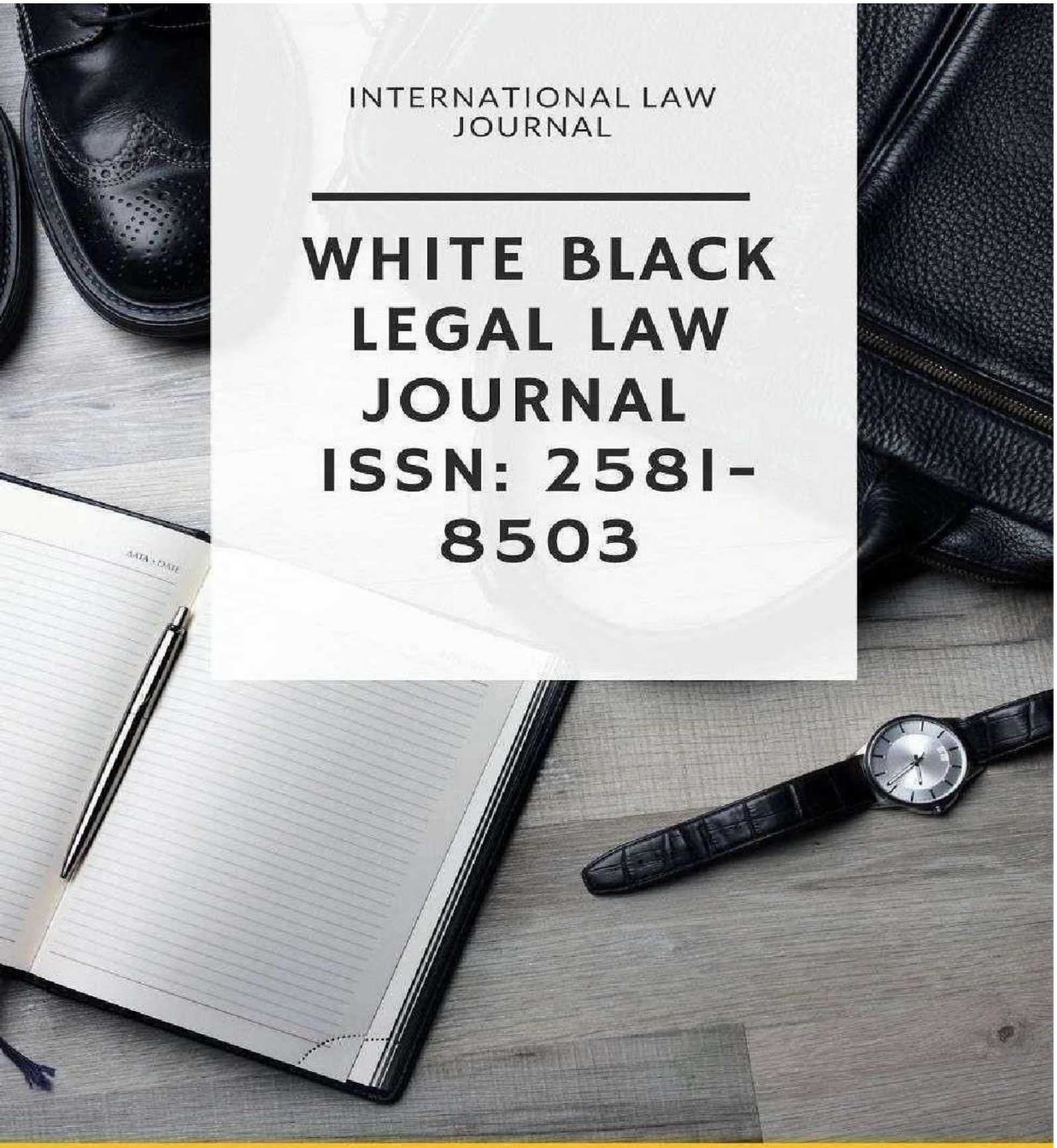

INTERNATIONAL LAW JOURNAL

WHITE BLACK LEGAL LAW JOURNAL

ISSN: 2581-8503

Peer - Reviewed & Refereed Journal

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Volume 3 Issue 7 | June 2026 ISSN: 2581-8503

EVALUATING THE POST-TRIPS PATENT FRAMEWORK IN INDIA

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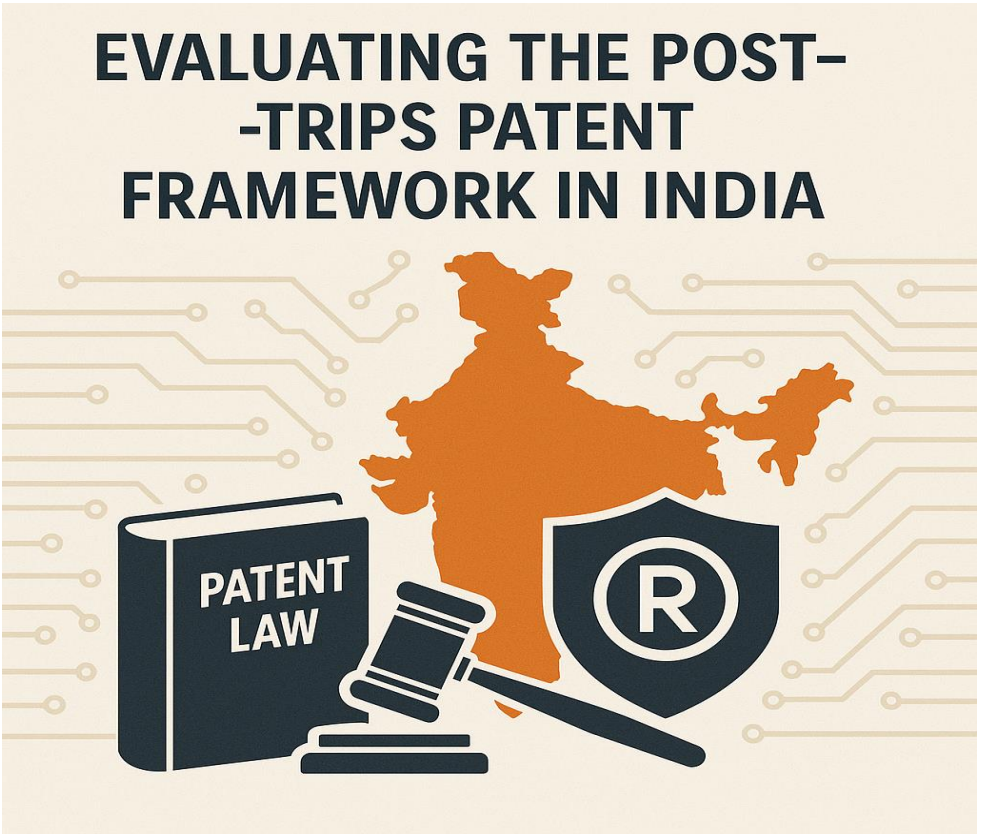

Abstract

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), adopted in 1995 under the World Trade Organization (WTO), significantly altered the global intellectual property landscape by harmonising minimum standards of protection. For India, a developing country with a strong tradition of generic pharmaceuticals and flexible patent laws, the TRIPS mandate required a paradigm shift. India amended its Patents Act, 1970, through a series of amendments (1999, 2002, and 2005) to bring its domestic framework into compliance.[1]

This paper evaluates the post-TRIPS patent framework in India, examining both its alignment

[1]WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* (15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C) 1869 UNTS 299.

with international obligations and its socio-economic consequences. It explores key features of the amended Patents Act, including product patents in pharmaceuticals, the introduction of provisions like compulsory licensing, and Section 3(d), which restricts "evergreening" of patents.[2] These provisions reflect India's attempt to balance TRIPS compliance with public interest concerns, particularly access to affordable medicines.

