circuit decisions emphasise the point that the absence of a proof of usefulness or function of a single piece of the information contained within a database will not be seen to deny functionality if the invention is structurally comparable to disclosed information.[40] This type of distinction shows a fundamental understanding of the construct of anticipation and is quite prominent when concerns of molecular biology are discussed. However, there are limitations that the courts recognise when the claim is expressed under functional or methodology-type language. This is the case whether the information had been disclosed digitally.[41]

B. Europe and United Kingdom

European patent practices recognise DSI as "prior art," albeit focusing primarily on the question of enablement or technical contribution. The European Patent Convention recognizes any piece of information that has been made available to public knowledge through written or oral

[38] 35 U.S.C. § 102(a)(1) (2018).
[39] In re Gleave, 560 F.3d 1331, 1337-38 (Fed. Cir. 2009).
[40] Id.
[41] Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1379-81 (Fed. Cir. 2003).

descriptions, use, or other means as "prior art."[42] The European Patent Office has traditionally interpreted sequence data available in public databases as "written descriptions," while the jurisprudence of European courts underlines the significance of the "undue difficulty" criterion.[43]

It must be mentioned that there is a distinction in European law between sequence information being disclosed and a specific technical teaching being revealed. While the publication of sequence information will result in lack of novelty regarding claims to such sequences, novel technical uses and innovations may still satisfy the requirements of patentability as long as such functionality cannot be inferred from the prior disclosure.[44] The UK courts too, recognize the significance of online disclosures in databases, in situations where an expert can understand the information presented there.[45]

Finally, jurisprudence from the United Kingdom, although in full agreement with the patent legislation in Europe, may be of additional help in understanding the reasoning applied in digital previous art problems. "In an analysis of the impact of the accessibility of internet databases on state of the art, UK courts seem to agree that their content is included in the state of the art if a human skilled in the art could be reasonably expected to search for, understand, and thus use such information." In patent infringement suits in biotechnology, courts also measure whether a human skilled in the art would be inclined to use specific genetic databases included in the state of the art, in addition to whether he/she would have perceived the information included to be pertinent to the patent in question.[46]

C. India

India is only recently taking into account the concept of prior art through DSI, since patent cases arising out of disputes in relation to genomic databases are rare in India. However, the Patent Act of 1970 recognises prior publications and public knowledge as grounds for rejecting the novelty of the invention.[47] In the event of publicly available genetic databases, prior art relevance may be assumed before the filing date of the patent.

[42] European Patent Convention art. 54.
[43] European Patent Office, *Guidelines for Examination* pt. G-IV, 7 (2023).
[44] T 154/04, Estimating Sales Activity/Duns Licensing Assocs. (EPO Bd. App. 2006).
[45] Generics (UK) Ltd v. H. Lundbeck A/S [2009] UKHL 12, [2009] 2 All ER 652.
[46] Id.
[47] Patents Act, 1970, §§ 13, 29 (India).

The Indian patent law demonstrates caution in relation to patentability of naturally occurring biological material by means of Section 3(c) and 3(j) of the Patents Act, 1970.[48] While Section 3(c) excludes patenting of the mere discovery of any new property of known substance, Section 3(j) makes plants and animals or essentially biological processes of production ineligible. It can be concluded that claims referring to naturally occurring DNA sequences without any changes will most likely be refused due to a lack of novelty or statutory exclusions..

Further judicial developments within Indian patent law show that there is an evident trend for patent law in India to impose stricter conditions for patentability in areas like pharmaceutics and biotechnological inventions. The case of Novartis AG v. UOI proved that a patent should only cover the improvement which shows an increase in real efficacy, although not directly linked with DSI. This judicial decision reflects judicial reluctance to grant patents covering the entire field in the area of scientific development.[49]

Finally, the patent application examination procedure within India also implies detailed disclosure in biotechnology patent applications. According to the Guidelines for the Examination of Biotechnology Patent Applications, applicants should provide complete sequence listings and functional descriptions required to reproduce the claimed invention.[50]

Jurisprudential comparison reveals an emerging trend towards the legal relevance of publicly available DSI as prior art in leading patent regimes. At the same time, there remain differences in regard to the approach taken towards functional claiming, technological contributions, and enablement standards. More developed patent regimes have developed better approaches to the examination of genomic prior art, while less developed patent systems face certain challenges in integrating sophisticated digital biological information into the process of patent analysis. These differences reveal the continuing need for doctrinal refinement and worldwide harmonisation in regulating DSI under biotech patents legislation.

