# Patent Reform and Public Health:India's TRIPS Journey in Pharmaceutical Law

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***Abstract***

***This article critically examines the transformative impact of the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India's pharmaceutical sector, tracing its evolution from a process-patent-driven generics powerhouse to a globally integrated innovation hub. It contrasts the pre-TRIPS era—marked by the 1970 Patent Act, reverse engineering, and affordable drug access—with the post-2005 landscape shaped by product patentability, Section 3(d) anti-evergreening safeguards, and compulsory licensing provisions. Through legislative analysis and case studies of Zydus Cadila and Biocon, the paper explores how Indian firms adapted via biosimilars, novel drug delivery systems, and strategic global alliances. It also assesses the resurgence of multinational corporations, the rise of Global Capability Centres (GCCs), and India's expanding role in global value chains. The study concludes that India's TRIPS-compliant regime, while challenging, has successfully balanced innovation incentives with public health imperatives, offering a replicable model for developing countries navigating intellectual property reforms.***

***Index Terms- TRIPS Agreement, Indian Patent Act 2005, Generic Drug Industry, Pharmaceutical Innovation.***

## I. INTRODUCTION

India's pharmaceutical sector has undergone a historic transformation over the past five decades, evolving from a market dominated by foreign multinational corporations (MNCs) and high drug prices to becoming the world's largest supplier of generic medicines and a central actor in global health. This seismic shift was catalysed by two key factors: the implementation of the Indian Patent Act of 1970, which favoured process over product patents, and, a generation later, India's compliance with the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Acceptance of TRIPS, culminating in the pivotal 2005 Patents (Amendment) Act, fundamentally realigned India's intellectual property regime, reshaping patent law, market structure, innovation incentives, and global competitiveness [1,2].

This report provides a comprehensive analysis of the Indian pharmaceutical market before and after TRIPS implementation, with particular focus on patent law evolution, the fortunes of the generic industry, changes in innovation climate, drug accessibility and pricing, and the changing role of MNCs. It critically examines legislative milestones, especially the 2005 amendment, strategic responses by domestic and foreign firms, the role of compulsory licensing and anti-evergreening measures like Section 3(d), and broader market and public health repercussions domestically and internationally. Case studies on Zydus Cadila and Biocon illustrate post-TRIPS technological upgrading and global integration [3].

## II. THE PRE-TRIPS ERA: PATENT ACT 1970 AND INDIA'S PROCESS PATENT REGIME

### 2.1 Historical Legacy and Structure

At independence, India's pharmaceutical landscape was heavily fragmented and disadvantaged. The market was controlled by Western MNCs - holding as much as 80-90% of product patents and dominating finished drug sales [4]. The sector's regulatory framework, based on the colonial Patents and Designs Act of 1911, permitted product patents, which meant Indian manufacturers could neither develop nor market proprietary drugs within India, stifling local technological capacity and perpetuating high drug prices.

Against this backdrop, the Indian government, following two commissions (Justice Bakshi Tek Chand, 1949, and Justice Rajagopala Ayyangar, 1959), enacted the Indian Patent Act of 1970. This law was revolutionary: it abolished product patents for food, medicine, and chemicals and allowed only process patents - meaning Indian firms could patent new ways to make a drug, but not the drug itself[5,4]. Patent terms were shortened to 5-7 years for pharmaceuticals (much lower than most Western standards), automatic licenses of right could be issued after three years, and broad government powers limited monopolistic abuses.

### 2.2 Impact on Market Dynamics and the Rise of Generics

The process patent regime provided Indian companies with a clear legal route to reverse-engineer and develop cheaper versions of patented drugs by altering the manufacturing process. Indian companies such as Cipla, Ranbaxy, Dr Reddy's, and Sun Pharma perfected these skills, quickly capturing a majority of domestic market share, displacing MNCs, and emerging as leading exporters of generic medicines [6,7].