The research situates India's framework within broader debates on intellectual property and development. Critics argue that TRIPS has disproportionately benefited multinational corporations by expanding monopolies and raising drug prices, while proponents contend that stronger patent protection fosters innovation and foreign investment.[3] India's post-TRIPS experience offers a unique case study of resistance, adaptation, and innovation in balancing these competing interests.

The paper concludes that while India has largely complied with TRIPS, it has also crafted innovative flexibilities that prioritise public health and developmental goals. However, challenges remain: pressures from bilateral trade agreements, disputes at the WTO, and tensions between innovation and access continue to shape the evolving framework. By critically analysing India's post-TRIPS trajectory, this study contributes to the discourse on how developing countries can reconcile global obligations with domestic priorities.

Keywords

TRIPS Agreement; Indian Patent Law; Compulsory Licensing; Section 3(d); Intellectual Property Rights; Access to Medicines; Innovation and Development; Post-TRIPS Framework.

Introduction

The adoption of the TRIPS Agreement under the World Trade Organization (WTO) in 1995 marked a watershed moment in global intellectual property law. By establishing uniform minimum standards for the protection of patents, copyrights, and trademarks, TRIPS sought to harmonise intellectual property rights (IPRs) across developed and developing nations.[4] For

[2]The Patents (Amendment) Act 2005, s 3(d).
[3]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 211.
[4]WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* (15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C) 1869 UNTS 299.

India, a country with a historically cautious approach to patents, especially in the pharmaceutical sector, the implementation of TRIPS posed profound legal and socio-economic challenges.

Prior to TRIPS, the Patents Act, 1970 reflected India's developmental priorities. It excluded product patents for pharmaceuticals and agrochemicals, allowing only process patents.[5] This flexibility enabled Indian generic manufacturers to produce affordable medicines, making the country the "pharmacy of the developing world." With TRIPS mandating product patents, India was required to undertake substantial legal reforms.

India amended its patent law in three phases: the Patents (Amendment) Act, 1999, introducing exclusive marketing rights (EMRs); the Patents (Amendment) Act, 2002, aligning definitions and procedural standards with TRIPS; and the Patents (Amendment) Act, 2005, introducing product patents in pharmaceuticals and biotechnology.[6] However, India simultaneously incorporated safeguards such as Section 3(d), which restricts patents on mere modifications of known substances (to prevent "evergreening"), and compulsory licensing provisions, to balance innovation with access to medicines.[7]

The Indian approach has been both praised and criticised. On the one hand, it demonstrates how developing countries can utilise TRIPS flexibilities to safeguard public health. On the other, multinational corporations and developed nations argue that India's framework discourages innovation and violates the spirit of TRIPS.[8]

This paper critically evaluates India's post-TRIPS patent framework, examining how it reconciles global obligations with domestic priorities of health, access, and development. It situates India's experience within wider debates on intellectual property and development, offering insights into the future of patent law in emerging economies.

[5]The Patents Act 1970, s 5 (repealed in 2005).
[6]Shamnad Basheer and Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d)' (2007) 5 Script-ed 232, 235.
[7]The Patents (Amendment) Act 1999; The Patents (Amendment) Act 2002; The Patents (Amendment) Act 2005.
[8]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 211.

Research Methodology

This research adopts a doctrinal and analytical methodology, focusing on the legal developments in India's patent regime following the implementation of the TRIPS Agreement. The primary objective is to critically assess how India has complied with TRIPS obligations while simultaneously incorporating domestic safeguards to address public interest concerns, particularly access to medicines.

The primary sources of this study include:

- International legal instruments such as the TRIPS Agreement (1995), which mandated product patents and uniform minimum standards of intellectual property protection.[9]
- Indian statutes, particularly the Patents Act, 1970, as amended in 1999, 2002, and 2005, which reflect India's legislative adaptation to TRIPS.[10]
- Judicial decisions, most notably the Novartis AG v Union of India (2013), which interpreted Section 3(d) of the Patents Act and affirmed India's resistance to "evergreening" of pharmaceutical patents.[11]

The secondary sources include scholarly writings, policy papers, and commentaries by intellectual property law experts such as Carlos Correa, Shamnad Basheer, and Prashant Reddy. These works provide critical perspectives on the impact of TRIPS on developing countries, as well as the unique role of India in shaping the global debate on patents and access to medicines.[12]Reports of the World Health Organization (WHO), World Intellectual Property Organization (WIPO), and WTO's TRIPS Council further inform the study by contextualising India's policies within the global IPR framework.

A comparative approach is employed to contrast India's experience with other developing nations such as Brazil and South Africa, which also grapple with reconciling TRIPS obligations and public health imperatives.

Finally, the research integrates a socio-legal perspective, recognising that patent law cannot be

[9]WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* (15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C) 1869 UNTS 299.
[10]The Patents (Amendment) Act 1999; The Patents (Amendment) Act 2002; The Patents (Amendment) Act 2005.
[11]Novartis AG v Union of India (2013) 6 SCC 1.
[12]Shamnad Basheer and Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d)' (2007) 5 Script-ed 232; Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007).

divorced from its economic and humanitarian consequences. By situating India's patent reforms within the broader discourse of development and human rights, the study highlights the normative dimensions of intellectual property beyond mere legal compliance.

Hypothesis

This research is premised on the hypothesis that India's post-TRIPS patent framework successfully balances international obligations under TRIPS with domestic imperatives of public health, access to medicines, and developmental priorities. While India has largely complied with the requirements of TRIPS by introducing product patents and strengthening patent protection, it has also innovatively deployed legal safeguards—most notably Section 3(d) and compulsory licensing provisions—to prevent abuse of patent monopolies.[13]

The hypothesis further posits that India's approach demonstrates the strategic use of TRIPS flexibilities, setting an important precedent for other developing countries. By refusing to allow "evergreening" of patents and by granting compulsory licences in cases such as Bayer Corporation v Union of India (2013), India has shown that compliance with TRIPS need not come at the cost of public welfare.[14]

At the same time, the research hypothesises that India's framework is under constant external pressure, particularly from developed countries and multinational corporations, which argue that such measures discourage innovation and investment.[15] Despite this, India's patent law demonstrates that developmental states can construct a patent system that is both TRIPS-compliant and socially responsive.