V. Policy Implications: Innovation, Equity, and Global Governance of DSI

The management of Digital Sequence Prior art information does not exist in a policy or management vacuum, and it has significant policy implications for innovation, distributive justice,

[48] *Supra* note 35, at 11.
[49] Novartis AG v. Union of India, (2013) 6 SCC 1.
[50] Office of the Controller General of Patents, Designs & Trade Marks, Guidelines for Examination of Biotechnology Applications for Patent (2013).

and global governance. As genomic information becomes crucial to biotechnology research and innovation, determinative legal status has implications for innovation drivers and the capacity to distribute or use the innovations arising from biological resources. The policy question lies in the balance to be struck on innovation drivers through property rights, on the one hand, and the quest to ensure distributive justice in the management of biodiversity, on the other.

The acceptability of DSI as prior art also provides a critical gatekeeping function from the perspective of the innovator. Taking into account accessible sequence information as prior art denies overly general patents that extend to protect fundamental facts about biology, as seen in the example above.[51] The security granted to the prior art state pertains to a critically important knowledge base for genomics-based innovations as a result of its preventative effect on the monopolisation of information that is openly accessible.[52]

At the same time, apprehension is felt that heavy reliance on DSI as prior art may create an unintended negative influence on incentives for investments in research-based industries of biotechnology. Industries such as drug development, agricultural technology, or synthetic biology often rely on research-based activities to discover novel functions or applications of available sequences. Since DSI will indicate how such functions or applications are obvious, innovators could be confronted with an increased level of unclearness pertaining to patents.[53] The standards for patentability must be adjusted in such situations to ensure that contributions of substance, such as unforeseen therapeutic applications, novel vehicles of delivery, or novel approaches to gene editing, remain viable despite access to underlying sequences of DNA.

With regard to issues of equity, these present an additional level of complexity to this policy analysis. For countries that boast rich biodiversity, these nations have always argued that digitalisation can lead to the exploitation of biological resources without mutual benefit-sharing,[54] especially when DSI is at arm's length and later employed when patenting occurs, with DSI being employed as prior art to inform patenting decisions. Currently, if DSI is made available at arm's length and subsequently utilised, nations providing such information may suffer an additional layer of disadvantage. This disadvantage arises from the loss of control over resources originating within

[51] Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1046-49 (1989).
[52] Michael Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 *Science* 698, 699-701 (1998).
[53] Dan L. Burk, *Patent Law and the Genome*, 1 J. MARSHALL REV. INTELL. PROP. *L.* 1, 18-21 (2001).
[54] Ruth L. Okediji, Traditional Knowledge and the Public Domain, 5 *Indian J.L. & Tech.* 1, 26-30 (2009).

their borders. It is further compounded by impediments to patenting that could otherwise have stimulated economic growth within these nations. These concerns consequently necessitate the implementation of access and benefit-sharing mechanisms. They also represent broader critiques of bioprospecting and "bio-colonialism" within biodiversity governance regimes.[55]

These issues have gradually come to be accepted and appreciated under various global biodiversity conventions. The recent decisions made under the Convention on Biological Diversity have legitimised the design of global benefit-sharing for the use of digital sequence information, highlighting the political acknowledgement of the insufficiencies in access to and sharing of contemporary dematerialised genetic data.[56] Proposals presently under consideration range across global policies with financing mechanisms such as user contributions, subscription methods, and the use of benefit-sharing commitments related to the commercialisation rather than access to the genetic data.

Patent regulation is very intricately linked with these issues. Accommodating DSI as prior art is based on open scientific principles and helps to delimit exclusivity. Conversely, patent regimes are among a handful of regimes that have the potency to access information on the business exploitation of genetic information. This resulted in calls for a greater obligation to disclose information on DSI within patent specifications. This approach is justified in terms of transparency and the facilitation of broader benefit-sharing. However, such disclosure obligations raise concerns regarding the complexities and legal ambiguity they may introduce. This is particularly the case if these obligations are framed as foundational to patent validity, as they could dissuade innovation.

Secondly, the administration of DSI at the global level also faces some difficulties in terms of scientific capacity. The technologically advanced countries with adequate infrastructure in gene sequencing and knowledge of bioinformatics tend to use open-access genetic information appropriately. On the contrary, there are many technologically backward countries in the world that are not equipped appropriately to transform DSI into economically viable products.[57] Hence, it is seen that despite DSI being open-access and unpatentable, its effective utilisation is likely to

[55] Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge 49-52 (1997).
[56] Convention on Biological Diversity, Decision 15/9, Digital Sequence Information on Genetic Resources (2022).
[57] Carlos M. Correa, *Access to Genetic Resources and Benefit-Sharing: Challenges for Developing Countries*, 21 J. WORLD INTELL. PROP. *1*, 9-12 (2018).

remain in technologically advanced countries. The status of DSI as prior art ensures its public domain nature, but not its utilisation without any restriction.

