

GENETIC INFORMATION AND MARKET SUPREMACY: A STUDY ON DIGITAL AND ALGORITHMIC BIOPIRACY IN MODERN BIOTECHNOLOGY UNDER PATENT AND COMPETITION LAWS

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ABSTRACT

Undeniably, machines and humans have begun to co-exist due to the rise of artificial intelligence and machine learning. These technologies have entered the domains of biotechnology, genomics, and biodiversity-based innovative processes, creating numerous opportunities from digitised biological data. The conceptualisation of digital and algorithmic biopiracy, particularly in genomic and computational biotechnology, is the focal point of this paper. This concept can be understood as the appropriation of knowledge associated with biodiversity through technical and AI-driven processes, in which algorithmically generated outputs are protected by patent law without compliance with access and benefit-sharing obligations. This biopiracy operates through patent rights and digital control over biological data, raising concerns not only regarding environmental issues but also within the purview of patentability and competition laws. Algorithms with technical effect can be protected under the patent regime, and granting patents over AI-derived biological innovations without scrutinising the data can potentially lead to monopolisation. Such patent protection can create anti-competitive consequences and ensure a dominant position and disproportionate control over the essential algorithmic inputs in various pillars of modern biotechnology. Algorithmic biopiracy can significantly cause anti-competitive concerns in bio-digital markets by granting exclusive control, affecting market participation. The paper demonstrates the interconnectivity between patent and competition laws in countering digital and algorithmic biopiracy by adopting a doctrinal and comparative approach, and analyses the legal frameworks of patent and competition law with reference to various global perspectives on algorithmic and digital

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biopiracy in modern biotechnology. The study highlights significant legal lacunae in addressing this biopiracy within the ambit of anti-competitive practices and economic concerns, and questions the adequacy of existing patent law and competition law frameworks in effectively addressing the issues in ensuring dynamic market competition and fair access to biological knowledge.

KEYWORDS: Patent, Biopiracy, Algorithm, Digital, Biotechnology, Competition.

INTRODUCTION

Patent law plays a vital role by granting exclusive rights to the inventors. Due to innovative aspects, Biotechnology holds a significant position in the Patent law. It holds an unavoidable place in the modern, technologically advancing society. It actively integrates biological science with the technological processes in order to develop new products in various pillars of biotechnology, like in pharmaceuticals, agricultural, industrial applications and mostly in genomic and computational processes.

In modern biotechnology, biological materials are not used or stored in the traditional laboratory methods, but rather, they have been transformed into data and datasets that possess patentability value. If the sources used for the invention relating to biotechnology, collected from any specific population, holding inventive value, the benefit must be shared properly with such groups by the inventors. If any appropriation of biological resources, genetic materials or any related knowledge capable of patentable claims had been utilised with no prior consent or benefit sharing, it amounts to Biopiracy.

It is pertinent to note that traditional and earlier forms of biopiracy, known to the public involves physical extraction of resources, like any plant varieties or medicinal products and patenting the same, making the accessibility of the resources complicated and ensuring no benefits reach the hands of the people from whom such resources had been extracted. However, in the case of genetic components, sequences, microbial data, and datasets, which are converted to digital form, analysed, and forwarded for patent claims, this is done without proper recognition of the actual source of the collected material.

In patent regimes, if broader claims are made, particularly over isolated genes, functional sequences, or any biological processes, it can create an adverse impact on biological resources as private property. The intersection of algorithmic and computational tools used in genomic biotechnology has potentially increased concerns regarding biopiracy.

It is pertinent to note that biotechnology can be considered as a genus operating applied biological innovation. In contrast, Bioinformatics is a subdomain that supports biotechnological research through computational analysis of biological data. The application and development of AI in bioinformatics, particularly through AI-based diagnostics, demonstrate its emergence as a transformative force in the traditional biotechnological landscape.

In genomic and computational biotechnology, when a genome is sequenced, it generates numerous digital datasets that cannot possess any valuable meaning. Through bioinformatics, the data will be analysed by the algorithms, and then the same will be compared with the existing genomes, which will be used as references to identify necessary patterns like disease-causing gene variants, etc. The resulting algorithmic and digital output based on the analysis will later be used in biotechnology to develop drugs or apply gene-editing techniques, etc. Thus, these outputs are capable of clearly identifying the important elements to be studied from the genomic data, which amounts to a biotechnological innovation and potentially raises patentability concerns.

