DATA EXCLUSIVITY AND THE PHARMACY OF THE WORLD: INDIA'S RESISTANCE, THE GLOBAL HEALTH STAKES, AND THE CASE FOR A LIABILITY RULE

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ABSTRACT

India has long served as the "pharmacy of the world" and a strong supporter of the generic pharmaceutical industry in order to secure the accessibility and affordability of drugs to the general public both domestically and internationally. Over the years, India has created a holistic anti-evergreening framework, including Section 3(d) of the Patents Act, 1970, compulsory licensing, and pre- and post-grant opposition mechanisms, which represent one of the most carefully constructed public health-oriented patent regimes in the developing world.

Data exclusivity is a TRIPS-plus obligation that developed countries advocate for, which can completely bypass patent laws and safeguards to provide evergreening-like benefits such as market exclusivity by restricting the use of clinical trial data for approval of generics. It poses a structural threat to existing pro-public health laws and operates within the regulatory domain, conferring market exclusivity without any of the public interest safeguards applicable to other intellectual property rights.

By reference to the utility theory of justification for intellectual property, this paper examines India's refusal to adopt data exclusivity as a measure to protect the social contract of IP law, and proposes a liability-based compensation model as a fair and balanced alternative to market-exclusivity-based data protection. The paper concludes that India's defensive stance is not a mere policy preference but a legally correct and essential requirement to ensure that intellectual property serves its primary purpose: the advancement of public welfare alongside the encouragement of innovation.

Keywords: Data Exclusivity; TRIPS Article 39.3; Section 3(d) Patents Act 1970; Pharmaceutical Evergreening; Compulsory Licensing; Liability Rule; Generic Medicines; TRIPS-Plus

I. INTRODUCTION

The pharmaceutical industry occupies a uniquely sensitive position when viewed from both the public and industry perspectives. Discovering a new drug and bringing it to market is an extraordinarily expensive undertaking, yet drugs are essential commodities with the power to save lives and hence are not merely products but guarantors of the right to life. Both sides in this debate possess equally compelling arguments about why their interests should be prioritised in pharmaceutical legislation. The industry contends that it should be entitled to recoup the benefits of its research and capital investment, and that generic manufacturers should not be permitted to produce equivalent versions prematurely. The public health perspective holds that medicines are essential commodities and that whenever there is an opportunity to make patented drugs more affordable and accessible, steps should be taken to facilitate it. This tension becomes particularly pressing in a country such as India, with a population of 1.4 billion people still in a phase of development.

This conflict between private incentive and public necessity finds its theoretical basis in the utility theory of intellectual property, according to which the validity and fairness of any exclusive right derives not from the inherent moral claims of the creator but from its capacity to maximise overall social welfare by balancing the benefit of the innovation against the cost of restricted access. A utilitarian assessment of the pharmaceutical patent system suggests that the law must serve as a well-calibrated instrument, granting exclusivity sufficient to encourage research and development while ensuring that the resulting medicines remain affordable. Accordingly, any expansion of the exclusivity term, whether through patent term extensions, evergreening, trivial secondary patents, or data exclusivity, must be rigorously tested against social utility. If the marginal gain in innovation is outweighed by the erosion of public health access, the expansion fails the normative test upon which intellectual property law is built and should not be permitted.

From a public welfare perspective, patents already provide a balance between innovation incentives and public benefit. Data exclusivity thus operates as a second, parallel tool on the same subject matter, through which an originator pharmaceutical company can obtain years of market monopoly even without a valid patent, and should therefore not be adopted.

The pre-1970 patent framework, which permitted product patents in pharmaceuticals, resulted in foreign companies filing the majority of patents and thereby creating monopoly-like conditions with exorbitant drug prices that denied Indian citizens affordable healthcare. On the recommendations of the Ayyangar Committee, product patents for pharmaceuticals were abolished after 1970, spurring the growth of India's generic drug industry and establishing its reputation as the pharmacy of the world. This changed when India joined the TRIPS Agreement, which required the reinstatement of product patents in pharmaceuticals. India responded by utilising TRIPS flexibilities and addressing pharmaceutical evergreening through Section 3(d), pre-grant and post-grant oppositions, compulsory licensing, and the Bolar exemption. These mechanisms have, to date, been effective in protecting the generic industry and ensuring affordable medicines.

