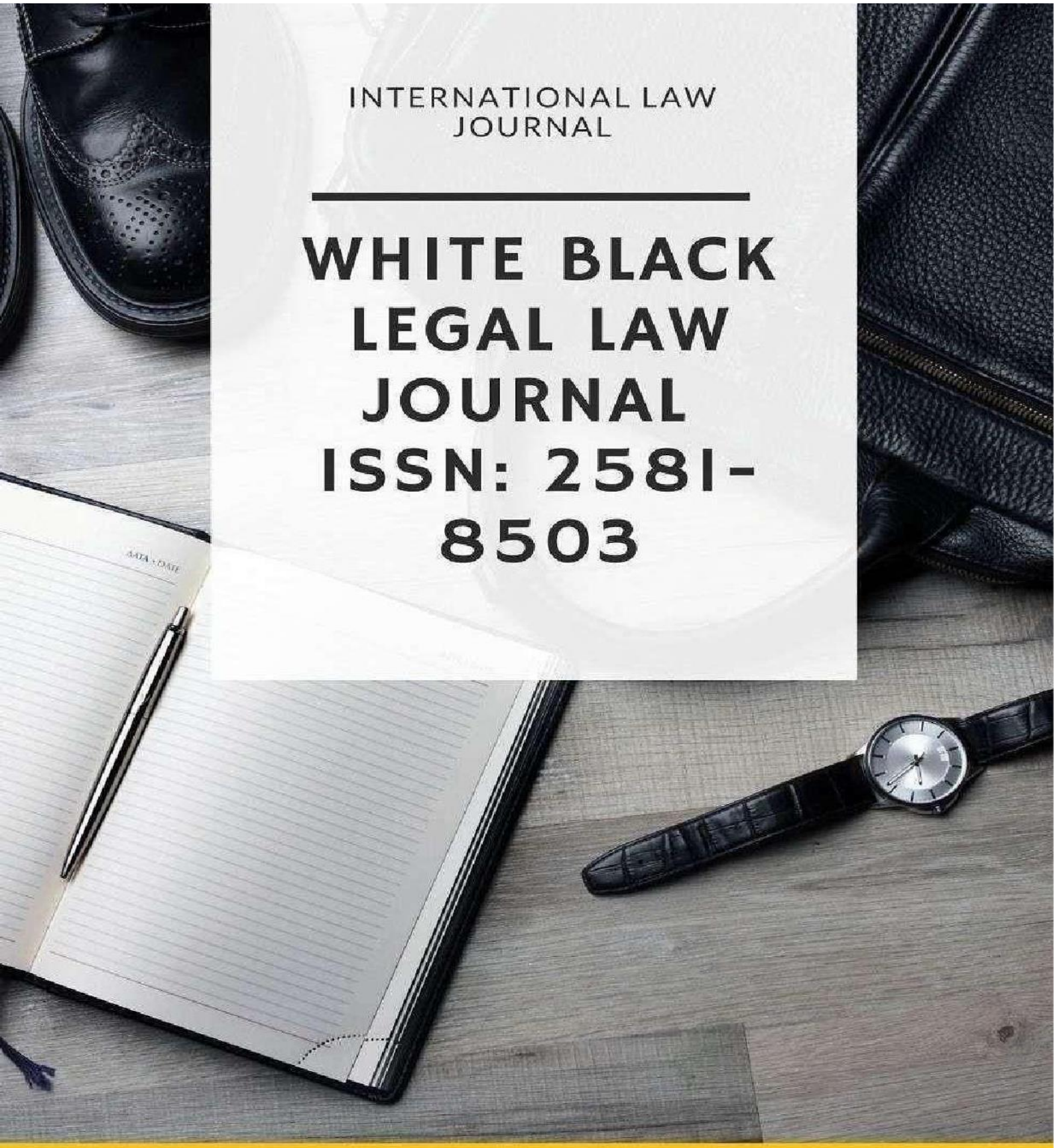

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INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY AND DIGITAL HEALTH CARE: BALANCING INNOVATION, DATA, AND THE RIGHT TO HEALTH IN INDIA