Finally, the hypothesis assumes that the future trajectory of India's patent framework will depend on its ability to resist pressures from bilateral and regional trade agreements (such as FTAs with TRIPS-plus provisions) and continue leveraging the balance between innovation and access.[16]

[13]The Patents (Amendment) Act 2005, s 3(d).
[14]*Bayer Corporation v Union of India* (2014) 60 PTC 277 (Bom).
[15]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 211.
[16]Frederick M Abbott, 'The Future of the Multilateral Trading System in the Context of TRIPS' (2016) 20 J Intl Economic L 91.

Research Questions

This research is guided by the following central questions:

1. **How did the TRIPS Agreement transform India's patent law framework, particularly with respect to pharmaceuticals and biotechnology?**
   – This explores the transition from the Patents Act, 1970 (process patents) to the post-2005 regime allowing product patents.
2. **To what extent has India complied with its obligations under TRIPS while simultaneously incorporating public interest safeguards?**
   – This examines the use of provisions like Section 3(d), compulsory licensing, and opposition mechanisms.
3. **How has the Indian judiciary interpreted and shaped the post-TRIPS patent framework?**
   – This focuses on landmark cases such as Novartis AG v Union of India (2013) and Bayer Corporation v Union of India (2014).
4. **What have been the socio-economic impacts of the post-TRIPS patent framework in India, particularly on access to medicines and the domestic pharmaceutical industry?**
   – This includes assessing India's role as the "pharmacy of the developing world."
5. **What challenges does India face in preserving TRIPS flexibilities in the face of TRIPS-plus obligations under bilateral and regional trade agreements?**
   – This considers the risks posed by external pressures from developed countries and multinational corporations.

Literature Review

The literature on India's post-TRIPS patent framework reveals a rich debate over the balance between intellectual property protection and public health. Scholars and institutions have analysed India's amendments to the Patents Act, judicial interpretation of TRIPS flexibilities, and the global implications of India's stance.

1. TRIPS and Its Global Impact

The TRIPS Agreement has been described as the most comprehensive international treaty on

intellectual property, mandating uniform minimum standards across WTO members.[17] Critics argue that TRIPS disproportionately benefits developed countries and multinational corporations by extending patent monopolies, particularly in pharmaceuticals.[18] Developing countries, including India, faced the challenge of reconciling TRIPS with public health obligations.

Frederick Abbott notes that TRIPS altered the global political economy of intellectual property by shifting power from national legislatures to international trade law.[19] For countries like India, this meant a significant reduction in policy space for tailoring IP regimes to domestic needs.

2. The Indian Patents Act and Amendments

India's Patents Act, 1970 was initially designed to foster industrial growth and ensure access to affordable medicines by excluding product patents in pharmaceuticals and agrochemicals.[20] The post-TRIPS amendments (1999, 2002, and 2005) aligned India with TRIPS but also introduced safeguards to protect public interest.

Shamnad Basheer and Prashant Reddy argue that Section 3(d) of the Patents (Amendment) Act, 2005, is India's most innovative legal safeguard. It restricts patents on mere modifications of existing drugs, thereby curbing "evergreening."[21] This provision was upheld by the Supreme Court in Novartis AG v Union of India (2013), a landmark ruling that reinforced India's commitment to balancing innovation and access.[22]

3. Compulsory Licensing and Access to Medicines

The literature also highlights India's use of compulsory licensing as a TRIPS flexibility. In Bayer Corporation v Union of India (2014), the Bombay High Court upheld a compulsory licence for a cancer drug, citing public interest and affordability.[23] This decision was widely praised by public health advocates but criticised by pharmaceutical companies, who argued it undermined innovation incentives.

[17]WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* (15 April 1994, Marrakesh Agreement Establishing the WTO, Annex 1C) 1869 UNTS 299.
[18]Peter Drahos, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 117.
[19]Frederick M Abbott, 'The Future of the Multilateral Trading System in the Context of TRIPS' (2016) 20 J Intl Economic L 91, 95.
[20]The Patents Act 1970, s 5 (repealed in 2005).
[21]Shamnad Basheer and Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d)' (2007) 5 Script-ed 232, 237.
[22]*Novartis AG v Union of India* (2013) 6 SCC 1.
[23]*Bayer Corporation v Union of India* (2014) 60 PTC 277 (Bom).

Carlos Correa emphasises that compulsory licensing is a legitimate tool under TRIPS, provided certain conditions are met, and India's use of it demonstrates how developing countries can creatively deploy flexibilities.[24]

4. Judicial Interpretation and International Repercussions

Judicial decisions in India have been pivotal in shaping the post-TRIPS framework. The Novartis case, in particular, has been studied extensively. Rochelle Dreyfuss notes that India's judiciary has acted as a "gatekeeper" to ensure that patents serve social utility rather than private monopolisation.[25]

However, these rulings have also triggered international disputes. The US Trade Representative has repeatedly placed India on its "Priority Watch List" for allegedly weak IP enforcement, reflecting tensions between global trade interests and domestic health policies.[26]

5. TRIPS-Plus Pressures and Future Challenges

Another significant theme in the literature is the rise of TRIPS-plus obligations through bilateral and regional trade agreements. Scholars warn that such agreements, often promoted by developed countries, demand higher standards of IP protection than TRIPS, threatening India's policy space.[27] Abbott argues that defending TRIPS flexibilities will be critical for India to preserve its role as a supplier of affordable medicines to the developing world.

6. Synthesis of Literature

Overall, the literature highlights that:

- India has complied with TRIPS but resisted its excesses by using flexibilities.
- Section 3(d) and compulsory licensing provisions are cornerstones of India's public interest safeguards.
- Courts in India have played an activist role in ensuring patents serve social goals.
- India's stance has international implications, both positive (global access to medicines) and negative (trade tensions).
- The future trajectory will depend on India's ability to withstand TRIPS-plus pressures.

[24]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 223.
[25]Rochelle C Dreyfuss, 'TRIPS-Round II: Should Users Strike Back?' (2004) 71 U Chicago L Rev 21, 43.
[26]Office of the United States Trade Representative (USTR), *Special 301 Report 2022*.
[27]Sisule F Musungu and Graham Dutfield, *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organization (WIPO)* (Quaker UN Office 2003) 14.

Thus, the existing scholarship underscores the hybrid character of India's patent framework: simultaneously TRIPS-compliant and development-oriented.

Chapter 1: The Evolution of Patent Law in India

1.1 Early Origins of Patent Law in India

Patent law in India has always been closely tied to the nation's developmental priorities. The earliest legislation, the Act VI of 1856, was modelled on the British Patent Law of 1852 and introduced during the colonial period. The Act granted exclusive rights to inventors for 14 years, but its primary purpose was to protect British interests rather than foster indigenous innovation. Subsequent legislations, including the Indian Patents and Designs Act, 1911, reinforced this colonial legacy by granting monopolies to foreign corporations, which often stifled local enterprise.