However, over the last two decades, data exclusivity has emerged as a novel threat, being a distinct form of intellectual property right being pressed upon developing countries by developed nations. Data exclusivity refers to a defined period during which a regulatory authority does not accept or approve a marketing authorisation application from a third party that relies, directly or indirectly, upon preclinical and clinical data submitted by the originator, without the originator's consent. This operates independently of patent status and often stems from Free Trade Agreements or the domestic laws of developed nations, justified under Article 39.3 of TRIPS.

Data exclusivity remains immune to every safeguard that the Indian legal system has created against pharmaceutical evergreening. Section 3(d) cannot block a data exclusivity claim because data exclusivity is not a patent right. Pre-grant and post-grant oppositions are equally inapplicable. Compulsory licensing is effectively neutralised. Since patents already balance innovation and access, introducing data exclusivity undermines public welfare by prolonging monopolies. Data exclusivity therefore constitutes a threat arising in the regulatory domain where India's current defences are absent. This paper argues that India's resistance to data exclusivity is legally correct, that the demand for exclusivity has no basis in international law, and that a liability-based

compensation model represents the principled and sufficient response to the originator industry's legitimate interests in clinical trial data.

RESEARCH QUESTIONS

1. Whether the introduction of pharmaceutical data exclusivity in India would undermine the existing balance between innovation incentives and public access to affordable medicines?

2. Whether India's continued resistance to data exclusivity is justified from the perspective of public health, generic competition, and the utility-based theory of intellectual property law?

3. Whether confidentiality-based protection of clinical trial data can serve as a more balanced alternative to market-exclusivity-based protection?

RESEARCH HYPOTHESIS

India's refusal to adopt data exclusivity is legally correct because Article 39.3 of TRIPS does not require market exclusivity, only confidentiality. Data exclusivity fails the utility theory test for intellectual property rights since its cost to public health access outweighs any marginal gain in innovation incentive. A liability-based compensation model is a sufficient and more balanced alternative, as it protects originator interests in clinical trial data without granting a market monopoly that bypasses India's existing anti-evergreening framework.

RESEARCH METHODOLOGY

This research is doctrinal and draws upon the analysis of international agreements, domestic legislative frameworks, and bilateral trade instruments as foundational sources. It further includes a comparative analysis examining how data exclusivity has been structured and operationalised in the United States and the European Union. A normative evaluation grounded in the utility theory of intellectual property is undertaken to assess whether data exclusivity satisfies the justification for granting intellectual property and exclusivity rights. The paper culminates in a prescriptive proposal, advancing a liability-based compensation model as a legally coherent and policy-sound alternative to market exclusivity.

II. ARTICLE 39.3 OF TRIPS AND THE INTERPRETIVE FAULT LINE

Data exclusivity was first formalised around the 1980s in the United States. The United States has since consistently advocated for data protection terms internationally, claiming that Article 39.3 of the TRIPS Agreement encompasses data exclusivity, as it obliges Members to protect undisclosed test data submitted for marketing approval of pharmaceutical products against "unfair commercial use." The central question is whether "unfair commercial use" mandates a fixed exclusivity period prohibiting regulatory authorities from relying on the originator's data, or whether it requires only that the originator's data not be disclosed, misappropriated, or commercially exploited by competitors. The United States, the European Union, and various multinational pharmaceutical corporations have consistently lobbied for the former interpretation.

India, maintaining a public-first approach, has consistently held the contrary position. A regulatory authority exercising a public health function does not constitute a "commercial" competitor within the meaning of Article 39.3. The provision is concerned with unfair commercial use, that is, misappropriation of data by competitors or industry participants, and does not bar government regulators from relying on such data. The exception "where necessary to protect the public" further supports India's anti-exclusivity stance, as CDSCO's approval of generic drugs is a public-spirited act aimed at making life-saving drugs accessible. This interpretation also aligns with the utility-based understanding of intellectual property law, under which exclusive rights are justified only so long as they serve the greatest public welfare and do not merely create private monopolies at the cost of public access.

