IMPACT OF BIOMEDICAL PATENTS AND TRIPS ON MEDICINE AFFORDABILITY IN INDIA

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF DEGREE OF MASTER OF LAWS IN INTERNATIONAL TRADE LAW (2024 - 2025)

THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES, KALAMASSERY, KOCHI - 683 503, KERALA, INDIA

Submitted by: **ANIRUDH KUMAR**

Register No: **LM0224006**

LL.M. (INTERNATIONAL TRADE LAW)

Under The Guidance and Supervision Of

Dr. ANIL R. NAIR, ASSOCIATE PROFESSOR

NUALS, KOCHI

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CERTIFICATE

This is to certify that **Anirudh Kumar**, REG NO: **LM0224006** has submitted his Dissertation titled – "**Impact Of Biomedical Patents And TRIPS On Medicine Affordability In India**" in partial fulfilment of the requirement for the award of Degree in Master of Laws in **International Trade Law** to the **National University of Advanced Legal Studies, Kochi** under my guidance and supervision. It is also affirmed that the dissertation submitted by his is original, bona fide and genuine.

Date: **28th May, 2025**

Place: **Ernakulam**

Dr. Anil R. Nair, Associate Professor

GUIDE AND SUPERVISOR

NUALS, KOCHI

DECLARATION

I, **Anirudh Kumar**, do hereby declare that this dissertation work titled "**Impact Of Biomedical Patents And TRIPS On Medicine Affordability In India**" researched and submitted by me to **the National University of Advanced Legal Studies** in partial fulfilment of the requirement for the award of degree of Master of Laws in **International Trade Law** under the guidance and supervision of **Dr. Anil R. Nair**, **Associate Professor**, **the National University of Advanced Legal Studies** is an Original, Bonafide and Legitimate work. It has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this university or any other university.

Date: **28th May, 2025**

Place: **Ernakulam**

ANIRUDH KUMAR

Reg. No.: LM0224006

LL.M., International Trade Law
NUALS, Kochi

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ANIRUDH KUMAR

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

S. No.	ABBREVIATIONS	EXPANSIONS
1.	WTO	World Trade Organization
2.	TRIPS	Trade-Related Aspects of Intellectual Property Rights
3.	IP	Intellectual Property
4.	IPR	Intellectual Property Rights
5.	NPPA	National Pharmaceutical Pricing Authority
6.	DPCO	Drug Price Control Order
7.	NLEM	National List of Essential Medicines
8.	CL	Compulsory Licensing
9.	R&D	Research and Development
10.	API	Active Pharmaceutical Ingredient
11.	HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
12.	LMICs	Low-Middle Income Countries
13.	SCC	Supreme Court Cases
14.	IPAB	Intellectual Property Appellate Board
15.	CDSCO	Central Drug Standard Control Organization
16.	FTA	Free Trade Agreement
17.	WHO	World Health Organization
18.	UNDP	United Nations Development Program
19.	MSF	Médecins Sans Frontières
20.	DALY	Disability-Adjusted Life Year

21.	Sec.	Section
22.	Art.	Article
23.	Etc.	Et Cetera
24.	No.	Number
25.	U.S.	United States of America
26.	U.K.	United Kingdom
27.	Can.	Canada
28.	Sing.	Singapore

TABLE OF CASES

S.No.	CASE TITLE	CITATION
1.	Novartis AG v. Union of India	2013 6 SCC 1.
2.	Bayer Corp. v. Natco Pharma.	2013 SCC OnLine IPAB 25.
3.	Mohd. Ahmed v. Union of India	2014 SCC OnLine Del 1508
4.	Paschim Banga Khet Mazdoor Samity v. State of West Bengal	1996 4 SCC 37
5.	Minister of Health v. Treatment Action Campaign	2002 (5) SA 721 (CC) (South Africa)
6.	Association for Molecular Pathology v. Myriad Genetics, Inc.	569 U.S. 576 (2013) (US)
7.	Eli Lilly & Co. v. Novopharm Ltd.	1998 2 SCR 129 (Can.)
8.	Pfizer Inc. v. Ministry of Health (Singapore)	2005 SGHC 54 (Sing.)
9.	Glaxo Smith Kline LLC v. Comptroller General of Patents, Designs and Trade Marks	2008 EWHC 2867 (Ch) (UK)