AUTHORED BY - AKHILA S T

I. Introduction

The merging of biotechnology and digital health has reshaped the landscape of intellectual property law. On one side is an industry producing inventions such as gene sequences, recombinant drugs, genetically modified seeds, and AI-driven diagnostics that challenge traditional ideas about what can be patented. Conversely, the healthcare system considers access to these innovations a matter of constitutional and human rights, especially since the right to health is embedded in Article 21 of the Indian Constitution and supported by the Directive Principles. Located between these two areas is a fragmented regulatory environment: the Patents Act of 1970 reflects developmental concerns from the 1970s; the Information Technology Act of 2000 predates the rise of the data economy; the Digital Personal Data Protection Act of 2023 is just beginning to be tested with electronic health records; and no law specifically governs inventions created by machines.

The TRIPS Agreement globalized minimum standards of patent protection, and the 2001 Doha Declaration on TRIPS and Public Health responded by affirming the primacy of public health and the freedom of member states to use TRIPS flexibilities.[1] India occupies a central position in this global negotiation: it is the world's largest supplier of generic medicines, yet its own statute, through provisions such as Section 3(d), deliberately narrows the patentability of incremental pharmaceutical inventions. [2]

[1] Paulina Krukowska-Siembida, Patent Protection in the TRIPS Agreement and the Right to Health: Can They Be Reconciled?, 28 Studia Iuridica Lublinensia 89 (2019), https://doi.org/10.17951/sil.2019.28.4.89-100..

[2] Shriyash Maindarkar, SECTION 3(D) OF PATENT ACT: PROBLEM OR BENEFICIAL TO PHARMACEUTICAL SECTOR, Zenodo (CERN European Organization for Nuclear Research) (2022), https://doi.org/10.5281/zenodo.6370386; Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, University Of Pittsburgh Law Review (University of Pittsburgh) (2007), https://lawreview.law.pitt.edu/ojs/lawreview/article/view/79..

This article examines the IP framework governing biotechnology and digital health care in India through three lenses. First, it analyzes the patentability of biotechnological inventions — genes, life forms, and their morality-based exclusions. Second, it interrogates the digital turn: software-implemented diagnostics, AI inventorship, and the treatment of health data as both a protected asset and a privacy concern. Third, it situates the entire edifice within the access-to-medicines debate, examining compulsory licensing, trade secrecy, and the constitutional right to health, before proposing reforms to reconcile innovation incentives with public-health imperatives.

II. Patenting the Living: Biotechnology and the Indian Patent Regime

A. Subject-Matter Boundaries and Morality Exclusions

The patentability of biotechnological inventions is contested at the level of subject matter itself, because biotechnology draws its raw material from living organisms — a domain traditionally outside the commercial enclosure of the patent system. [3]Comparative divergences are stark. The United States, through 35 U.S.C. s.101, has historically taken a broad view of what may be patented; the European Patent Convention, through Article 53(a), and the European Union's Biotech Directive, through Article 6, exclude inventions contrary to morality and public order; India, through Section 3(b) of the Patents Act, 1970, excludes inventions contrary to public order or morality, "which causes serious prejudice to human, animal or plant life or health or to the environment". Scholars comparing these regimes have argued that India's morality clause is dangerously indeterminate, leaving patent controllers to exercise unguided discretion, and that a clearer definition of "morality" and "contrary to public order" is required as biotechnological advances accelerate.[4].

The moral contours of biotechnology patenting are not merely philosophical; they determine the fate of specific inventions. India's Patents Act also excludes, in Section 3(i), "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings" — an exclusion that TRIPS does not require, leaving member states free to decide whether to protect new therapeutic uses of known products[5] The Supreme Court's reading of Section 3(d), introduced by the 2005 amendment, has become the single most

[3] Helen P Azyu & Avishek Chakraborty, Interface between Legal and Moral Implications on Patenting Biotechnological Inventions: A Comparative Analysis of the Patents Law of India, the US and the EU, 30 Journal of Intellectual Property Rights (2025), https://doi.org/10.56042/jipr.v30i3.6108

[5] Janice M. Mueller, The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation, University Of Pittsburgh Law Review (University of Pittsburgh) (2007), https://lawreview.law.pitt.edu/ojs/lawreview/article/view/79..

consequential provision in Indian pharmaceutical law: it denies patentability to new forms of known substances unless they demonstrate "enhanced efficacy," thereby disciplining the practice of evergreening.[6] Scholarly assessments of Section 3(d) remain divided; critics argue that Indian courts have missed key interpretive points even as the provision disciplines the industry, while defenders see it as a public-health bulwark.