India's public-first approach is not limited to trade negotiations. It is also evident in its domestic patent framework, particularly through Section 3(d), where the Supreme Court in *Novartis AG v. Union of India* insisted on "therapeutic efficacy" before allowing secondary pharmaceutical protection. It is further reflected in pharmaceutical injunction cases such as *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, CS(OS) 89/2008, where the Delhi High Court refused an interim injunction and treated patient welfare and affordability as part of the balance of convenience in patent litigation. India's reading of Article 39.3 is therefore consistent with its broader legal approach that intellectual property protection cannot be separated from access to affordable medicines.

The Doha Declaration reinforces this interpretation, affirming that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health," a principle that has consistently supported India's resistance to data exclusivity demands

in trade negotiations.[1] This position is especially significant because India is not merely protecting its domestic market, but also its role as the pharmacy of the world. India's pharmaceutical industry is valued at around USD 60 billion, is projected to reach USD 130 billion by 2030, and accounts for around 20% of global generic medicine supply.[2] This manufacturing capacity was vividly demonstrated during COVID-19, when India's vaccine and pharmaceutical production became central to global public health response. Any interpretation of Article 39.3 that blocks generic approval therefore carries consequences far beyond India.

The Satwant Reddy Committee opined that data exclusivity for pharmaceuticals was not a mandatory requirement under international law and that it is against India's public health interests and constitutional obligations.[3] The Committee held that TRIPS Article 39.3 was fully satisfied through existing confidentiality and non-disclosure obligations and did not require a fixed exclusivity period. India's resistance to data exclusivity in trade negotiations with EFTA, the United Kingdom, the European Union, and against continuing pressure reflected in the USTR Special 301 Report, should not be understood as a rejection of data protection itself. It is a rejection of monopoly-based data exclusivity where confidentiality-based protection is already sufficient.

III. DATA EXCLUSIVITY AS REGULATORY EVERGREENING: BEYOND PATENT LAW'S REACH

Data exclusivity functions as a workaround to anti-evergreening laws by providing monopoly-like exclusivity over test data while operating outside the jurisdiction of patent law. A trivial improvement in a drug whose patent was refused under Section 3(d) can receive data exclusivity by submitting data and obtaining CDSCO marketing approval, effectively compelling generic entrants to spend substantial funds and years in clinical trials to generate original data. This is the core threat: a drug that India's legal system correctly refuses to protect under patent law can still enjoy years of de facto monopoly at the regulatory stage, beyond the reach of any existing anti-evergreening mechanism.

[1] WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, ¶ 4 (Nov. 14, 2001).
[2] Gov't of India, Ministry of Chemicals & Fertilizers, Dep't of Pharmaceuticals, Annual Report 2025–26, at 25 (2025).
[3] Gov't of India, Ministry of Chemicals & Fertilizers, Report of the Expert Committee on Test Data Protection (Satwant Reddy Committee) 39 (2007).

The consequences are best illustrated by the *Novartis* litigation. In 2013, the Supreme Court held the beta crystalline form of imatinib mesylate to be non-patentable under Section 3(d) for failing to demonstrate enhanced therapeutic efficacy. Without a valid patent, generic manufacturers were free to produce imatinib at affordable prices. Had data exclusivity been operative in India and had Novartis applied for it, Novartis could have enjoyed five years of data exclusivity from the date of marketing approval for Glivec, entirely notwithstanding the patent refusal, thereby neutralising the purpose of Section 3(d). All secondary pharmaceutical patents rejected under Section 3(d) would similarly be susceptible to data exclusivity protection, effectively halting generic competition.