Furthermore, such outputs are a crucial component of biotechnological invention, and they become tools for biopiracy if they are not acquired under the proper conditions. Also, control over the algorithmic outputs used in genomic and computational biotechnology poses serious anti-competitive threats. If proprietorship is granted to genomic datasets, it can create substantial barriers to entry into the marketplace, apart from environmental and healthcare concerns. Practices such as patent thicketing, clustering, evergreening, misuse of data exclusivity provisions, and dominance through biotechnological data can potentially distort various markets and result in public concerns. Thus, the outputs generated cannot be used in this manner, raising serious questions about the entire genomic biotechnological field. Therefore, the intersection of patent law, biotechnology, bioinformatics, and algorithmic innovation needs clear scrutiny through the principles of competition law.

BACKGROUND OF THE STUDY

It is evident that the biotechnological advancements is increasingly dependent on bioinformatics and algorithmic outputs to access the biological data and from the results to create an innovative process or product. The algorithms are utilised to analyse the DNA sequences, identify variants, predict genomic functions and study the protein structures. These generate the results, which can be referred as algorithmic outputs. These are necessary for genetic diagnostics, gene editing, drug discovery and even in precision medicine, which shows

a significant evolution from laboratory focused experiments to data-driven innovation. However, this essential shift also raises questions regarding concerns on patent law frameworks.

Concerning Patent law, algorithmic outputs derive interpretations from naturally occurring genetic information which primarily resides in the grey area between the patentable and non-patentable inventions as well as the position between discovery and an invention. In addition to this, the output generation through software and AI tools also questions the fundamental aspects of patent law. Even though, the technical contribution is considered, that may be serve in all the cases where it may lead to failure of incentivisation of the work.

In the lens of biotechnology, if such incentivisation is provided without addressing the actual population which supported with the knowledge can potentially leads to biopiracy, not in the conventional way but in the digital manner. This will affect the community as well as the other companies in the marketplace when the dominance is exerted through anti-competitive measures. Thus, an analysis of role of algorithmic outputs, the consequences of patentability of such outputs, how potentially it affects the respective community if it is acquired without consent, and imbalance between the patent and competition laws framework is necessary to understand the implications of digital and algorithmic biopiracy in the patent and competition perspectives.

The integration of bioinformatics and algorithm outputs into genomic and computational biotechnology has significantly transformed the traditional aspects of biological innovation. However, existing patent regimes address the conventional methods used in biotechnology like giving primary focus to the laboratory-based inventions. At first place, there is an inadequacy in properly addressing the innovations derived through interpretation and computational analysis of naturally occurring genetic information like incorporation of bioinformatics and interpretation through algorithmic outputs and pros and cons of such usage in both the lens of biopiracy and anti-competitive concerns. The need for addressing the biotechnological inventions in the competition law perspective is essential because the future advancements can potentially focus on the economic benefits as well as the public concerns. To sustain in the marketplace, embracing technological advancements in biotechnology is also crucial.

But it is pertinent to note that the patent regime is inadequate in referring digital and algorithmic biopiracy, affecting both the people and fellow competitors in the market due to inherent

loopholes and fundamentally questioning whether such incentivisation of outputs can provide overarching powers to the companies, leading to monopolisation and unfair competition.

CONCEPT OF DIGITAL AND ALGORITHMIC BIOPIRACY

ROLE OF COMPUTATIONAL GENOMICS IN BIOTECHNOLOGY

In modern biotechnology, computational genomics plays a significant role in transforming the industry of biotechnology according to technological and scientific advancements. Computational genomics is the interdisciplinary field that potentially utilises advanced statistical and computational methods to analyse the data regarding the whole genome and to derive conclusions regarding the biological functions controlled by the DNA sequences.¹

It utilises various fields like mathematics, computer science and genomics to conclude and has various applications like biotechnology that may potentially lead to the development of new bioproducts, synthetic medicines and precision medicines.