The inequities of the colonial patent regime became increasingly apparent after independence in 1947. Foreign firms dominated the pharmaceutical sector, and life-saving drugs were sold at exorbitant prices.[28] For instance, studies in the 1960s revealed that India had some of the highest drug prices in the world, largely due to foreign control over patented medicines. This situation catalysed a demand for reform that culminated in the Patents Act, 1970, a landmark legislation designed to prioritise national development and access to medicines.

1.2 The Patents Act, 1970: Development-Oriented Reform

The Patents Act, 1970, enacted on the recommendations of the Justice N RajagopalaAyyangar Committee Report (1959), fundamentally reshaped India's intellectual property regime.[29] The Act excluded product patents in the fields of food, chemicals, and pharmaceuticals, restricting protection to process patents only. This meant that while the method of producing a drug could be patented, the drug itself could not.

The rationale was to ensure that pharmaceutical monopolies would not undermine public health. Indian companies could legally reverse-engineer drugs using alternative processes, thereby producing generic medicines at significantly lower costs. This policy transformed India into a global hub for affordable generics, earning it the title of the "pharmacy of the developing world."[30]

[28]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 215.
[29]Justice N Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (1959).
[30]Ellen F M Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB 2009) 34.

Key features of the 1970 Act included:

- A shorter patent term of 7 years for process patents.
- Compulsory licensing provisions to prevent abuse of patent rights.
- Exclusion of agricultural and food products from patentability.
- Focus on domestic technological development.

The Act struck a balance between incentivising innovation and ensuring access, reflecting India's commitment to social justice enshrined in Article 21 of the Constitution (Right to Life).

1.3 The TRIPS Agreement and Global Patent Harmonisation

The global intellectual property landscape changed dramatically with the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995 as part of the WTO framework. TRIPS introduced uniform minimum standards of IP protection, requiring all WTO members to:

- Provide product patents in all fields of technology.
- Grant a 20-year patent term.
- Strengthen enforcement mechanisms.
- Eliminate discrimination in patent protection across sectors.

For India, TRIPS posed a challenge to its development-oriented patent system. The 1970 Act was now inconsistent with TRIPS requirements, particularly the exclusion of product patents in pharmaceuticals and agrochemicals.[31]

1.4 India's Phased Compliance with TRIPS

To reconcile domestic priorities with global obligations, India adopted a phased amendment process over a 10-year transition period (1995–2005), as allowed for developing countries under TRIPS.

1. **The Patents (Amendment) Act, 1999**
    - Introduced Exclusive Marketing Rights (EMRs) for new pharmaceutical products until full TRIPS compliance.
    - Created a "mailbox" system for patent applications filed after 1995, to be examined after 2005.

[31]Frederick M Abbott, 'The WTO TRIPS Agreement and Global Economic Development' (2000) 72 Chi-Kent L Rev 385.

2. **The Patents (Amendment) Act, 2002**
    - Brought significant changes, including a 20-year patent term (TRIPS Art. 33).
    - Streamlined procedures for opposition and compulsory licensing.
    - Aligned Indian law with TRIPS standards in terms of patentability and enforcement.

3. **The Patents (Amendment) Act, 2005**
    - Completed India's TRIPS compliance by allowing product patents in pharmaceuticals, biotechnology, and agrochemicals.
    - However, it also introduced safeguards such as Section 3(d) (anti-evergreening) and strengthened compulsory licensing provisions.

This phased approach reflects India's strategy of compliance with resistance, balancing global trade obligations with domestic developmental imperatives.

1.5 Balancing Sovereignty and Global Obligations

India's experience highlights a tension between sovereignty in policymaking and the constraints of globalisation. While TRIPS required harmonisation, India's amendments show how developing countries can creatively deploy TRIPS flexibilities. For example, Section 3(d) restricts patents on minor modifications unless they demonstrate enhanced efficacy.[32] Similarly, compulsory licensing under Section 84 ensures patented products remain affordable and accessible.

This balancing act positioned India as a leader among developing nations, resisting pressures from developed countries and multinational corporations while fulfilling WTO obligations.[33]

The evolution of patent law in India reflects a journey from colonial subordination to developmental sovereignty, and finally to global compliance under TRIPS. The Patents Act, 1970 created a framework that prioritised access and industrial growth. With TRIPS, India was compelled to amend its laws, but it innovatively used flexibilities to safeguard public interest. This hybrid trajectory—marked by compliance, resistance, and innovation—provides the foundation for evaluating India's post-TRIPS patent framework, which continues to balance global trade obligations with the constitutional imperative of social justice.

[32] *Novartis AG v Union of India* (2013) 6 SCC 1.
[33] Office of the US Trade Representative, *Special 301 Report 2022*.

Chapter 2: Key Features of the Post-TRIPS Patent Framework

2.1 Introduction

The Patents (Amendment) Act, 2005 marked a watershed in India's intellectual property regime, completing its compliance with the TRIPS Agreement by introducing product patents in pharmaceuticals, biotechnology, and agrochemicals. While the reform aligned India with global standards, it also triggered concerns about public health, drug prices, and access to essential medicines. To address these, India embedded a range of safeguards and flexibilities within its patent law.

This chapter examines the key features of the post-TRIPS patent framework in India, with a focus on product patents, Section 3(d), compulsory licensing, patent opposition mechanisms, and enforcement provisions. These elements illustrate how India has attempted to balance TRIPS compliance with its constitutional obligation to safeguard public health and promote access to knowledge.

2.2 Introduction of Product Patents

The 2005 Amendment abolished Section 5 of the Patents Act, 1970, which previously restricted pharmaceutical and agrochemical patents to processes only. As a result, product patents became permissible in all fields of technology.

This change aligned India with Article 27 of TRIPS, which requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

The shift was profound. For the first time in three decades, pharmaceutical companies in India could seek patents on the drugs themselves, not merely their manufacturing processes. While this was hailed as a step towards incentivising innovation and attracting foreign investment, critics feared it would lead to monopolistic pricing and restrict generic competition.[34]

The exclusive marketing rights (EMRs) regime (introduced in 1999) acted as a bridge, granting temporary rights to patent applicants until full product patent protection came into effect in 2005.

2.3 Section 3(d): The Anti-Evergreening Provision

Among the most distinctive features of India's patent law is Section 3(d), which excludes from patentability "the mere discovery of a new form of a known substance which does not result in

[34]Peter Drahos, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 117.

the enhancement of the known efficacy of that substance." This provision was designed to curb evergreening—a strategy by which pharmaceutical companies file patents on minor modifications of existing drugs to extend monopoly protection.