Data exclusivity has the potential to harm India's entire TRIPS flexibility framework. Where a compulsory licence is granted under Section 84 of the Patents Act, 1970, the licensee acquires the right to manufacture the drug but must also obtain regulatory approval before producing or selling it. Such approval is granted on proof of bioequivalence, which requires reference to the originator's clinical data. If regulators are prohibited from using that data, they cannot grant approval until the generic company provides its own original test data, rendering India's public health safeguards operational in text only. Moreover, unlike patents, data exclusivity has no challenge mechanism and no public health safeguards; an originator company need only submit data to CDSCO to automatically secure protection.

IV. THE GLOBAL STAKES: INDIA AS THE PHARMACY OF THE WORLD

The stakes of this debate extend well beyond India's borders. As the leading supplier of low-cost generic medicines to both domestic and international markets, India's response to data exclusivity carries global consequences. India's pharmaceutical industry is valued at USD 60 billion and is projected to reach USD 130 billion by 2030. India is the largest global supplier of generic medicines, accounting for around 20% of global supply, supplying 90% of the WHO's measles vaccine demand and 60% of vaccines procured by UNICEF.[4] Any practice that deters or blocks generic drug manufacturing in India has immediate consequences not just for patients in India, but for patients across the world.

[4]Gov't of India, Ministry of Chemicals & Fertilizers, Dep't of Pharmaceuticals, Annual Report 2025–26, at 25 (2025).

The generic pharmaceutical industry depends entirely on the abbreviated drug approval process, which allows CDSCO to grant approval through bioequivalence testing by reference to established clinical data from the original manufacturer. The introduction of pharmaceutical data exclusivity in India would delay this approval for five to ten years from the date of each originator's marketing approval across every new drug entering the Indian market, irrespective of its patent status. The generic industry, which supplies over fifty percent of Africa's medicines, approximately forty percent of US generic demand, and over seventy percent of globally procured antiretrovirals, cannot conduct independent clinical trials on hundreds of drugs simultaneously, as the financial burden would be catastrophic. Every exclusivity period granted would produce a monopoly for the originator, with severe consequences for patients who currently depend on affordable generic competition.

In Jordan, where data exclusivity was introduced through the US-Jordan Free Trade Agreement, a study found that of 103 medicines registered and launched after 2001 with no patent protection, at least 79 percent had no competition from a generic equivalent as a direct consequence of data exclusivity.[5] Similarly, during the India-EFTA negotiations in February 2024, MSF warned that data exclusivity would[6] delay the registration of generic versions of new medicines or new formulations for a set period, even when there is no patent on the medicine, and welcomed India's resistance in protecting global generic supply.[7]

Although data exclusivity was excluded from the main body of the India-EFTA Trade and Economic Partnership Agreement signed on 10 March 2024, the accompanying Record of Understanding on Intellectual Property states that India and the EFTA parties are to hold further discussions on data exclusivity provisions within one year of the agreement entering into force:[8]

> *"…With regard to Article 15 (Undisclosed Information) of Annex 8.A (Protection of Intellectual Property) of the Agreement, the Parties have reached the following understanding: In implementing Article 15, Parties agree to enter into*

[5]Médecins Sans Frontières [MSF], Europe! Hands Off Our Medicine (Briefing Note, Apr. 2011).

[6]MSF South Asia, Millions of People's Access to Affordable Medicines at Risk if India-EFTA Trade Deal Finalised as Is (2024), https://msfsouthasia.org/millions-of-peoples-access-to-affordable-medicines-at-risk-if-india-efta-trade-deal-finalised-as-is/ (last visited May 14, 2026).

[7]Id.

[8]India-EFTA Trade and Economic Partnership Agreement, Record of Understanding on Intellectual Property, signed Mar. 10, 2024, Bern, Switzerland.

consultations, one year after entry into force of this agreement, to discuss issues relating to protection of undisclosed information from unfair commercial use…"

MSF has characterised this as a continuing risk, warning that certain clauses in the agreement "could significantly undermine the use of existing public health measures enshrined in Indian patent law."[9] The Record of Understanding demonstrates that India's resistance may still remain vulnerable to incremental negotiated erosion. The battle over data exclusivity is not concluded; it has simply been deferred.