B. Gene Patents: Practice Without Doctrine

Gene patenting illustrates the gap between statutory prohibition and administrative practice. While the Patents Act, 1970, prohibits the patenting of naturally occurring substances, patents covering genetic material and nucleotide sequences have nonetheless been granted by the Indian Patent Office.[7]In the absence of clarifying case law, researchers examining the prosecution history of patents actually granted by the IPO have documented the standards actually applied to nucleotide sequence claims, noting the persistence of a practice that the statute's text appears to foreclose. This doctrinal vacuum is significant because the commercial value of diagnostics and personalized medicine increasingly rests precisely on genetic-sequence claims.

C. Agricultural Biotechnology and Farmers' Rights

Biotechnology's reach extends into agriculture, where IP rights intersect with farmers' foundational claims. The TRIPS-mandated expansion of IP protection into agricultural biotechnology has generated intense concern about food security, biodiversity, and the concentration of proprietary control over seeds[8]. Analyses of India's response to TRIPS have argued that amendments to the Patents Act confer strong rights on upstream producers of proprietary agricultural inputs, enabling monopoly price control over seeds for twenty years and determining the conditions under which farmers and researchers may use patented processes and products. The litigation involving Monsanto's Roundup Ready soybeans, Bt cotton, and Bt eggplant in Brazil and India illustrates how private royalty-collection systems were adapted to local agrarian conditions, effectively reproducing the corporation's American-

[6] Shriyash Maindarkar, SECTION 3(D) OF PATENT ACT: PROBLEM OR BENEFICIAL TO PHARMACEUTICAL SECTOR, Zenodo (CERN European Organization for Nuclear Research) (2022), https://doi.org/10.5281/zenodo.6370386; Apoorva Dixit, Section 3(D) Of Patent Act: Problem or Beneficial To Pharmaceutical Sector, 83 7308 (2020), https://testmagzine.biz/index.php/testmagzine/article/download/4857/4019..

[7] Bhavishyavani Ravi, Gene Patents in India: Gauging Policy by an Analysis of the Grants Made by the Indian Patent Office* (2013), http://nopr.niscair.res.in/bitstream/123456789/20283/1/JIPR%2018%284%29%20323-

[8] Ram Prasad, An Overview of Intellectual Property Rights in Relation to Agricultural Biotechnology, 11 AFRICAN JOURNAL OF BIOTECHNOLOGY (2012), https://doi.org/10.5897/ajb12.262.

style IP power irrespective of differences between India's patent and plant-variety laws.

India's legislative answer has been the sui generis Protection of Plant Varieties and Farmers' Rights Act — the only instrument of its kind that formally recognizes farmers' rights. Yet critical scholarship on the PPV&FR Act documents persistent setbacks in implementation, arguing that the politics of biodiversity and IP in India has "compromised the meaningful implementation of farmers' rights" [9]. The tension between the breeders' rights demanded by the biotechnology industry and the farmers' rights demanded by agrarian communities thus remains unresolved, with the PPV&FR Act representing an experiment whose promise has yet to be realized.[10] .

III. The Digital Turn: Software, AI, and Digital Health IP

A. Computer-Related Inventions and the Section 3(k) Problem

Digital health care is built on software. Diagnostic algorithms, telemedicine platforms, electronic health records, and AI-based clinical decision support all raise the threshold question of whether computer-implemented inventions can be patented in India. Section 3(k) of the Patents Act excludes "a mathematical or business method or a computer program per se or algorithms" — an exclusion whose scope has been litigated and re-litigated for two decades. For much of that period, the examination of computer-related inventions was governed by guidance documents of contested validity: the Indian Patent Office published CRI Guidelines on 21 August 2015, withdrew them following civil-society protests, and reissued a revised version in 2016 that reaffirmed the exclusion of software per se and introduced a three-step test for Section 3(k).