In order to achieve the practical biological advancements, computational genomics utilises bioinformatics algorithms that eventually generate the algorithmic outputs necessary for the identification and interpretation of variations and sequences in genes. For instance, Multiple sequence-alignment algorithms can potentially generate outputs that help identify gene mutations associated with a particular disease. This can be achieved by comparing across genomic sequences and used in developing diagnostic tests and therapies.² Thus, it is evident that computational genomics significantly applies the generated outputs and helps in transforming raw biological data into new biotechnological inventions.

WHAT ARE ALGORITHMIC OUTPUTS

Algorithmic outputs can be understood as the results that can potentially help in interpreting new aspects of the complex datasets. It can be generated by advanced computational models used in all fields of bioinformatics and computational genomics in biotechnology, particularly in medical sciences.³ These outputs are derived from the genomic data. It differs from the normal computer outputs, which usually automate already defined tasks alone. These algorithms are generated through bioinformatics and encompass gene functions, protein structures, and other related information. The evolution of genetic resources into abstract outputs potentially induces commercial exploitation even without physical access to that

¹ Lee S, *Computational Genomics: The Future of Biotechnology, Harnessing the Power of Genomics Data for Innovation and Discovery*, <https://www.numberanalytics.com/blog/computational-genomics-future-biotechnology>

² *Key Bioinformatics Algorithm*, FIVEABLE, <https://fiveable.me/lists/key-bioinformatics-algorithms>

³ World Intellectual Property Organisation [WIPO], *WIPO Technology Trends 2019: Artificial Intelligence* 25–30 (2019), <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1055.pdf>

particular biological material, which may consequently derogate the obligations of benefit sharing under the Convention on Biological Diversity⁴ (CBD) and Nagoya Protocol.⁵

It is pertinent to note that the bioinformatics algorithm plays a significant role in generating the outputs to interpret the issues. The bioinformatics algorithms can be understood as the computational engines that are capable of altering raw biological data into meaningful data. It is essential to understand not only the functions of such algorithms but also why they work. These are closely associated with addressing the questions relating to evolution, diseases, and the functions of genes⁶.

These act as tools to determine the association and correspondence between the DNA sequences, genes, and genetic variations that may be crucial to identify in different traits⁷. Algorithmic outputs are the results of bioinformatics algorithms. The tools of computational bioinformatics hold significance in understanding the correspondence between DNA sequences and genes, and in identifying characteristics that may reflect traits or diseases.

DIGITAL BIOPIRACY IN THE LENS OF COMPETITION LAW

Since the algorithms hold an important position in computational genomics in biotechnology, they can also lead to various issues in the aspects of inappropriate and unfair usage. It is well known that biopiracy occurs when there is an unauthorised usage, access, extraction and/or exploitation of the biological resources without prior consent or benefit sharing to the actual community that holds the knowledge of such resources.⁸ It is clear that using the bioinformatics algorithms as a tool, the outputs can be generated, and such generated elements and outputs, like isolated gene functions, compounds, etc can potentially have the value of patentability. Though mere algorithms cannot be patented per se, by using such algorithmic outputs, if any novel invention has been made, such can amount to proprietorship under patent law.

In these cases, Digital Biopiracy can arise when those algorithms are processed, the genetic data can be assessed, and it can be converted into knowledge that can be protected by a patent regime. It provides proprietorship to such data, without informing and sharing the benefit with the communities, where it paves the way to claim exclusive rights over such biological

⁴ Convention on Biological Diversity, 1760 UNTS 79, 31 ILM 818 (1992)

⁵ Nagoya Protocol on Access To Genetic Resources and the Fair And Equitable sharing of Benefits arising from their utilisation to the Convention On Biological Diversity, 2010 3008 U.N.T.S. 3.

⁶ Supra note. 2

⁷ GeeksforGeeks. (2024, April 26). *Bioinformatics and its Application*. GeeksforGeeks. <https://www.geeksforgeeks.org/biology/bioinformatics-application/>

⁸ Agrani Bati, *BIO-PIRACY: A GLOBAL CONCERN AND PROTECTION OF TRADITIONAL KNOWLEDGE IN INDIA*, NLUA Journal of Intellectual Property Rights ISSN: 2583-8121 (Online) Volume 3 Issue 1.

information that originates specifically from any indigenous regions.⁹ From the perspective of competition law, Biopiracy not only affects the indigenous communities but has the potential to distort the marketplace through monopolising the biotechnological inventions. It can consequently result in increasing restrictions on access to knowledge and stifling innovation.