Price controls, notably through the Drug Price Control Orders (DPCO) from 1970 onwards, and targeted industrial policies that favoured domestic over foreign investment, further enhanced accessibility and affordability of medicines. For example, DPCO 1979 brought 370 drugs under price control, reducing the average price per dose of many essential medicines [8,9]

By the early 1990s, India was essentially self-sufficient in drug manufacturing, with thousands of local firms and a robust generic export orientation. Medicines in India were among the world's cheapest and generics became a staple in developing countries dependent on imports from India - laying the groundwork for India's future as the "pharmacy of the world"[10,5].

## III. TRIPS AGREEMENT: REQUIREMENTS AND INDIA'S COMPLIANCE TIMELINE

### 3.1 The TRIPS Mandate and Negotiating Transitional Periods

The WTO's TRIPS Agreement, effective January 1, 1995, ushered in an era of minimum global standards for intellectual property protection. For India and other developing nations, the most significant TRIPS provisions mandated product patents for all technologies, including pharmaceuticals, for a term of at least 20 years [11]. This requirement contradicted the process-patent-only regime that had fostered the Indian generics industry.

Understanding the social-economic stakes and after intensive negotiation, India secured a transition period until January 1, 2005, to introduce product patents on pharmaceuticals, coupled with interim "mailbox" provisions: from 1995, the Indian patent office was obliged to accept pharmaceutical product applications ("mailboxed" until examination post-2005), and grant Exclusive Marketing Rights (EMRs) for certain drugs, should they meet TRIPS' criteria[3].

### 3.2 Enacting Compliance: 1999, 2002, and 2005 Amendments

- **Patents (Amendment) Act, 1999**: Established mailbox and EMR provisions, allowing firms to file product patent applications and obtain marketing rights if granted patents abroad, in line with TRIPS Articles 70.8 and 70.9 [1].
- **Patents (Amendment) Act, 2002**: Defined "invention", raised patent term to 20 years for all technologies, reformed compulsory licensing, and aligned definitions and enforcement mechanisms with TRIPS.
- **Patents (Amendment) Act, 2005**: The pivotal amendment, omitting Section 5 and introducing full product patentability for pharmaceuticals, food, and chemicals from January 1, 2005. It also reinforced Section 3(d) (anti-evergreening), expanded

compulsory licensing (sections 84 and 92A), created pre- and post-grant opposition, and further harmonised Indian law with TRIPS, while safeguarding public health [12,1].

## IV. THE 2005 AMENDMENT TO THE INDIAN PATENT ACT: KEY CHANGES

### 4.1 Product Patents, Section 3(d), and Other Safeguards

- **Product Patents**: For the first time since 1970, the Act permitted patents on pharmaceutical molecules themselves, not just the processes, with a 20-year exclusivity from date of filing [12].
- **Section 3(d) - Anti-evergreening**: Explicitly barred patents for "the mere discovery of a new form of a known substance" unless a significant enhancement of therapeutic efficacy is demonstrated. The Explanation to section 3(d) provided a comprehensive list (salts, esters, ethers, polymorphs, etc.) that, unless efficacy is improved, are not patentable [13,7].
- **Compulsory Licensing**: Section 84 strengthened grounds for compulsory licenses-public interest, unaffordable pricing, and lack of local working-while section 92A enabled export-oriented compulsory licenses to countries with insufficient manufacturing, implementing the Doha Declaration on TRIPS and Public Health [14,15].
- **Pre- and Post-grant Opposition**: Formalised mechanisms for third parties to challenge patent applications, supporting transparency and oversight [16].
- **Research and Bolar Exemptions**: Section 107A allowed limited use of patented inventions for research, regulatory submission, and parallel importation, facilitating generics development and access.