In the United States, by contrast, the Supreme Court's decision in *Alice v. CLS Bank* required software claims to be tied to hardware and to amount to "significantly more" than an abstract idea before they could be patent-eligible. The Court of Justice of the European Union and the EPO-adjacent jurisprudence insist on a technical solution to a technical problem. India's trajectory has been idiosyncratic: courts have gestured toward a "technical effect" standard, but the 2025 Draft CRI Guidelines — analyzed by commentators as proposing a structured examination with "seven stambhas" and a five-step test of inventive step, building on cases

[9] Karine Peschard, Farmers' Rights and Food Sovereignty: Critical Insights from India, 41 The Journal of Peasant Studies 1085 (2014), https://doi.org/10.1080/03066150.2014.937338

[10] Karine Peschard, Farmers' Rights and Food Sovereignty: Critical Insights from India, 41 The Journal of Peasant Studies 1085 (2014), https://doi.org/10.1080/03066150.2014.937338; Sourabh Batar, Sui Generis Systems and Farmer's Rights: The PPV&FR Act as India's Legislative Response to Agricultural IP Challenges, 6 Journal of international commercial law and technology 1645 (2025), https://doi.org/10.61336/jiclt/25-01-154..

such as *Ferid Allani v. Union of India* and the *Ericsson* litigation — represent the latest, still-unsettled attempt to define when software becomes patentable.[11] For digital health specifically, the practical consequence is uncertainty at the very heart of the innovation economy: an algorithm that diagnoses diabetic retinopathy may or may not clear Section 3(k), depending on how its claims are drafted and which guideline the examiner applies.

B. AI Inventorship and the Machine as Creator

The deeper doctrinal challenge is posed by AI systems that autonomously generate inventions. In which patent applications naming an AI system as the inventor were filed with the European Patent Office, the UK Intellectual Property Office, and the United States Patent and Trademark Office, the debate crystallized. The inventions at issue, including a blinking light and a fractal food container, were unremarkable; the question was whether a machine can be an "inventor" at all.[12] The world's patent offices answered in the negative, and the scholarly consensus is that, as of now, only natural persons can be inventors, with DABUS serving as the paradigmatic illustration of the limits of the human-centered patent system. Commentators have argued that the patent system's foundational premises — the inventor as a rational, human actor — are ill-equipped for generative AI, and that the system must be "rethought in-depth and adapted to the conditions of creation and invention in the AI age." [13]Some scholars propose that legislatures act proactively rather than reactively, before technology outpaces law.

For the biomedical sector, these questions are not theoretical. AI has revolutionized drug research and discovery, personalized medicine, and medical diagnostics, generating complex IP challenges around inventorship, protection of AI-generated works, data ownership, and licensing across the United States, the European Union, China, and India.[14]. Patent-filing data from India between 2010 and 2025 show vigorous activity in AI-healthcare innovation, concentrated in medical imaging, diagnostics, and predictive analytics. Yet the legal scaffolding lags: in India, algorithms cannot be patented; there is no specific legislation

[11] Jyoti Sain Dass, Demystifying Inventive Step in Computer-Related Inventions: A Critical Analysis of India's Draft CRI Guidelines 2025, International Journal of Science and Research (IJSR) 1444 (2026), https://doi.org/10.21275/sr26122192239..