Also, when a dominant entity holds ownership towards the inventions based on such algorithmic outputs and uses the same with the intention to exclude its rivals from its way, it marks a potential abuse of dominant position in the market. Thus, it is necessary to understand that Biopiracy in this aspect is two-fold, which can disrupt the enjoyment of the indigenous community through such biological resources and through overarching rights; it can affect the rivals and disrupt fair competition in the market. For instance, a plant genome is stored in a public database where the algorithm identifies the medicinal property of the gene while analysing the genome. Through the value of such property, a company claims exclusive protection through a patent for a drug on the basis of that gene. In such circumstances, this amounts to biopiracy when there is no prior informed consent or equitable benefit sharing reached the respective community.

PATENTABILITY OF ALGORITHMIC OUTPUTS IN GENOMIC AND COMPUTATIONAL BIOTECHNOLOGY

Patents are granted as an exclusive right to the respective owner to prevent any other third party from making, using, or commercially exploiting an invention for a limited period, which is mostly up to 20 years in most of the jurisdictions. This monopolistic control is justifiable as it is intended for the incentivisation of any invention made that eventually benefits the public as a whole.¹⁰ However, it is pertinent to note that such incentivising exclusive rights may become a monopolistic approach when such protection overarches to fundamental knowledge on the resources or any essential information holding outputs.

As stated earlier, the algorithmic and digital outputs in genomic and computational biotechnology are inclusive of gene disease associations, predictions on gene mutation, and gene variations regarding traits or diseases through bioinformatics and AI. These are indeed produced through computational processes and actively represent the interpretations of naturally occurring biological data in modern genomic biotechnology. From these

⁹ *ibid*

¹⁰ What is a Patent? Patent Meaning & Definition | 9 Major Benefits. (2026). Intepat.com. <https://www.intepat.com/blog/patent-meaning-significance>

characteristics, it is necessary to answer whether such outputs can potentially hold the value of being an “invention” by itself or a mere abstract algorithm.

In Indian Patent law, algorithms per se cannot be patented.¹¹ The provision deliberately excludes algorithms and computer programmes within the ambit of patent protection in India. In addition to that, the mere discovery of a natural phenomenon can never be patented in India.¹²

Thus, the functions of algorithmic outputs are mere identification and analysis of the biological data, which can be excluded from the purview of patent protection if the claim was made independently. However, if the claim is made as the method or system that utilises such outputs for achieving a technical effect or it possesses an inseparable link with the hardware, the protection under patent can be claimed.

The case that cannot be ignored in the circumstances where the patentability of computational inventions is discussed is *Ferid Allani v. Union of India*¹³, emphasising Section 3(k) cannot act as an absolute barrier for patent protection. This case clarified the position of patentability of computational relations, where the claim for protection can be made when the claimed invention demonstrates any technical effect or contribution. The algorithmic outputs can be patented when they are capable of solving technical issues and producing an industrial outcome without theoretical and information-providing outputs per se. In genomic biotechnology, these outputs can be protected under the ambit of a patent only when they are integrated clearly with the technical system and show industrial applicability, like the improvement of efficiency in gene sequencing.

The landmark case of *Association for Molecular Pathology v. Myriad Genetics, Inc.*¹⁴ speaks about the extent of patent protection to the naturally occurring genetic information. It was made clear from this case that when genetic information was identified through technologies and isolated, such information cannot be patented merely on this ground. The principle can be applied in the aspect where proprietorship on naturally occurring substances cannot be claimed due to the extraction made through technological tools. This is the exact focal point that answers why patenting such outputs can threaten the aspect of discovery into an unjustified monopoly.