The Novartis AG v Union of India (2013) case exemplifies the significance of Section 3(d). Novartis sought a patent for its cancer drug Glivec, claiming that the beta-crystalline form of imatinib mesylate was more stable and bioavailable. The Supreme Court rejected the application, holding that improved bioavailability did not demonstrate "enhanced therapeutic efficacy" as required under Section 3(d).[35]

The judgment affirmed India's commitment to prioritising genuine innovation over incremental changes. It also set a global precedent for other developing countries seeking to resist evergreening while remaining TRIPS-compliant.[36]

Scholars argue that Section 3(d) represents an innovative use of TRIPS flexibilities, allowing India to balance innovation with affordability.[37] At the same time, it has drawn criticism from multinational corporations, which claim it discourages investment and undermines incentives for R&D.

2.4 Compulsory Licensing

Another cornerstone of India's post-TRIPS framework is compulsory licensing (CL) under Section 84 of the Patents Act. A compulsory licence may be issued if:

1. The reasonable requirements of the public with respect to the patented invention are not satisfied.
2. The invention is not available to the public at a reasonably affordable price.
3. The invention is not being worked in the territory of India.

India's first compulsory licence was granted in Bayer Corporation v Union of India (2014) for the cancer drug Nexavar (sorafenib tosylate). Bayer priced the drug at ₹2.8 lakh per month, while Natco Pharma offered to sell it at ₹8,800. The Controller General of Patents granted Natco a compulsory licence, citing affordability and availability.[38]

The Bombay High Court upheld the decision, emphasising that patents cannot be used to restrict access to life-saving medicines. This case showcased India's proactive use of TRIPS Article 31, which explicitly permits compulsory licensing.

[35] *Novartis AG v Union of India* (2013) 6 SCC 1.
[36] Ellen F M Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB 2009) 67.
[37] Shamnad Basheer and Prashant Reddy, 'The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d)' (2007) 5 Script-ed 232, 236.
[38] *Bayer Corporation v Union of India* (2014) 60 PTC 277 (Bom).

Internationally, the decision drew sharp criticism from pharmaceutical companies and the US government but was celebrated by public health advocates as a landmark in defending the right to health.[39]

2.5 Patent Opposition Mechanisms

India also strengthened opposition procedures in the 2005 Amendment. The law provides for both:

- **Pre-grant opposition (Section 25(1))**: allows any person to challenge a patent application before it is granted.
- **Post-grant opposition (Section 25(2))**: allows opposition within one year of the grant of a patent.

These mechanisms empower civil society, patient groups, and competitors to challenge frivolous or abusive patent claims. The NGO Cancer Patients Aid Association successfully used pre-grant opposition against Novartis in the Glivec case.

Opposition mechanisms thus serve as democratic checks on the patent system, enhancing accountability and preventing unjustified monopolies.

2.6 Patent Term and Enforcement

India aligned with TRIPS Article 33 by extending the patent term to 20 years for all inventions. Stronger enforcement provisions were also incorporated, including remedies for infringement and customs measures to block imports of infringing goods.

However, enforcement in India remains relatively cautious compared to developed countries. Courts often weigh patent enforcement against public interest, reflecting a socio-legal approach that prioritises affordability and accessibility.[40]

2.7 Public Interest Safeguards

The post-TRIPS framework embeds multiple safeguards designed to protect public health and development:

- Section 3(d) (anti-evergreening).
- Compulsory licensing (Sections 84–92).
- Parallel imports (Section 107A).

[39]Frederick M Abbott, 'The WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries' (2002) 20 Wis Intl LJ 493.
[40]F. Hoffmann-La Roche Ltd v Cipla Ltd (2009) 40 PTC 125 (Del).

- Opposition mechanisms (Sections 25(1) and 25(2)).
- Judicial emphasis on Article 21 (Right to Life) in interpreting patent law.

These provisions collectively demonstrate India's innovative balancing of global obligations with domestic imperatives.

The post-TRIPS patent framework in India represents a hybrid model: it complies with TRIPS by granting product patents and strengthening enforcement, yet simultaneously deploys legal safeguards to prevent abuse of patent monopolies. Features like Section 3(d), compulsory licensing, and opposition mechanisms illustrate India's determination to protect public health and access to medicines.

This balancing act has made India a global leader among developing countries, offering a model of how TRIPS flexibilities can be operationalised. At the same time, the framework continues to face challenges, including international criticism, TRIPS-plus pressures, and tensions between innovation and access.

Chapter 3: Judicial Interpretation and Policy Debates

3.1 Introduction

The judiciary has played a decisive role in shaping India's post-TRIPS patent framework. While the legislature incorporated TRIPS-compliant provisions through amendments to the Patents Act (1999, 2002, and 2005), it is the interpretation and enforcement of these provisions by courts that has determined their real-world impact. Indian courts have often been tasked with balancing patent rights against public health concerns, particularly in the pharmaceutical sector.

This chapter examines how landmark judicial decisions have interpreted provisions such as Section 3(d) and compulsory licensing, and how courts have contextualised intellectual property within India's constitutional framework, especially the right to life under Article 21. It also explores policy debates triggered by these rulings, highlighting tensions between innovation, access to medicines, and India's global trade obligations.

3.2 Judicial Approach to TRIPS Flexibilities

Indian courts have adopted a development-oriented judicial philosophy, emphasising that intellectual property rights cannot override fundamental rights.[41] In interpreting TRIPS-related

[41]Shamnad Basheer, 'India's Tryst with TRIPS: The Patents (Amendment) Act 2005' (2005) 1 Indian J L & Tech 15, 21.

provisions, the judiciary has consistently prioritised public interest and access to medicines over strict monopolisation by patent holders. This approach contrasts with courts in many developed countries, where patent rights are interpreted primarily through the lens of private property.

The Indian judiciary has also actively acknowledged the flexibilities available under TRIPS, such as compulsory licensing, opposition procedures, and exceptions to patentability. By grounding its reasoning in these flexibilities, the judiciary has reinforced India's sovereign right to design a patent system tailored to its developmental needs.

3.3 Landmark Judicial Decisions

(a) Novartis AG v Union of India (2013)

This case is the defining moment in India's post-TRIPS patent jurisprudence. Novartis sought a patent for the beta-crystalline form of imatinib mesylate, marketed as the cancer drug Glivec. The Patent Office rejected the application under Section 3(d), reasoning that the modification did not demonstrate "enhanced therapeutic efficacy."

Novartis challenged the decision, arguing that Section 3(d) violated TRIPS and the Indian Constitution. The Supreme Court upheld the rejection, holding that increased bioavailability did not amount to enhanced efficacy.

The Court's ruling reinforced several principles:

- Section 3(d) is a legitimate safeguard against evergreening.
- TRIPS compliance does not prevent states from protecting public health.
- The right to health under Article 21 justifies limiting patent monopolies.