**Table1: Patent Laws, Market Dynamics, and Industry Behaviour**

| Feature | Pre-TRIPS Era (before 2005) | Post-TRIPS Era (after 2005 amendment) |
|---|---|---|
| Patent protection | Process patents only (7 years) | Product and process patents (20 years) |
| Generic drug industry | Thrived via reverse engineering | Constraints on patented drugs, focus on off-patent |
| Innovation incentives | Limited, focus on process innovation | Enhanced R&D, focus on NCEs, biosimilars, alliances |
| Drug pricing/access | Low prices via generics, DPCO | Higher prices for new patented drugs, mitigated via CLs, NLEM, Section 3(d) |
| Multinational companies | Limited manufacturing, high import | Increased FDI, partnerships, patent filings, GCCs |
| Compulsory licensing | Rarely used, not codified | Used for pricing/public health (Natco v Bayer etc.) |
| Anti-evergreening (Section 3(d)) | Not applicable | Strong patentability filters, a landmark in Novartis |
| Market focus | Domestic self-sufficiency, emerging exports | Global value chain integration (CRAMS/exports) |
| Regulatory structure | BICP/initial Drug Price Control | NPPA, NLEM, DPCO 2013 (market-based pricing) |
| Global market participation | Limited | Aggressive generics expansion, biosimilars, US/EU exports |
| Technological upgrading | Focus on formulations/processes | NCEs, NDDS, biosimilars, GCCs, digital innovation |

## V. THE POST-TRIPS ERA: RESTRUCTURING OF INDUSTRY, INNOVATION, AND ACCESS

### 5.1 Evolution of the Generic Drug Industry

**Before-TRIPS:**

Generic manufacturers flourished by legally reverse-engineering drugs, supplying domestic and international markets cheaply. These firms-Cipla, Dr Reddy's, Ranbaxy, Sun Pharma, Zydus, Aurobindo, among others-not only undercut MNCs domestically but became dominant exporters to developing economies.

**After TRIPS (2005 onward):**

- Patent barriers on new drugs forced generic firms to focus on off-patent molecules, value-added generics, and complex generics (e.g., drug delivery, combination products, biosimilars).
- Indian companies entered the US and EU markets in force; by 2023, India supplied 40% of all US generics, and exports reached over $30 billion per year [17,18].
- The generics industry adapted via strategic alliances, contract research and manufacturing services (CRAMS), licensing agreements, and parallel innovation on biosimilars [5].
- Long-term, the post-TRIPS landscape led to technological upgrading of leading firms and a greater focus on compliance with international regulatory standards [19].

### *5.2 R&D Investment and Innovation Incentives*

TRIPS was expected to move Indian pharma up the value chain by incentivising novel drug discovery, not just generic production. The reality has been complex:

- **R&D Spending:** After 2005, R&D intensity among leading Indian firms rose sharply-from below 1.5% of sales in the 1990s up to 7% by 2016 for some companies[7]. Sun Pharma, Dr Reddy's, Cipla, and others invested heavily in new chemical entities (NCEs), biosimilars, and novel drug delivery systems (NDDS) [7].
- **Global Alliances:** Indian firms formed R&D alliances with MNCs for technology transfer, clinical development, and marketing. For instance, Glenmark, Biocon, and Zydus Cadila have robust pipelines and have off-licensed or co-developed molecules with international partners [20].
- **Technological Upgrading:** Indian companies have developed and commercialised breakthrough drugs (e.g., Zydus's Lipaglyn, Biocon's biosimilar insulins, anticancer biosimilars) and expanded their product portfolio to complex generics and biosimilars globally [20,21].
- **Innovation Hubs:** Leading multinationals and domestic giants are investing in Global Capability Centres (GCCs) in India to leverage local STEM talent for advanced R&D, AI-driven drug discovery, and digital health innovation [22].

### 5.3 Access to Medicines and Pricing Policies

TRIPS compliance raised major concerns about access to medicines-especially fears that product patents would hike drug prices, narrow generic supply, and limit access for the poor.

**Government Safeguards and Market Responses:**

- **Compulsory Licensing:** India operationalised TRIPS flexibilities early. The first compulsory license (Natco v. Bayer, 2012) dramatically reduced the price of liver cancer drug Nexavar from ₹280,000/month (Bayer) to ₹8,800/month (Natco), setting a global precedent [23,24].