[12] Dagmar Gesmann-Nuissl & Stefanie Meyer, Gyro Gearloose or Little Helper?—Two Perspectives of AI and Patent Law, in Advances in Science, Technology & Innovation/Advances in science, technology & innovation 319 (2026),

[13] Sigrid Sterckx & Julian Cockbain, Is Artificial Intelligence a Threat to the Patent System? Some Reflections on AI, Creativity and Inventorship, with Illustrations from the DABUS Case, in Edward Elgar Publishing eBooks 140 (2024),

[14] Abhijit Poddar & Suresh Ranga Rao, Evolving Intellectual Property Landscape for AI-Driven Innovations in the Biomedical Sector: Opportunities in Stable IP Regime for Shared Success, 7 Frontiers in Artificial Intelligence 1372161 (2024)

governing AI in health care; and regulators have only begun to appreciate that software itself may constitute a "software as a medical device"[15]. The pandemic-era proliferation of AI-empowered eHealth applications has amplified these issues, raising questions about whether such inventions satisfy the inventive step and disclosure requirements at all.[16].

C. Data, Platforms, and the New Digital Health Economy

Digital health IP extends beyond patents to the data that the entire ecosystem depends on. Health data — collected through wearables, telemedicine consultations, and electronic health records — is simultaneously the input to AI training, the subject of trade-secret protection, and the object of a constitutional privacy claim. In India, that privacy dimension was constitutionalized by *Puttaswamy*, while the statutory architecture has only recently emerged: the Digital Personal Data Protection Act, 2023, regulates the collection, processing, and storage of personal digital data, and is regarded as a transformative step for the healthcare sector [17] The Act introduces defined roles — Data Principal, Data Fiduciary, Data Processor, Consent Manager — and patient rights of correction and erasure, against the legislative backdrop of the National Health Policy, 2017, the Srikrishna Committee report, and high-profile breaches such as the 2022 All-India Institute of Medical Sciences cyberattack[18]

Yet sector-specific lacunae persist. The DPDP Act replaced Section 43A of the Information Technology Act and the SPDI Rules. Still, the proposed health-specific frameworks, such as DISHA and the Health Data Management Policy, are not rendered redundant by the general statute. Clinicians and researchers face genuine ambiguity about how the Act applies to digital patient consultations and medical research.[19]. Comparative assessments against the EU and US frameworks identify significant gaps — including limited protection for health data, ambiguity around paper records and retrospective consent, and unresolved questions regarding medical tourism and cross-border data flows — that could leave Indian patients exposed even under the new law. The intersection of data protection, trade secrecy, and IP law in health care thus remains one of the most under-theorized spaces in Indian jurisprudence.

[15] Krishnan Ganapathy, Artificial Intelligence and Healthcare Regulatory and Legal Concerns, Telehealth and Medicine Today (2021),
[16] Enrico Bonadio & Magalí Contardi, Artificial Intelligence, Patents and Health Innovation, in Edward Elgar Publishing eBooks 188 (2023)
[17] Amit Chail, Surinder Kumar & Ranjit Singh Lahel, The Digital Personal Data Protection Act and Rules: Implications for Health Care and Strengths, Weaknesses, Opportunities, and Challenges Analysis, Journal of Marine Medical Society (2026),
[19] Anubhuti Sood et al., Challenges and Recommendations for Enhancing Digital Data Protection in Indian Medical Research and Healthcare Sector, 8 npj Digital Medicine 48 (2025)

IV. Data as a Protected Asset: Clinical Trial Data, Trade Secrecy, and Access

A. Data Exclusivity and TRIPS Article 39.3

Pharmaceutical innovation not only results in patents but also in regulatory data—the extensive clinical trial dossiers necessary for marketing approval. Whether this data can be protected from reliance by generic competitors depends largely on Article 39.3 of the TRIPS Agreement. This article obliges members to safeguard undisclosed test data against unfair commercial use and disclosure, allowing release only "where necessary to protect the public" or when measures are in place to prevent unfair commercial exploitation.

India has opted not to establish a data-exclusivity regime. Instead, it relies on breach of confidence doctrines, enabling generics to depend on bioequivalence studies rather than duplicating original trial data, which facilitates early market entry. This approach has helped make India a key producer of affordable medicines. However, this stance is increasingly challenged—especially by trading partners like the U.S. and EU—who press for data exclusivity, raising debates about whether such policies would boost R&D or disrupt India's balanced patent framework. The core issue extends beyond trade compliance; it concerns which types of innovation are rewarded and whether a system based on data monopolies can align with a constitutional focus on health.