This judgment was celebrated by health activists worldwide, as it ensured continued generic production of life-saving cancer drugs. However, it also triggered backlash from multinational corporations and developed countries, which claimed it undermined incentives for innovation.[42]

(b) Bayer Corporation v Union of India (2014)

This case concerned India's first compulsory licence under Section 84 of the Patents Act. Bayer's patented drug Nexavar was priced at ₹2.8 lakh per month, unaffordable for most Indian patients. Natco Pharma applied for a compulsory licence, offering to sell the drug at ₹8,800 per month.

[42]Ellen F M Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB 2009) 67.

The Controller General of Patents granted the licence, which was upheld by the Intellectual Property Appellate Board (IPAB) and later by the Bombay High Court.

The Court held that affordability and public access are critical components of patent law in India, and that patentees cannot exploit monopolies to the detriment of society. This case exemplified India's willingness to operationalise TRIPS Article 31 on compulsory licensing in favour of public health.

(c) F. Hoffmann-La Roche Ltd v Cipla Ltd (2009)

In this case, Swiss multinational Roche alleged patent infringement by Cipla, an Indian generic manufacturer, over the cancer drug Erlotinib. While the Delhi High Court acknowledged Cipla's infringement, it refused to grant an injunction, citing public interest in access to affordable medicines.

The judgment highlighted the judiciary's equitable balancing of patent enforcement with the constitutional right to life. It established that patents cannot be enforced in a manner that undermines access to essential drugs.

(d) Other Notable Cases

- **Merck v Glenmark (2015)**: Delhi High Court granted an injunction in favour of Merck against Glenmark's generic production, reflecting the judiciary's nuanced approach in distinguishing between strong and weak patent claims.[43]
- **Boehringer Ingelheim v Controller of Patents (2018)**: Patent applications for incremental modifications were rejected, reinforcing Section 3(d).[44]

Together, these cases illustrate how courts have consistently resisted expansive interpretations of patent rights, while carefully ensuring TRIPS compliance.

3.4 Constitutional Dimensions of Patent Jurisprudence

Indian courts have frequently invoked Article 21 of the Constitution (Right to Life) to justify restrictions on patent rights. In Paschim Banga Khet Mazdoor Samity v State of West Bengal (1996), the Supreme Court recognised access to health care as part of the right to life.[45] This principle has influenced subsequent patent jurisprudence, ensuring that IP rights are subordinated to constitutional rights.

[43] *Merck v Glenmark* (2015) 64 PTC 417 (Del).
[44] *Boehringer Ingelheim v Controller of Patents* (2018) 254 DLT 564.
[45] *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37.

This constitutional grounding differentiates India from Western jurisdictions, where patents are treated primarily as commercial rights. In India, patents are seen through a socio-legal lens, embedded within broader developmental and human rights concerns.

3.5 Policy Debates Triggered by Judicial Decisions

Judicial interventions in India's post-TRIPS framework have sparked intense policy debates, both domestically and internationally.

- **Public Health Advocates**: NGOs like Médecins Sans Frontières (MSF) and civil society organisations hail India's judicial approach as a model for other developing nations. They argue that Section 3(d) and compulsory licensing are vital for ensuring access to affordable medicines.
- **Pharmaceutical Multinationals**: Corporations and industry groups like PhRMA argue that India's restrictive patent standards discourage foreign investment and undermine incentives for innovation.
- **Government Policy Makers**: India's government has defended its patent law as TRIPS-compliant, citing WTO's Doha Declaration on TRIPS and Public Health (2001), which affirms members' rights to use flexibilities.[46]
- **International Pressures**: The United States has consistently placed India on its Special 301 Priority Watch List, criticising its patent regime as "weak." Trade tensions have escalated, with India defending its policies as necessary for developmental equity.

3.6 India's Influence on Global IP Debates

India's judicial decisions have had a profound impact beyond its borders. The Novartis and Bayer cases are frequently cited in international discussions on TRIPS flexibilities and public health. India's stance has emboldened other developing countries like Brazil, South Africa, and Thailand to adopt similar strategies.[47]

By operationalising TRIPS flexibilities in a development-friendly manner, India has positioned itself as a normative leader in the global IP debate, challenging Western models that prioritise corporate monopolies.

[46]WTO, *Doha Declaration on the TRIPS Agreement and Public Health* (2001), WT/MIN(01)/DEC/2.
[47]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 245.

3.7 Criticisms of Judicial Activism

While widely praised, India's judiciary has also faced criticism for allegedly overstepping its mandate. Critics argue that:

- Judicial interpretations sometimes create uncertainty for investors.
- Courts may be substituting legislative judgment with judicial activism.
- Over-reliance on judicial safeguards may discourage R&D investment in India.[48]

These criticisms highlight the tension between legal certainty for investors and flexibility for public health—a balance that India continues to negotiate.

Judicial interpretation has been central to the evolution of India's post-TRIPS patent framework. By upholding safeguards such as Section 3(d) and compulsory licensing, the judiciary has reinforced India's development-oriented approach, grounding patent law in constitutional commitments to health and life.

At the same time, these rulings have intensified policy debates on the trade-offs between innovation and access. While multinational corporations criticise India's restrictive patent standards, global health advocates celebrate them as models of justice. India's judiciary thus plays a dual role: guardian of constitutional rights at home and catalyst for global debates on the future of intellectual property.

Chapter 4: Socio-Economic Impact of the Post-TRIPS Framework

4.1 Introduction

The transformation of India's patent system following the TRIPS Agreement was not merely a legal or institutional shift; it was a change with far-reaching socio-economic consequences. Intellectual property laws affect industries, markets, and—most importantly—people's access to essential goods such as medicines. In a country with vast income inequalities and significant public health challenges, the implications of patent law reform extend well beyond the legal domain.

This chapter analyses the socio-economic impact of the post-TRIPS framework in India, focusing on four dimensions: (i) access to medicines, (ii) growth of the domestic pharmaceutical industry, (iii) foreign investment and innovation, and (iv) developmental and human rights perspectives.

[48]Rochelle Dreyfuss, 'Patent Law and Public Health: Beyond TRIPS Flexibilities' (2016) 19 J World Intellectual Prop 65.

4.2 Access to Medicines

4.2.1 India as the "Pharmacy of the Developing World"

India has long been described as the "pharmacy of the developing world" because of its robust generic pharmaceutical industry.[49] By reverse-engineering patented drugs under the process-patent regime of the Patents Act, 1970, Indian companies produced affordable medicines for both domestic and global markets. This role was particularly significant in the fight against HIV/AIDS, where Indian firms like Cipla supplied antiretroviral drugs at a fraction of the cost charged by Western companies.

The introduction of product patents in 2005 raised fears that India's capacity to supply affordable generics would be curtailed. However, safeguards such as Section 3(d) and compulsory licensing mitigated these fears by ensuring that monopolistic pricing could be challenged.