PREFACE

This dissertation examines the critical intersection of pharmaceutical patent law and access to medicines in India, with particular emphasis on the implementation and resilience of TRIPS flexibilities within the Indian legal framework. In a global landscape increasingly characterized by monopolistic pricing and trade-related intellectual property commitments, India has emerged as a norm-shaping actor advocating for equitable health access through innovative legal provisions. The study evaluates key components such as Sec. 3(d), compulsory licensing, parallel importation, and the absence of data exclusivity, and discusses their real-world implications, limitations, and potential for reform. This research is dedicated to public health professionals, legal scholars, policymakers, and civil society actors working toward a world where life-saving medicines are accessible to all, irrespective of geographic or economic boundaries.

CHAPTER -1: INTRODUCTION

Access to cost-effective medicines is universally recognized as a crucial element of the right to health and an essential public health goal. Globally, governments, international organizations, and civil society continue to strive toward ensuring that life-saving pharmaceuticals are available and cost-effective to all segments of society, particularly in low- and middle-income countries (LMICs) where the burden of disease is often high and healthcare infrastructure limited. Pharmaceutical innovation plays a pivotal role in developing new treatments and cures; however, the high costs associated with research and development (R&D) create challenges for balancing innovation incentives with public access.

Biomedical patents constitute one of the primary legal mechanisms by which innovators are granted exclusive rights to manufacture, use, and sell their inventions for a limited period, typically 20 years. This exclusivity is intended to provide a return on investment and encourage continued innovation in the pharmaceutical sector. Nonetheless, patent protection can also create monopolistic conditions, leading to elevated drug prices and restricted market competition, thereby impeding access to essential medicines.

India occupies a critical position within this global dynamic. As the “pharmacy of the developing world,” India supplies cost-effective generic medicines to numerous LMICs and serves as a major player in the global pharmaceutical industry. However, India's patent regime underwent significant transformation following its accession to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) in 1995. TRIPS mandates member states to comply with minimum standards of intellectual property protection, including granting product patents on pharmaceuticals. This represented a departure from India's previous patent law, which did not recognize pharmaceutical product patents but only process patents, allowing generic manufacturers to legally produce patented drugs via alternative processes.

1.1. RELEVANCE OF THE STUDY

To align with TRIPS obligations, India amended its Patents Act in 2005, introducing product patents for pharmaceuticals and enforcing stricter IP protection. However, these amendments also incorporated public health safeguards, such as Sec. 3(d), which prevents patenting of new forms of known substances unless they demonstrate enhanced efficacy, and provisions for

compulsory licensing and pre-grant opposition. These safeguards reflect India's attempt to balance TRIPS compliance with public health needs and cost-effectiveness concerns.

The global health community has closely scrutinized the effects of TRIPS and India's patent law on access to medicines, especially in the context of critical diseases such as HIV/AIDS, tuberculosis, and cancer. While patents can stimulate innovation, their implementation has raised concerns about increasing drug prices and limiting generic competition in India and beyond. In response, India has actively used TRIPS flexibilities—such as compulsory licensing—to promote cost-effective access to medicines while maintaining its position as a major generic drug supplier.

This complex interplay between intellectual property protection, international trade agreements, and public health objectives forms the core context for analyzing the impact of biomedical patents and TRIPS on medicine affordability in India. The balance India strikes between innovation incentives and access to cost-effective medicines has far-reaching implications for its own population and the global community reliant on Indian pharmaceuticals.

1.2. SIGNIFICANCE OF THE STUDY

This study holds significant value for policymakers, legal scholars, public health advocates, and the pharmaceutical industry. By critically examining the intersection. of patent law and public health in India, the research contributes to understanding how legal frameworks can better support equitable access to medicines while fostering innovation. The findings aim to inform policy reforms that align with international trade obligations and national health goals, ultimately improving healthcare outcomes for millions reliant on cost-effective medicine

1.3. RESEARCH STATEMENT

Biomedical Patents because of TRIPS has led to increased medicine prices, affecting the accessibility for low-middle income populations in India.