- **Section 3(d) and Judicial Oversight:** Key to preventing 'evergreening', Section 3(d) has led to the denial of secondary patents for drugs like Novartis's Glivec, unless therapeutic efficacy is proven. The 2013 Supreme Court upholding of Section 3(d) in Novartis v. Union of India reaffirmed this stance [25,7].
- **Drug Price Controls:** NPPA (National Pharmaceutical Pricing Authority) and a revised DPCO (2013) enforce price controls on all essential drugs listed in the National List of Essential Medicines (NLEM). DPCO methodology shifted from cost-based to market-based pricing. While price ceilings improved affordability for many, some evidence suggests mixed impacts on overall market pricing, especially in hospital channels and for non-NLEM drugs [8].
- **Jan Aushadhi Campaign/Public Procurement:** Government programs like the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and targeted procurement have further enhanced availability of low-cost generics [19].

**5.4Public-Health-Outcomes:**

Despite initial fears, India continues to supply affordable medicines domestically and globally. Generic competition limited price rises for many drugs, though prices for patented new molecules (often for cancer, HIV/AIDS, rare diseases) remain significantly higher, subject to Section 3(d) filter and potential compulsory licensing in public interest [19,2].

## VI. SECTION 3(D) AND THE INDIAN MODEL OF ANTI-EVERGREENING

Section 3(d) of the amended Patent Act is globally recognised as a best-practice safeguard against "evergreening" a strategy wherein pharmaceutical firms seek to extend patent protection by trivial modifications of existing drugs. Key aspects:

- **Legal Criteria:** "Mere discovery of a new form of a known substance, which does not result in enhancement of known efficacy... is not patentable." The Supreme Court has interpreted "efficacy" in the pharmaceutical context as "therapeutic efficacy" [13].
- **Novartis v. Union of India (2013):** The beta crystalline form of Imatinib Mesylate ("Glivec") was denied a patent on grounds of insufficiently improved efficacy over the known molecule, even though it was patented abroad. The Court explicitly recognised Section 3(d)'s role in ensuring only non-trivial, socially valuable inventions receive protection, and as a tool to balance TRIPS and public health needs [7,25].
- **Global Influence:** Section 3(d) has inspired similar legal debates and legislative proposals in Brazil, South Africa, and the Philippines as a practical model for developing countries balancing innovation and access [11].
- Compulsory Licensing: Balancing Innovation and Access

India's compulsory licensing provisions are codified in sections 84 and 92A of the Patents Act. These allow for licensing of patented products to third parties under specific grounds: unmet public requirements, excessive pricing, or lack of local working.

**Landmark Use:**

- **Natco v. Bayer (2012):** First issuance for a patented oncology drug (Nexavar). Royalty was set at 6-7% of net sales, and Natco was required to maintain a low price, ensure local supply, and pay ongoing royalties to the patent holder [26,27].
- **Export-oriented Licensing:** Section 92A allows Indian firms to produce and export patented medicines to countries lacking manufacturing capacity, embodying the WTO Doha Declaration's public health flexibility.
- **Global Ramifications:** The case emboldened other developing countries to use compulsory licensing, including Thailand, Brazil, and South Africa, in their own public health emergencies [14,15].

Despite international controversy and reluctance to use compulsory licensing "too frequently" (after industry pressure and diplomatic negotiations), India's approach has maintained room for flexibility while largely adhering to TRIPS norms.

## VII. ROLE OF MULTINATIONAL PHARMACEUTICAL COMPANIES BEFORE AND AFTER TRIPS

### 7.1 Pre-TRIPS: Marginalised and Cautious

MNCs dominated the Indian pharmaceutical market before 1970, but following the 1970 Act, their market share plummeted from upwards of 80% to less than 20% by the early 2000s. MNCs limited investment, did little local manufacturing, and preferred to import and market off-patent drugs [4,27].