These factors illustrate the limitations inherent in using the patent system to attain distributive justice. While the restrictions on prior art block the monopolisation that might otherwise take place, they do not do so sufficiently to remedy underlying inequalities in innovation capacity. Therefore, additional strategies need to be devised that go beyond the patentability requirements and include aspects of technology transfer and international scientific cooperation.[58] These strategies go hand-in-hand with the requirements of the CBD and might help to alleviate the presumptions that open DSI frameworks inevitably cater unfairly to privileged parties.

Speaking of multilateral fragments, it remains a major problem as well. Discussions pertaining to biodiversity, intellectual property, and data policy are conducted through separate international institutions, each with its specific mandate and normative agendas. The CBD focuses heavily on equity and sovereign rights, the WIPO concentrates on intellectual property harmonisation, and leading scientific institutions.[59] Lack of coordination between these systems runs the danger of inducing as well as enforcing inconsistent or even contrary policy measures regarding DSI. They might view DSI as publicly accessible prior art, but simultaneously emphasise the implementation of a sharing obligation. There have been some improvements in the WIPO regime, which could point to an attempt at reconciliation between patent law and stewardship of biodiversity. For example, WIPO's 2024 Draft Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge proposes obligations for disclosure regarding the use of genetic resources and associated traditional knowledge in patent applications.[60] The convention, although not explicitly addressing DSI, reflects increasing international recognition that patenting and biodiversity governance can no longer exist separately.

VI. CONCLUSION: RECONCILING PATENT DOCTRINE WITH THE DIGITAL GENOMICS ERA

The emergence of DSI has brought into sharp view a profound tension between classic patent and the modern facts of genomic science. Patents had been devised in an era in which novelty was associated with a unique real-world artefact, an individual invention, and with knowledge flow

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[58] United Nations Conference on Trade and Development, *The Role of Science, Technology and Innovation in Sustainable Development* 33-36 (2018).

[59] WIPO, Draft Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, WIPO/GRTKF/IC/47/4 (2024).

[60] WIPO, Draft Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, WIPO/GRTKF/IC/47/4 (2024).

within a place-bound context. DSI, in turn, epitomises a form of dematerialised, globally circulating biological information that challenges the fundamental assumptions underlying originality, inventiveness, disclosure, and ownership. Since genomic information is at the same time the source, determining whether DSI is prior art has proved a salient doctrinal and policy choice with far-reaching ramifications.

This article has argued that a recognition of DSI as legally cognizable prior art should be entertained on the conditions of being made public and being technically enabling. This proposition is entirely in keeping with all of the fundamental purposes of patent law, which include averting the recapture of pre-established information, safeguarding the public domain, and ensuring that exclusive rights are properly awarded solely within the realm of legitimate technical improvements. A critical defensive function is played in limiting broadly expansible patents, which might monopolise existing information resources developed through the publicised efforts of science.[61] This particular study has also demonstrated that such a recognition is subject to nuanced qualification, particularly in the articulation of patents along application-oriented criteria.

Nevertheless, refinement within doctrinal law by itself cannot help solve the overarching issues of governance in DSI. The discussion in this essay on how policy addresses genomic data in intellectual property rights and its intersection with global inequalities and sustainable and distributive justice has not been without countries that are rich in genetic diversity and in resources expressing genuine and valid anxieties over how genetic data would generate economic rewards without sharing its benefits.[62] The recognition of DSI as prior work has not only been important to guard against any unjust monopoly but may exacerbate exclusionist perceptions in nations without technological capabilities to realise data with commercialisation.

This tension underscores the constraints of patent law as a mechanism for distribution. The patent theory is inadequate for addressing structural inequalities in scientific capability or historical trends of resource utilisation. Thus, attempts to incorporate equitable factors into patentability criteria may excessively strain the system and compromise legal certainty.

Global trends in this approach suggest that measured progress is being made. The establishment of the multilateral benefit-sharing framework concerning information in digital sequences under the Convention on Biological Diversity seeks to break the nexus between the territorial basis of

[61] Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150-53 (2012).
[62] Carlos M. Correa, *Innovation and Access to Medicines: Intersections with Patent Law* 87-90 (2016).

benefit-sharing practices and their link with the movements of digital data flows. Another development is the establishment of a standard of procedure concerning disclosure in patent regulation under discussion within the WIPO, aiming to improve transparency without transforming patent agencies into biodiversity law enforcement agencies. These efforts, in their own way imperfect, suggest that there is now a heightened recognition that the control of DSI requires coordination between legal systems rather than theological isolation