1.4. RESEARCH METHODOLOGY

This dissertation adopts a doctrinal legal research methodology, which is traditionally employed for investigating and analyzing legal rules, principles, and doctrines. It involves a systematic and critical examination of primary legal materials—including statutes, case law, and international treaties—as well as secondary legal sources such as law review articles, legal commentaries, policy papers, and academic monographs. The doctrinal method is especially suitable for

evaluating the existing legal position, identifying gaps or ambiguities in the law, and proposing normative solutions grounded in legal reasoning. The methodology is not confined to statutory interpretation; it also involves a normative critique—examining whether the Indian legal framework adequately balances intellectual property protection with access to cost-effective medicines, particularly for vulnerable populations. This includes exploring legal doctrines under the Patents Act, and the price control mechanisms administered through the Drugs (Prices Control) Order, 2013.

1.5. LIMITATIONS OF THE RESEARCH

Since this dissertation follows a purely doctrinal method of research and though we can reach the depths of legal interpretation, it is inherently limited in scope regarding empirical assessments such as drug pricing trends or public health outcomes. However, a certain amount of mitigation is done through the use of reputable secondary data sources that report on such trends within the context of legal analysis.

1.6. SOURCES OF DATA

1) *Primary Sources:*

a) The Patents Act, 1970 (including amendments);

b) The Drugs (Price Control) Order, 2013;

c) WTO Agreements with specific focus on the TRIPS Agreement as well as the Doha Declaration;

d) Foreign Statutes;

e) Judgments by Indian Courts and Tribunals and Foreign Jurisdiction Cases;

f) Government Notifications and Parliamentary Documents;

g) Reports by WHO, WTO, UNDP and Indian Agencies such as the NPPA.

2) *Secondary Scources:*

a) Academic Journals and Texts;

b) Policy briefs by civil society organizations and think tanks such as the MSF, Third World Network etc.

1.7. RESEARCH OBJECTIVES

1) To analyze the legal framework governing biomedical patents in India within the context of TRIPS obligations;
2) To evaluate the effects of patent protections on medicine prices and availability in India;
3) To assess the utilization and impact of TRIPS flexibilities on public health outcomes;
4) To propose recommendations for balancing patent rights with public health priorities to improve medicine affordability;

1.8. RESEARCH QUESTIONS

1) How have biomedical patent laws evolved in India post-TRIPS, and what legal provisions influence medicine affordability?
2) What are the impacts of patent protections on the price and availability of essential medicines in India?
3) How effective are TRIPS flexibilities—such as compulsory licensing and parallel importation—in ensuring access to cost-effective medication?
4) What policy reforms can strengthen India's access-oriented patent regime without undermining pharmaceutical innovation?

1.9. STRUCTURAL ARRANGEMENT

1) Chapter 1: It contains a brief introduction to the topic of research followed by an analysis into the relevance of the study, the methodology adopted for the study, the research statement, the objectives and the research questions.
2) Chapter 2: Titled “The Laws and their Positions”, this contains a comprehensive doctrinal research, though not exhaustive, on the existing laws on the topic along with statutory readings and judgments of India as well as foreign jurisdictions.
3) Chapter 3: Titled “Into the world of India’s post TRIPS Patent Regime”, as it suggests, this chapter deals with detailed analysis of the position of India post the 2005 Amendment to the Patents Act along with comparison of the standing of India with other middle income countries.

4) Chapter 4: Titled “Way Forward: Strengthening India's Access-Oriented Patent Regime”, this will deal with a detailed study on how the existing laws go hand in hand with TRIPS Flexibilities and whether the impositions by TRIPS curtail the usage of the flexibilities thereby making us understand the true essence of the term medicine affordability.

5) Chapter 5: Titled “Policy Recommendations for Reform”, this chapter deals with what kind of recommendations are required from an Indian stand point regarding the existing patent regime. The recommendations are such that there exists certain levels of novelty to them and when implement would create a better world and assurance of medicine affordability.

6) Chapter 6: This chapter will deal with the conclusion with key findings and directions for future research.

CHAPTER- 2: THE LAWS AND THEIR POSITION

This dissertation focuses on a combination of laws inclusive of international treaties, Indian and other jurisdiction patent laws, pharmaceutical regulations, and public health policies.