B. The Quiet Growth of Trade Secrecy

While patent discussions have traditionally dominated access debates, scholars are now emphasizing trade secrecy as an even more subtle barrier.Human rights frameworks recognize the right to health and the benefit of scientific progress, both requiring states to ensure medicine access. However, trade secrets hinder researchers from sharing clinical trial data, weaken pandemic responses by impeding manufacturing scale-up, and discourage whistleblowing on industry misconduct—all of which threaten health security. When manufacturing processes are kept secret, strategies like compulsory licensing and technology transfer become less effective.

C. The New Frontier: Digital Health Data

The spread of digital health tools intensifies these issues, transforming them into complex data governance challenges. In India, rapid adoption of electronic health records has led to increased cyber threats, exposing gaps in existing legal protections. The DPDP Act, 2023, offers a broad response, but health-specific regulations like DISHA and the Health Data Management Policy

remain inconsistent and uncertain.

Hospitals must invest heavily in IT infrastructure, digitization, and staff training to comply, driving up costs. Patients stand to benefit from greater control over their data through consent mechanisms, but risks stem from exemptions and unclear provisions. For IP professionals, the complexity is heightened by the fact that the same data can be a trade secret, a protected personal data under the DPDP Act, and an input for patentable diagnostics—all at once, operating under multiple overlapping legal regimes coordinang principle.

V. Access, Health, and the Limits of IP: TRIPS, Doha, and Compulsory Licensing

A. The Global Architecture

The TRIPS Agreement globalized pharmaceutical patents and, in doing so, generated the most sustained confrontation between IP law and the right to health in modern legal history. Developing countries, where three-quarters of the world's population lives but which account for less than 10% of the global pharmaceutical market, face rising drug prices without commensurate R&D investment for diseases affecting their populations. The Doha Declaration of 2001 was the pivot: it recognized the gravity of public-health problems afflicting developing and least-developed countries, affirmed that intellectual property protection is important for the development of new medicines, and confirmed the freedom of WTO members to grant compulsory licenses, to determine grounds for their grant, and to establish their own exhaustion regimes.[20]

B. India's Compulsory Licensing Jurisprudence

India has translated these flexibilities into domestic law through Sections 84 and 92 of the Patents Act, 1970. The first — and still the paradigm — exercise of Section 84 came on 9 March 2012, when the Controller of Patents granted Natco Pharma a compulsory license for Bayer's patent on sorafenib, used to treat advanced liver and kidney cancer[21]. The Intellectual Property Appellate Board upheld the decision in early 2013. Scholarly assessments of *Natco v. Bayer* treat it as establishing the benchmark for compulsory licensing on grounds of

[20] Paulina Krukowska-Siembida, Patent Protection in the TRIPS Agreement and the Right to Health: Can They Be Reconciled?, 28 Studia Iuridica Lublinensia 89 (2019), https://doi.org/10.17951/sil.2019.28.4.89-100; DN Matthews & Carlos Correa, The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health, Queen Mary Research Online (Queen Mary University of London) (2011),

[21] Enrico Bonadio, Compulsory Licensing of Patents: The Bayer-Natco Case, City Research Online (City University London) (2012),

unaffordability and failure to work the invention in India. Critics have questioned whether the decision satisfies the non-discrimination principle of Article 27 TRIPS defenders point to its deterrent effect, which has nudged innovator companies toward voluntary licensing and more reasonable pricing[22] Subsequent commentary has examined the tussle between profit-driven pharmaceutical companies and welfare-oriented governments seeking cheaper access to essential medicines, including in the COVID-19 context, where governments explored compulsory licensing to secure vaccines and treatments [23]The jurisprudential signal from India is consistent: the courts and the patent office will uphold patent rights as a general principle, but public health retains priority.