India has faced coordinated, cumulative pressure from multiple fronts to adopt data exclusivity provisions. The UK-India CETA negotiations and the EU-India Free Trade Agreement of January 2026 each presented renewed demands, which India again resisted. For its very resistance to data exclusivity, the United States Trade Representative's 2025 Special 301 Report retained India on its Priority Watch List, flagging the "absence of statutory protection for clinical trial data."[10] India's sustained resistance across all these forums over multiple decades is as strategically important as its substantive legal arguments.

V. THE MIDDLE GROUND: A LIABILITY RULE IN PLACE OF EXCLUSIVITY

The United States provides five years of data exclusivity for new chemical entities under the Hatch-Waxman Act, 1984, and twelve years for biologics.[11] The European Union's "8+2+1" framework provides up to eleven years of post-approval protection, further extendable through Supplementary Protection Certificates.[12] Developed countries accordingly advocate for data protection and exclusivity laws in other nations to protect the clinical trial data of their originator companies when those companies enter markets such as India. This is largely attributable to the extraordinary expense and time required for clinical trials, and the view that originator companies should be remunerated through special protection for their data.

Under Indian law as it currently stands, when a generic manufacturer seeks approval for a drug, it must prove the bioequivalence of its product vis-à-vis the patented drug. Once bioequivalence is

[9]MSF South Asia, supra note 6.

[10]Office of the U.S. Trade Representative, 2025 Special 301 Report 54 (2025).

[11]Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), 21 U.S.C. § 355(j)(5)(F); 21 C.F.R. § 314.108 (2024).

[12]Directive 2001/83/EC of the European Parliament and of the Council, art. 10(1) (as amended by Directive 2004/27/EC); Council Regulation (EC) No. 469/2009 on Supplementary Protection Certificates.

established, the DCGI may access the clinical data provided by the original drug manufacturer and, on that basis, grant marketing approval to the generic version. The generic manufacturer is therefore not required to undergo the lengthy clinical trial process, enabling it to offer the drug at a substantially lower price.

If data exclusivity were adopted in India, the DCGI would be prohibited from relying on the originator's data for marketing approval, and generic manufacturers would be required to undertake fresh clinical trials or wait for the exclusivity period to expire. This would delay generic entry, sustaining higher patented drug prices in the absence of competition. Moreover, a form of data exclusivity evergreening becomes possible: if patent protection is sought for an initial twenty years and data exclusivity is then claimed for a further eight years, the effective period of commercial exclusivity could extend to twenty-eight years. Further minor modifications could then attract renewed data exclusivity protection. If generic manufacturers must commence clinical trials from scratch, their capital expenditure increases substantially, with a corresponding effect on drug prices.

Jerome Reichman proposed a more balanced alternative, contending that "negotiators should replace the norm of exclusive control over data with a liability rule, or take and pay rule, in which generic manufacturers can use original manufacturers' clinical trial data in exchange for reasonable compensation."[13] This would acknowledge the proprietary character of clinical trial data without conferring market exclusivity, and without displacing the regulatory approval pathway on which global generic competition depends.

India's policy has been consistent throughout: Article 39.3 of TRIPS requires only confidentiality protections, and the adoption of data exclusivity undermines the generic industry's role as a pillar of global public health. The constitutional right to health under Article 21, as interpreted by the Supreme Court, creates an obligation to act against regulatory barriers to affordable medicines.[14] India's resistance to TRIPS-Plus demands is thus in support of global public health and is not merely an expression of industry preference.

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[13]J.H. Reichman, Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Compensatory Liability Regime (Duke Univ. Sch. of Law, SSRN Working Paper, 2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1433392 (last visited May 14, 2026).

[14]Consumer Educ. & Research Ctr. v. Union of India, (1995) 3 SCC 42; Paschim Banga Khet Mazdoor Samity v. State of W. Bengal, (1996) 4 SCC 37.