### 7.2 Post-TRIPS: Reinvestment, GCCs, and Industry Resurgence

Acceptance of product patents enhanced India's appeal for FDI and strategic partnerships. MNCs subsequently:

- **Re-entered Clinical and Manufacturing Investment:** MNCs increased local manufacturing, research investment, and regulatory-compliant supply chains. By 2025, more than 55 global healthcare and life sciences companies will operate Global Capability Centres (GCCs) in India, focused on clinical trials, regulatory science, AI-driven molecular discovery, and global supply chain management [22].
- **Mergers, Acquisitions, and Partnerships:** Notable examples include Daiichi Sankyo's acquisition of Ranbaxy, Abbott's acquisition of Piramal Healthcare's domestic formulation unit, and extensive tie-ups between Indian firms and Pfizer, GSK, Sanofi, Bayer, and Novartis [27,22].
- **Market Share Growth:** MNC market share, after decades of decline, reversed course, increasing from around 20% in 2008 to over 28% in 2010; with further growth anticipated as patent protection covers new drugs and as GCCs drive innovation and bring high-value work to India [22].
- **AI and R&D Hubs:** AI-driven drug discovery, predictive safety, and smart clinical trial design are now common in India-based innovation hubs of Novartis, AstraZeneca, Bayer, and others, supported by local STEM talent and vast patient pools for clinical research.

Scepticism persists about India's IP enforcement and regulatory data protection, influencing full-scale, basic drug discovery investment by MNCs. However, the capability arbitrage-India providing indispensable contributions to global R&D pipelines-is widely acknowledged.

## VIII. INDIAN PHARMACEUTICAL PARTICIPATION IN GLOBAL VALUE CHAINS (GVCS)

The restructuring of the global pharmaceutical GVC has seen India transition from a local manufacturer of generics to a global player participating at higher value-added stages of research, development, contract manufacturing, and biosimilars production [5].

- **CRAMS Model:** Indian firms have become integral to the global research and manufacturing supply chain, supporting clinical trials, R&D, and regulatory filings for MNCs worldwide [3].
- **Biosimilar Leadership:** Companies like Biocon and Zydus Cadila successfully launched biosimilars approved in advanced markets (US, EU, Japan) and have acquired or partnered with global companies (e.g., Biocon's acquisition of Viatris's biosimilar business) to operate in over 120 countries [21].
- **Innovation in NCEs and NDDS:** Novel drugs like Zydus's Lipaglyn exemplify successful Indian innovation reaching both the domestic and international market [5,10].
- **Global Export Footprint:** By 2024, India accounted for 40% of US generics, $30.5 billion in exports annually, and supplied over 200 countries, including 30+ reliant on Indian APIs and finished drugs [17,28]

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### 8.1 Case Studies: Technological Upgrading of Zydus Cadila and Biocon

*Zydus Cadila*

- Developed Lipaglyn (saroglitazar), India's first NCE for diabetic dyslipidemia, which received international orphan drug status and is marketed in India and exported to multiple regions [5,10].
- Engaged in international strategic alliances, biosimilar launches (e.g., adalimumab, the world's first biosimilar), and was the first Indian firm to launch an H1N1 flu vaccine.

*Biocon*

- Evolved from fermentation enzyme production to a global leader in biosimilars, complex biologics, and novel molecules.
- Strategic partnerships with Mylan, Sandoz, Viatris, Serum Institute, and Adagio accelerated global access to biosimilars, insulins, and monoclonal antibodies, reaching over 120 countries (as of 2023-24) [21].
- Biocon's biosimilars portfolio spans diabetes, oncology, immunology, and beyond, with major regulatory approvals in the US, EU, Japan, and emerging markets.