¹¹ The Patent Act, 1970, §3(k)

¹² The Patent Act, 1970, §3(c)

¹³ *Ferid Allani v. Union of India*, Dec 12, 2019

¹⁴ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)

If the mere algorithmic outputs were granted a patent shield, the monopolistic approach can be seen not through the physical products or substances but rather through essential knowledge inputs. These are essential for any biotechnological invention, and when this has been derived without benefit sharing and attempting to monopolise in the purview of technical effect can harm the field of modern genomic biotechnology. These outputs function as necessary elements to be referred to in diagnosis and drug development, where if these are provided with exclusive rights can potentially affect the marketplace participants from offering alternative tests using the knowledge, potentially restrict the research access and stagnates the further innovation in the field. In addition to this, when there is non-compliance with Access to Benefit Sharing, it significantly undermines the market foreclosure.

Thus, Indian patent law prevents digital biopiracy and encourages a fair competitive marketplace. However, it is pertinent to note that mere assertions of technical contributions cannot be considered as a ground of patentability where the strict adherence to the “real technical effect” condition is to be followed. There is a need to revise the guidelines in this regard periodically, and the aspect of technical effect must be keenly observed according to the cases. On this basis, patent protection must be granted when it comes to genomic and computational biotechnology with clear assertions.¹⁵

ANTI-COMPETITIVE DIMENSIONS AND STRATEGIES IN ALGORITHM USAGE IN GENOMIC BIOTECHNOLOGY

Digital and algorithmic biopiracy can likely occur in cases where the algorithmic outputs are appropriated and granted patent protection without complying with Access and Benefit-Sharing obligations. It clearly differs from traditional biopiracy due to the exploitation of information derived from biological data by altering and converting the publicly available knowledge into a private asset. In addition to biotechnological concerns, it can also potentially cause serious anti-competitive concerns.

In cases when the algorithmic outputs are made inaccessible in the guise of “technical effect” they can stifle innovation. The technical contribution is a necessary ground, but it cannot be considered as a sole justification for the grant of patent protection to an algorithm if it does not comply with the essential aspects of patent and ABS compliance. It is against innovation because it can restrict the development of alternative solutions in diagnosis, drug development and any other crucial process in genomic biotechnology, due to such protection.

¹⁵ Microsoft Technology Licensing LLC v The Assistant Controller of Patents and Designs, C.A. (COMM.IPD-PAT) 29/2022

It is also significant to note that strategic patent thicketing, exclusive licensing of the patent and misusing the protection through data exclusivity can be considered as notable anti-competitive strategies that may be used by the dominant entities.

PATENT THICKETING

Patent Thicketing is a strategy of creating a dense web of overlapping patents that are closely interrelated regarding a particular product, research or technology, which prevents any competitor from entering the market in such regard.¹⁶ It pushes the competitors to negotiate for multiple licenses as the only way, and this poses a high level of infringement risks. It keeps the competitors in a constant fear of developing alternative technologies due to litigation, licensing or prohibition through high royalty imposition. Even though there is no deliberate case seen in digital and algorithmic biopiracy, this sector of genomic and computational biotechnology is also highly prone to the risk of thicketing due to its nature.

This practice is prominently seen in biotechnology, where this field includes higher investment in genetic research.¹⁷ Patent Thicketing can also be used in this sector due to the active involvement of algorithmic outputs and information derived from biological resources, and converting the same into digital data. Due to multiple overlapping patents, the dominant entities can hold more control and transform non-commercial biological information into proprietary assets, restricting access to the available information by giving it a shape. Thus, this can be considered as the potential obstacle as a threat of biopiracy on one hand, as well as an anti-competitive practice in other hand in genomic biotechnology.

LICENSING TRENDS

The strategic licensing of patents can also contribute as an anti-competitive measure, where it is prominently used by dominant entities. This strategic usage looks like protecting the rights, but implicitly, it amounts to aggressive enforcement of their exclusive rights. It can be in the way of express and deliberate restrictive licensing conditions or implied strategic conditions. This practice significantly affects competitors from accessing essential technologies. The licensing terms must not be exerting the dominance but rather impose fair conditions.¹⁸ In the landmark case of *Federal Trade Commission v. Qualcomm Inc.*¹⁹, though the act of the party was considered hyper competitiveness regarding the “no license, no chips” policy, it will not

¹⁶ *What is Patent Thickets - An Analysis*. (n.d.). www.globalpatentfiling.com.