VI. CONCLUSION AND SUGGESTIONS: THE SOCIAL CONTRACT OF INTELLECTUAL PROPERTY LAW

Data exclusivity, if accepted by India as an intellectual property right, would directly affect generic pharmaceutical manufacturers, driving drug prices higher both domestically and globally. India has been correct in resisting pressure from developed countries, exercised through free trade agreements, to incorporate data exclusivity. The question of data exclusivity is not a mere matter of policy but concerns how societies distribute the costs and benefits of medical innovation. From a utility-based understanding of intellectual property law, exclusive rights are justified only when they ultimately serve public welfare, and not when they merely create private monopolies at the cost of access to medicines. Innovation and public welfare must be balanced such that neither is excessively compromised.

Society grants patent rights for twenty years in exchange for full disclosure of an invention to the public, enabling the innovator to benefit commercially from the fruits of their labour, after which society may freely utilise the innovation. If data exclusivity is additionally introduced, two overlapping intellectual property protections operate over the same pharmaceutical product, extending exclusivity periods and deterring competition, keeping essential medicine prices high and unaffordable. This would be contrary to the very balance on which intellectual property law is premised.

Just as a patent system that permits drug evergreening undermines the social contract that justified the patent monopoly, a free trade agreement granting data exclusivity without any of the safeguards applicable to the patent system is even less justifiable. Data exclusivity confers all the commercial protection that a patent would provide, even in situations where the drug or its modified form may fail Section 3(d) and remain unpatentable. If permitted, data exclusivity laws would not directly contradict the language of the Patents Act, but they would contradict the spirit of Section 3(d), which was enacted to prevent unjustified pharmaceutical monopolies.

If introduced in India, data exclusivity would render the patent-based anti-evergreening framework largely irrelevant for new drugs. India's policymakers and legal community must understand this threat and continue to resist it with the same firmness demonstrated in recently concluded trade negotiations. India need not reject all protection of clinical trial data; confidentiality and non-disclosure protection can and should continue. However, India must firmly reject any attempt to

formalise monopoly-based data exclusivity that prevents regulatory reliance and delays generic entry.

India should introduce a compulsory-licence-like provision for essential life-saving drugs, which would permit the DCGI to refer to clinical trial data where the originator company declines to supply the drug at an affordable price, where the drug is of a life-saving nature, and where no alternative remedy exists for the treatment of the disease. The determination of whether a drug qualifies as life-saving shall be made by the DCGI on a case-by-case basis, assessing mortality burden, disease prevalence, and the availability of alternatives, without a fixed numerical threshold, in the spirit of Section 3(d) of the Patents Act. Affordability shall be determined by the government by reference to average per capita income, notified via official gazette from time to time. The mechanism may be triggered by the government, generic companies, or civil society organisations, and a decision must be reached within a maximum of one year, after which the DCGI shall be entitled to rely on the clinical data regardless.

In all other instances, there should be a system of royalty-based use of clinical data, or a one-time settlement, or profit-sharing arrangement by the generic company in exchange for use of the clinical data. The royalty shall not exceed 2–7% of profits, extendable to 8% in special circumstances, and any one-time settlement shall be calculated on the basis of projected profits over five years. Negotiations between the parties shall follow structured evidentiary steps within a defined period of six months, requiring both parties to submit relevant cost, profit, and market data at specified stages. If no agreement is reached within this period, the rate shall be automatically fixed at 5% and the generic company may proceed without further negotiation or delay. Clinical data shall not be protected after the expiry of the patent term, and shall be subject to scrutiny for evergreening-like attempts, in which case protection shall not be granted.

India has thus far succeeded in balancing corporate profit with public health. But as it progresses towards becoming a developed nation, trading away Section 3(d) or accepting TRIPS-Plus exclusivity obligations in exchange for improved trade terms may appear attractive in the short term. India should nonetheless resist such pressure, as yielding would constitute a betrayal of its identity as a human-first civilisation and of the social contract that keeps life-saving medicine affordable for millions.

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