4.2.2 Impact on Drug Prices

Studies show that product patents have increased drug prices in certain cases, particularly for new patented medicines. However, India's generic industry has remained resilient, partly because most drugs patented after 2005 have not yet come off-patent, and partly due to opposition mechanisms that prevent frivolous patents. For instance, the rejection of Novartis's patent for Glivec ensured continued access to cheaper generic versions.

4.2.3 Compulsory Licensing and Affordability

The compulsory licence for Bayer's cancer drug Nexavar in 2012 dramatically reduced prices—Natco Pharma sold the drug at nearly 97% lower than Bayer's price. This case highlighted how India's framework directly influences affordability and saves lives. Public health advocates argue that without such measures, millions would be excluded from life-saving treatment.[50]

4.3 Growth of the Indian Pharmaceutical Industry

4.3.1 Expansion of Domestic Capacity

The Indian pharmaceutical industry, already well-established under the 1970 Act, has continued to grow post-TRIPS. Today, India is the third-largest producer of pharmaceuticals by volume and supplies over 20% of global generic medicines. Companies like Sun Pharma, Dr. Reddy's, and Cipla have expanded internationally, competing in developed markets while

[49] Ellen F M Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (AMB 2009) 23.
[50] Frederick M Abbott, 'The TRIPS Agreement and Access to Medicines' (2002) 5 J World Intellectual Prop 4.

maintaining strong domestic supply.

4.3.2 Export Growth

Exports have been a key driver of growth. In 2021–22, Indian pharmaceutical exports crossed USD 24 billion, with major markets including the United States, Africa, and Latin America.Safeguards like Section 3(d) have preserved the generic industry's ability to export affordable medicines, thereby benefiting global health.

4.3.3 Research and Development Challenges

Despite growth, critics argue that India's patent framework discourages high-level pharmaceutical R&D. Multinational corporations claim that weak patent enforcement reduces incentives for innovation.However, Indian firms have increasingly invested in research partnerships and biosimilars, suggesting that innovation can thrive even under balanced IP regimes.

4.4 Foreign Investment and Innovation

4.4.1 Foreign Direct Investment (FDI)

India has witnessed significant inflows of foreign direct investment in pharmaceuticals since 2005. Liberalisation measures and stronger IP protection have made India more attractive to global firms.[51] However, the impact of judicial rulings like Novartis and Bayer has led to mixed investor perceptions. While some argue these rulings deter investment, others note that India remains a vital market due to its scale and growth.

4.4.2 Multinational Corporations' Concerns

Global pharmaceutical giants often criticise India's patent framework, particularly Section 3(d) and compulsory licensing. Industry bodies such as PhRMA argue that these provisions reduce the certainty and profitability of patent rights. Nevertheless, India's government has consistently defended its laws as TRIPS-compliant, pointing to the Doha Declaration on TRIPS and Public Health (2001), which affirms members' rights to protect public health.

4.4.3 Domestic Innovation Landscape

Indian companies have gradually shifted towards more innovation-driven models. Several firms now file patents internationally, invest in biosimilars, and engage in collaborative R&D.[52] While innovation levels remain below those of developed countries, the patent framework has not stifled domestic growth but rather created a competitive environment.

[51]Department for Promotion of Industry and Internal Trade (DPIIT), *FDI Policy on Pharmaceuticals* (2021).
[52]Dinesh Abrol, 'Indian Pharma: Moving Towards Innovation?' (2014) 49 Economic & Political Weekly 12.

4.5 Developmental and Human Rights Perspectives

4.5.1 Right to Health as a Constitutional Imperative

Indian jurisprudence has repeatedly affirmed that access to health care is part of the fundamental right to life under Article 21 of the Constitution. This constitutional principle informs India's patent law by justifying safeguards such as Section 3(d) and compulsory licensing. By embedding human rights into IP law, India ensures that commercial monopolies do not override social welfare.

4.5.2 Impact on Global South Solidarity

India's approach has had ripple effects across the Global South. Countries like Brazil, South Africa, and Thailand have cited India's framework when resisting TRIPS-plus obligations in trade negotiations.[53] India's role in supplying affordable medicines has also enhanced its soft power and reputation as a defender of global health equity.

4.5.3 Balancing Development and Compliance

India's framework demonstrates that it is possible to comply with TRIPS while still prioritising development and public health. However, this balance is fragile. Bilateral trade agreements that impose TRIPS-plus standards—such as data exclusivity or patent term extensions—threaten to erode India's safeguards.[54]

4.6 Critiques and Counterarguments

- **Critique 1: Innovation Discouragement** – Critics argue India's strict standards discourage innovation.
- **Counterargument** – Evidence shows that incremental innovation often serves corporate profits more than patients; Section 3(d) ensures only meaningful innovation is rewarded.
- **Critique 2: Investment Deterrent** – Multinationals claim that compulsory licensing reduces investment.
- **Counterargument** – India's pharma market continues to grow, and investment flows remain robust, demonstrating that investors adapt to balanced frameworks.
- **Critique 3: Protectionism** – Some accuse India of using TRIPS flexibilities as protectionist tools.

[53]Carlos M Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre 2000).
[54]Sisule F Musungu and Graham Dutfield, *Multilateral Agreements and a TRIPS-Plus World* (Quaker UN Office 2003) 14.

- **Counterargument** – India's measures are explicitly permitted under TRIPS and align with the Doha Declaration on public health.

The socio-economic impact of India's post-TRIPS patent framework reveals a dual narrative. On one hand, product patents have raised concerns about higher drug prices and investor uncertainty. On the other, India's safeguards—Section 3(d), compulsory licensing, and opposition mechanisms—have preserved access to medicines, supported the growth of the generic industry, and ensured alignment with constitutional values of health and life.

India has successfully balanced compliance with TRIPS and commitment to public welfare, creating a patent regime that is both legally robust and socially responsive. The real challenge lies in defending this balance against TRIPS-plus pressures and continuing to innovate without undermining access.

Chapter 5: Challenges and the Road Ahead

5.1 Introduction

India's post-TRIPS patent framework has been praised for balancing international obligations with domestic imperatives such as access to medicines and industrial growth. Provisions like Section 3(d) and compulsory licensing have become models for other developing countries. Yet, India's framework continues to face internal pressures (from industry and judiciary), and external challenges (from developed countries, trade agreements, and multinational corporations).

This chapter explores five broad challenges to India's post-TRIPS patent system: (i) TRIPS-plus pressures, (ii) WTO disputes and diplomatic tensions, (iii) balancing innovation with access, (iv) domestic institutional challenges, and (v) future reforms and global leadership.

5.2 TRIPS-Plus Pressures

5.2.1 Bilateral and Regional Trade Agreements

A major challenge to India's patent regime comes from TRIPS-plus obligations embedded in bilateral and regional trade agreements (FTAs). Unlike TRIPS, which sets minimum standards, TRIPS-plus provisions often demand:

- Patent term extensions beyond 20 years.
- Data exclusivity (preventing generics from using clinical trial data).
- Restrictions on compulsory licensing.