## IX. DOMESTIC MARKET DYNAMICS AND POLICY REFORMS RELATED TO TRIPS

### 9.1 Policy Adaptation

- **Price Controls:** Continued but increasingly strategic price control on essential formulations by the NPPA. The NLEM is periodically updated, and market-based pricing (rather than cost-based) applies to most drugs.
- **Intellectual Property Administration:**Modernisation of the Indian Patent Office, electronic filings, expedited examination, and expanded training for patent examiners post-TRIPS amendments [29].
- **National IPR Policy (2016):** Promotes awareness, patenting activity, and commercialisation, especially among start-ups, MSMEs, and academia, while ensuring TRIPS flexibility for public health [30].

### 9.2 Market and Regulatory Challenges

- Regulatory backlogs, inconsistent application of Section 3(d), limited patent opposition success, and the struggle to balance innovation and access remain persistent issues [31].
- The government has shown political will to defend the right to health, especially via Section 3(d) and compulsory licenses, despite international pressure for 'TRIPS-plus' rules.

## X. GLOBAL MARKET IMPLICATIONS OF INDIA'S TRIPS COMPLIANCE

- India's alignment with TRIPS has facilitated integration into global pharmaceutical supply chains, legitimised Indian medicines in regulated markets, and propelled India to third place in global pharmaceutical production by volume.
- India has set global precedents for defending public health flexibilities under TRIPS, leading the developing country coalition in WTO IP debates, and providing a counter-model to IP-maximalist regimes [30,19].
- Indian companies are major suppliers for PEPFAR, the WHO, and other global procurement agencies, ensuring affordable access to HIV, malaria, tuberculosis, and COVID-19 drugs worldwide [19].
- India's "pharmacy of the world" position has also brought international scrutiny, legal challenges (such as EU border seizures and US Section 301 designation), and ongoing diplomatic negotiations for improved global IP norms [32].

**Table2: Key Differences in Indian Pharmaceutical Patent Regime Pre-TRIPS vs. Post-TRIPS**

| Feature | Pre-TRIPS Era (Before 2005) | Post-TRIPS Era (After 2005 Amendment) |
|---|---|---|
| Patent Type | Process patents only | Product and process patents allowed |
| Patent Duration | 5-7 years (pharma) | 20 years (all fields) |
| Generic Drug Industry | Thrived (reverse engineering) | Focus on off-patent/complex generics |
| Innovation Incentives | Limited R&D | Rising R&D, biosimilars, NCEs |
| Access to Medicines | High, via affordable generics | Enhanced safeguards (CL, Section 3(d)) |
| Role of Multinational Cos. | Limited, cautious engagement | FDI, M&A, GCCs, innovation partnerships |
| Anti-Evergreening Measures | Not applicable | Section 3(d), judicial scrutiny |
| Compulsory Licensing | Not codified | Active (Natco v. Bayer, Sec 92A exports) |
| Drug Pricing | Cost-based DPCO | Market-based DPCO, NLEM updated |
| Participation in GVCs | Limited export focus | Major global supplier, biosimilars, CRAMS |
| Global Impact | Local self-sufficiency | Global leader in generics, essential medicines |
| Public Health Outcomes | Improved affordability | Maintained access to innovation opportunities |
| Innovation Hubs | Nascent | GCCs, AI/drug discovery, global alliances |

## XI. CONCLUSION

India's acceptance of the TRIPS Agreement and its ratification into national law through the 2005 Patent (Amendment) Act fundamentally shifted the pharmaceutical landscape. The transition from a process patent-dominant to a TRIPS-compliant product patent system challenged the traditional generics model yet drove technological upgrading, innovation, and integration into the global value chain. Legislative measures, particularly Section 3(d) and a robust compulsory licensing framework, have helped to mitigate excessive monopolisation and ensure continued access to affordable medicines. The market and legal architecture have fostered increased R&D, deeper MNC engagement, and rapid expansion of Indian firms as global suppliers and innovators.

Today, India balances the needs of public health with incentivising innovation, serving both as a model for developing countries and as an indispensable partner and competitor in the global pharmaceutical industry. The ongoing challenge is to sustain this balance, ensuring the next generation of medicines is both accessible and achieves new heights of therapeutic and technological advancement.

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