<https://www.globalpatentfiling.com/blog/examining-various-dimensions-patent-thickets>

¹⁷ *Untangling Patent Thickets: The Hidden Barriers Stifling Innovation - TT CONSULTANTS*. (2024, June 26). ttconsultants.com. <https://ttconsultants.com/untangling-patent-thickets-the-hidden-barriers-stifling-innovation/>

¹⁸ *Mosanto Holdings Private Ltd. and ors v. Competition Commission of India and Ors*, W.P. (C) 1776/2016

¹⁹ *Federal Trade Commission v. Qualcomm Inc.*, No. 19-16122 (9th Cir. 2020)

remain the same circumstance, and it will amount to an anti-competitive measure when it exceeds the threshold of using licensing terms more strictly, non-beneficial to others in the marketplace. The licensing terms cannot be used as a mask to enforce the rights aggressively by any dominant entities.

In genomic and computational biotechnology, strategic licensing over bioinformatics algorithms and their outputs, like controlling access to gene-disease relation, algorithms associated with disease or traits, etc can stifle innovation and restrict the alternative research approach of other existing entities in the market. In addition to this, if the same strategy utilised towards the indigenous community from whom the information is collected, such restrictive licensing can potentially amount to algorithmic biopiracy due to alteration of biological knowledge into commercial products without proper appropriation. Thus, strategic licensing can lead to both patent law and competition law concerns and scrutiny upon this aspect is necessitated.

DATA EXCLUSIVITY AS AN ANTI-COMPETITIVE TOOL

Data exclusivity can be understood as a protection provided to the innovators for a particular period of time over any datasets or outputs that have been submitted for regulatory approval.²⁰ This is one of the best protections given to the proprietors for their invention, but it can also be utilised as a tool to abuse the exclusive rights. The algorithmic outputs can be considered as the essential inputs in genomics and computational biotechnology, which can be substantially misused for the self-serving purposes of dominant entities. This can potentially align with the aspects of digital biopiracy when terms were not complied. This incentivising aspect can be used as a shield, and the aspects of misappropriation may not be seen during such a temporary period. When the genetic resources in question without ABS compliance had been provided with exclusivity protection, it challenges the rights of the respective community and competitors simultaneously.

This can lead to reinforcement of anti-competitive practice through the data and information, where the aspect of data exclusivity can function as a catalyst for digital and algorithmic biopiracy. Hence, the actual objective of data exclusivity can be misused to create a barrier to entry and concentration of market power easily through combining with non-compliance to ABS and patent terms.

COMPARISON OF POSITIONS OF THE US AND EU WITH INDIA

²⁰ Supriya Malviya, *DATA EXCLUSIVITY AND RIGHT TO HEALTH: AN ANALYTICAL STUDY*, I P BULLETIN Vol. V Issue 1, JAN-JUN, 2024, Pg. 20-34.

There is no sufficient address towards the study by combining both the domains, but the principles and legislative measures can be interpreted in a way to represent the issue. Through the existing frameworks, the issues can be addressed to a certain extent.

THE UNITED STATES

The legislative frameworks in the US can be evidently seen to balance incentives for innovation and competition aspects, encouraging proper access to the resources in computational biotechnology and genomics. The Hatch-Waxman Act²¹ provides for data exclusivity for drugs, can implicitly protect the outputs used for drug development, disease and trait identification through genes by ensuring that the same cannot be used for the exertion of a dominant position. Furthermore, the Bayh-Dole Act²² permits the institutions to own inventions, including algorithms for genomic analysis, ensuring public access and private rights.²³ The States ensure the protection of the algorithms and prevention against improper usage, as different issues, but attempt to protect against the same, attempting to balance the private and public interests, but addressing the issue effectively is necessary.

EUROPEAN UNION

The ambit of competition and data exclusivity has been regulated by the EU in various ways, including algorithms to protect innovative practices and against anti-competitive measures. The focus was given to the pharmaceutical sector in most of the countries, where the regulatory data protection protects for 8+2+1 years, and the market protection is provided for 1 year.²⁴ The indirect protection can be the only path available at present in the cases of algorithmic outputs in biotechnology. In the aspect of Anti-trust law, the Digital Markets Act and antitrust rules of the EU prevent the exertion of dominance and anti-competitive agreements, particularly in digital markets, aligning with the protection of data and algorithms.²⁵ But there is a necessity to specifically address the algorithmic outputs and related emerging issues associated with genomic and computational biotechnology.