C. The Right to Health as Constitutional Backdrop

None of this occurs in a constitutional vacuum. The Indian Supreme Court has long treated the right to health as an integral part of the right to life under Article 21. Commentators continue to debate whether an explicit constitutional recognition of health as a fundamental right is required to make this commitment justiciable and enforceable. In the pharmaceutical-patent context, this right-to-health jurisprudence supplies the normative canon against which the patent bargain is evaluated: the disclosure of the invention in exchange for a temporary monopoly is legitimate only if it does not extinguish the state's obligation to ensure access to essential medicines[24] The pandemic dramatized this bargain globally, and the scholarly literature on trade secrecy, data exclusivity, and compulsory licensing converges on the same conclusion that IP rights, however necessary for innovation, must be institutionally constrained where life and health are at stake.[25]

VI. Toward a Coherent Framework: Reforms and Recommendations

This analysis suggests three interconnected reforms. First, there should be clearer doctrinal definitions of biotechnological subjects. The morality clauses in Section 3(b) need precise

[22] Ram Chaubey, Issues of Patent Law in the Pharmaceutical Industry: An Analysis of Emerging Jurisprudence Regarding Compulsory Licensing, 7 International Journal For Multidisciplinary Research (2025),
[23] V. Parthasarthi, Analysis of Compulsory Licensing in India and Its Perceived Impact During the Covid Era, 4 GLS Law Journal. 21 (2022)
[24] Vasudha Khanna, Neha Dumka & Atul Kotwal, Is India Ready for Fundamental Right to Health?, 11 International Journal of Community Medicine and Public Health 1730 (2024), http://dx.doi.org/10.18203/2394-6040.ijcmph20240920; Jaya Surya Kunal M. & Abraham S., Right to Health as a Fundamental Right in India: Legal Framework, Judicial Interpretation and Policy Challenges, Zenodo (CERN European Organization for Nuclear Research) (2026),
[25] Allison Durkin et al., Addressing the Risks That Trade Secret Protections Pose for Health and Rights., 23 PubMed 129 (2021), https://pubmed.ncbi.nlm.nih.gov/34194207; V. Parthasarthi, Analysis of Compulsory Licensing in India and Its Perceived Impact During the Covid Era, 4 GLS Law Journal. 21 (2022),

definitions, and the IPO's gene-patent practices should align with the law's exclusion of naturally occurring substances. While retaining the Section 3(d) framework, it should be applied with clear, consistent criteria to ensure that only genuine incremental innovations are rewarded, without unfair over- or under-protection.

Second, India must adopt a technology-sensitive approach to digital health IP. The ambiguities in Section 3(k) should be addressed through finalized CRI guidelines or legislative clarification. This will ensure AI-driven diagnostics and therapeutics qualify for protection when they show genuine technical innovation, while algorithms alone remain unpatentable. Regarding inventorship, India should proactively legislate or issue guiding principles for AI-assisted and AI-generated inventions, rather than leaving it to case law. This requires alignment among policymakers, clinicians, researchers, industry stakeholders, and patient advocates, as recommended by commentators on biomedical AI.

Third, a robust data governance framework should balance IP rights, privacy, and public health. Specific health data regulations should supplement the DPDP Act, 2023—completing the DISHA framework and the Health Data Management Policy—to prevent personal health data protections from becoming vague or inconsistent.

Additionally, India should continue to resist data exclusivity and strengthen protections for undisclosed information under the confidence law, which has supported affordable medicines. The issue of trade secrets also needs attention: transparency norms for regulatory data, manufacturing know-how during pandemics, and whistleblower protections should be incorporated into the framework, in line with international standards obligations.

VII. Conclusion

Biotechnology and digital health care represent the two great innovation frontiers of the twenty-first century. India sits at the centre of both — as a generic-manufacturing powerhouse, as a rapidly digitising healthcare market, and as a constitutional democracy committed to health as a right Its patent law is heir to a developmental tradition that disciplined pharmaceutical monopolies; its digital law is only now being written; and its courts have consistently placed public health above private right The challenge of the coming decade is to construct an intellectual property framework that is at once innovation-conducive, technologically literate,

and constitutionally faithful — one in which the patent bargain, the data regime, and the right to health are reconciled rather than merely traded off.