- Stronger enforcement mechanisms favouring patentees.[55]

The India–EU FTA negotiations have been particularly contentious, with the EU pressing India to adopt stricter IP protections. Acceptance of such provisions would dilute India's safeguards and undermine its ability to produce affordable generics.

5.2.2 Pressure from Developed Nations

The United States has consistently placed India on its Special 301 Priority Watch List, alleging "weak IP protection." US pharmaceutical lobbies such as PhRMA argue that India's Section 3(d) and compulsory licensing provisions violate the spirit of TRIPS. Diplomatic tensions, including threats of WTO disputes and trade sanctions, amplify these pressures.

5.3 WTO Disputes and Diplomatic Tensions

Although no formal WTO dispute has yet been filed against India's patent safeguards, the possibility remains a looming challenge. The Doha Declaration on TRIPS and Public Health (2001) affirms members' rights to use TRIPS flexibilities, but developed countries often interpret these flexibilities narrowly.

India must continually defend its framework in WTO forums, particularly its use of compulsory licensing and Section 3(d). These disputes carry not just legal, but also diplomatic and economic consequences, as trade relations with powerful economies are at stake.

5.4 Balancing Innovation and Access

5.4.1 The Innovation Argument

Critics argue that India's restrictive patent standards discourage pharmaceutical R&D investment.[56] They claim that without strong patent protection, companies will be reluctant to innovate, leading to dependency on foreign technology.

5.4.2 The Access Imperative

On the other hand, public health advocates insist that innovation cannot come at the cost of access. Millions of Indians still live below the poverty line, and drug affordability remains critical. Provisions like Section 3(d) ensure that only genuine innovation is rewarded, preventing frivolous patents that extend monopolies without significant therapeutic benefits.

5.4.3 The Middle Path

India's challenge is to create an ecosystem that incentivises innovation while maintaining

[55]Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 256.
[56]Peter Drahos, *Information Feudalism: Who Owns the Knowledge Economy?* (Earthscan 2002) 117.

affordability. This requires:

- Government investment in public R&D.
- Encouraging public–private partnerships.
- Strengthening institutions like the Council of Scientific and Industrial Research (CSIR).

5.5 Domestic Institutional Challenges

5.5.1 Patent Office Capacity

India's Patent Office suffers from backlogs, limited resources, and inadequate technical expertise. Efficient examination and opposition mechanisms are essential to ensure high-quality patents. Reforms to improve staffing, training, and digitisation are urgently needed.

5.5.2 Judicial Inconsistencies

While landmark judgments like Novartis and Bayer reinforced safeguards, inconsistent decisions in other cases create uncertainty. Courts sometimes issue injunctions that disproportionately favour patentees, raising questions about predictability in patent jurisprudence.

5.5.3 Awareness and Transparency

Many stakeholders, including small firms and patients, remain unaware of opposition procedures or compulsory licensing options. Strengthening legal literacy and civil society participation is crucial to making the patent system truly democratic.[57]

5.6 Future Reforms

5.6.1 Streamlining Patent Opposition

Strengthening pre- and post-grant opposition mechanisms can prevent frivolous patents from being granted. Civil society participation must be encouraged, and Patent Office procedures must become more transparent.

5.6.2 Promoting Domestic Innovation

India must boost domestic pharmaceutical R&D by:

- Offering tax incentives for innovation.
- Funding academic–industry partnerships.
- Supporting start-ups in biotechnology and biosimilars.[58]

[57]Médecins Sans Frontières (MSF), *Briefing Note on Access to Medicines* (2019).
[58]Dinesh Abrol, 'Indian Pharma: Moving Towards Innovation?' (2014) 49 Economic & Political Weekly 12.

5.6.3 Expanding Compulsory Licensing

Compulsory licensing should be extended beyond medicines to technologies critical for **climate change mitigation** and **public welfare**, such as renewable energy technologies. This would align India's patent law with sustainable development goals.

5.6.4 Harmonising with Global South

India should deepen alliances with other developing countries to resist TRIPS-plus pressures. Forums like BRICS and the South Centre provide opportunities to promote a development-oriented global IP order.

5.7 India's Role as a Global Norm Setter

India's patent framework has already influenced other developing nations. The Novartis and Bayer cases are frequently cited as models for balancing innovation and access. By continuing to resist TRIPS-plus demands and operationalising flexibilities, India can shape the future of global IP governance.[59]

India's post-TRIPS patent framework faces a complex road ahead. On one side are external pressures from developed countries, multinational corporations, and FTAs demanding stronger IP protection. On the other are domestic imperatives of affordability, access, and constitutional commitments to health and development.

The challenges are significant: institutional weaknesses, innovation deficits, and international trade tensions. Yet, India's ability to creatively deploy TRIPS flexibilities demonstrates that development and compliance are not mutually exclusive. By strengthening institutions, promoting domestic innovation, and resisting TRIPS-plus pressures, India can consolidate its position as a global leader in development-oriented intellectual property law.

Conclusion

The evolution of India's patent framework reflects the delicate balancing act between global obligations under TRIPS and the constitutional imperative of ensuring access to medicines. By introducing product patents in 2005, India aligned itself with the requirements of TRIPS, but at the same time, it innovatively employed flexibilities such as Section 3(d) and compulsory licensing to protect public health. This hybrid model has enabled India to remain TRIPS-compliant while safeguarding the needs of its population and maintaining its role as the

[59]Frederick M Abbott, 'The Future of the Multilateral Trading System in the Context of TRIPS' (2016) 20 J Intl Economic L 91.

"pharmacy of the developing world."

Judicial interventions have further shaped this framework. Landmark cases such as Novartis AG v Union of India and Bayer Corporation v Union of India demonstrate how courts have interpreted patent law through a socio-constitutional lens, ensuring that intellectual property rights do not override the right to life under Article 21. This judicial philosophy has set India apart from Western jurisdictions, reinforcing the principle that innovation must serve human welfare rather than corporate monopoly.

The socio-economic impacts of this framework have been significant. On one hand, India has preserved access to affordable medicines both domestically and globally, while its pharmaceutical industry has continued to grow as a major exporter of generics. On the other hand, multinational corporations and developed nations argue that India's approach discourages foreign investment and stifles innovation. This tension underscores the ongoing debate between protecting intellectual property and ensuring equitable access to essential goods.

Looking ahead, India faces mounting challenges, particularly from TRIPS-plus obligations in bilateral trade negotiations and diplomatic pressures from developed countries. Institutional inefficiencies within the Patent Office and the need to promote domestic R&D also remain pressing concerns. However, India's consistent use of TRIPS flexibilities demonstrates that it is possible to strike a balance between innovation and access, compliance and resistance.

In conclusion, India's post-TRIPS patent framework stands as a unique model for the Global South, showing that intellectual property regimes can be tailored to reflect developmental priorities. While the future will require vigilance against external pressures and internal weaknesses, India has laid the foundation for a patent system that is not only legally robust but also socially just.

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