Thus, it can be understood that the US and EU have data protection regimes linked with competition and patent law to protect innovation. Though they take measures to safeguard

²¹ The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417)

²² The Bayh-Dole Act or Patent and Trademark Law Amendments Act (Pub. L. 96-517, December 12, 1980)

²³ *Biologics and Biosimilars Landscape: IP, Policy, and Market Developments* | JD Supra. (2024). JD Supra. <https://www.jdsupra.com/legalnews/biologics-and-biosimilars-landscape-ip-5898809>

²⁴ Garattini, L., Badinella Martini, M., & Mannucci, P. M. (2021). Pharmaceutical patenting in the European Union: reform or riddance. *Internal and Emergency Medicine*. <https://doi.org/10.1007/s11739-021-02887-6>

²⁵ Team, S. P. (2025). *Digital Markets Act (DMA) Explained [2025]*. <https://Secureprivacy.ai/>; Secure Privacy. <https://secureprivacy.ai/blog/digital-markets-act-dma-explained-2025>

biotechnological innovations, they incorporate measures separately, and the concern of digital and algorithmic biopiracy is yet to be focused on and addressed. Even in India, the same concern arises, but the importance of the balance between public access and private rights is somehow given more necessity compared to other developed countries.

ADEQUACY OF THE EXISTING PATENT AND COMPETITION REGIME IN INDIA

The doctrinal connection between Patent and competition law, along with the aspects of biodiversity in the ambit of genomic and computational biotechnology, shows an inherent conflict in properly addressing the overlapping issues. The issue seems to be less serious, but it can potentially cause significant implications by combining different underlying principles in various legal domains in one particular biotechnological field. The patent law grants exclusive rights, which in certain cases can potentially conflict with the biodiversity principles due to the absence of a clear definition in the understanding of “technical effect” and its changing nature according to the cases.

From a competition law perspective, though there are evident practices of anti-competitive measures, the application of this law in IP cases remains inconsistent. Though there are cases aligning in the domains of both patent and competition laws, the concerns regarding anti-competitive measures are less focused, leading to the usage of anti-competitive strategies potentially remaining higher.

It is necessary to combine the principles actively to protect the rights of the aggrieved parties. The genomic data holder can affect the rights of the communities as well as restrict the active participation of the competitors effectively, if the principles in the patent and competition laws are not effectively utilised, depicting that there is a clear imbalance in the Indian framework.

CONCLUSION

The intersection of modern biotechnology, like computational genomics and AI, has created a complex concern called digital and algorithmic biopiracy. The terms are inherently different, where the former is wider, including the latter. There is a clear transition from physical storage to digital datasets. The traditional way of protecting the components is considered insufficient in this modern era. The new emerging issues, like this question the protection given by the Convention on Biological Diversity (CBD) and the Nagoya Protocol. The bioinformatics algorithms process the genomic sequences, and the outputs generated regarding various genes and their variants play a crucial role in computational genomics, where the dominant entities can also attempt to claim protection over them. The claim of patent protection through

undefined technical effects, non-physical access to the source material, and non-compliance to ABS are some of the potential ways through which the digital and algorithmic biopiracy can be made by such entities. This study depicts the existing patent and competition law frameworks in the US, EU and India, where it is found that there is an inadequacy in effectively addressing these new challenges regarding the bio-digital market. Due to this, it can potentially leave a lacuna in protecting the rights of the respective communities to whom the knowledge is known, as well as the emergence of an unfair market ambience in the marketplace due to monopolistic control over the information and strategic dodging of the responsibility in allowing public access to such biological resources. Though there are no evident cases now in this regard, there is a deliberate threat regarding this issue due to the development and technological advancements in modern biotechnology. To align the incentivisation and fair competition, Patent regimes should require compulsory disclosure of Digital Sequence Information and other details utilised for the generation of the algorithmic outputs from the biological resources. It is also necessary to clearly explain the technical effect and contribution to oppose the misuse of this aspect in genomic biotechnology. The competition law measures must also be scrutinised along with patent and biodiversity concerns to counter the strategies used in the bio-digital markets effectively.