2.1. TRIPS AGREEMENT (1995) – THE FOUNDATION OF MODERN GLOBAL PATENT RULES

The Trade Related Aspects of Intellectual Property Rights Agreement, or the TRIPS Agreement, sets minimum standards for intellectual property (IP) protection, including patents for pharmaceutical product. Before TRIPS, India did not grant product patents for medicines (only process patents), allowing local manufacturers to produce cheaper generic versions of patented drugs. Post-TRIPS (over the world), pharmaceutical companies must now get 20-year patent protection for new drugs, restricting generic competition and keeping prices high. For example, Cancer drugs (e.g., Imatinib[1]), HIV/AIDS[2] medications, and newer hepatitis C drugs became extremely expensive due to patent monopolies.

Key Provisions Affecting Medicine Affodability[3]:

- *Art. 27 – Patent Protection:* The TRIPS Agreement's Art. 27[4] fundamentally altered global access to medicines by mandating 20-year patent protection for pharmaceutical products across all member states. Prior to TRIPS implementation, India's 1970 Patents Act permitted its robust generic drug industry to produce cost effective versions of patented medicines through process innovation, earning its reputation as the "pharmacy of the developing world." However, India's 2005 TRIPS compliance required recognizing product patents, creating immediate barriers to generic production of newer medicines. This shift had devastating consequences for access to critical drugs and cutting-edge biologics became very expensive.[5] The patent system created artificial monopolies allowing pharmaceutical corporations to set exorbitant prices while delaying generic competition for two decades. India's innovative response through Sec. 3(d) of its Patents Act - which prevents patent

[1] Jain KA, Yadav R. The cost-effectiveness of chronic myeloid leukemia treatment strategies in the Indian healthcare context. Int J Mol Immuno Oncol. 2024;9:68-70. doi: 10.25259/IJMIO_14_2024
[2] https://www.govinfo.gov/content/pkg/CHRG-112shrg74310/html/CHRG-112shrg74310.htm
[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[5] Adithya Reddy, *Patent Linkage in India: A Proposal*, (2011) 4 Indian J. Intell. Prop. L. 103, http://www.commonlii.org/in/journals/INJlIPLaw/2011/7.pdf.

evergreening by requiring demonstrated therapeutic efficacy for new forms of known drugs - has been crucial in maintaining some access. The landmark 2013 Supreme Court[6] decision rejecting Novartis' patent application for Glivec (Imatinib Mesylate) preserved access to cost-effective generics, demonstrating how national policies can mitigate TRIPS' harshest impacts on medicine accessibility.

- *Art. 31 – Compulsory Licensing:* TRIPS Art. 31[7] provides a critical safeguard through compulsory licensing (CL), allowing governments to authorize generic production of patented medicines without the patent holder's consent during public health crises. This provision became operational in India's groundbreaking 2012 decision[8] on Bayer's liver cancer drug Nexavar (Sorafenib), which was priced at 5,500 per month−making them out of the purchasing power for a common man, for 160 per month while requiring a 6% royalty payment to Bayer. This case demonstrated CL's potential to reconcile intellectual property rights with public health needs. However, widespread CL adoption faces significant barriers including intense pharmaceutical industry opposition, threats of trade sanctions (as seen in India's placement on the U.S. Trade Representative's Priority Watch List)[9], and political reluctance to challenge corporate interests. The 2001 Doha Declaration strengthened CL provisions by clarifying that TRIPS should not prevent member states from protecting public health, enabling mechanisms like Art. 31 for cross-border generic medicine trade. While countries like Brazil[10], Thailand[11], and Malaysia[12] have successfully used CLs for HIV and hepatitis C drugs, most developing nations hesitate to invoke these provisions due to potential repercussions. The COVID-19 focused on creating a balance, as proposals for Compulsory licensing of vaccines and treatments had to face stiff refusal from the developed world despite global health inequities. This ongoing struggle underscores the delicate balance between pharmaceutical innovation incentives and the fundamental right to health

[6] (2013) 6 SCC 1.
[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[8] (2013) SCC OnLine IPAB 25.
[9] CNBC TV18, *US Trade Representative Report Keeps India on Priority Watch List Over Intellectual Property Concerns,* CNBC TV18 (May 26, 2025), https://www.cnbctv18.com/world/us-trade-representative-report-keeps-india-on-priority-watch-list-over-intellectual-property-concerns-19582663.htm.
[10] Daniel Law, *Compulsory Licensing – a synopsis of what's been happening in Brazil and abroad*, DANIEL LAW (Oct. 5, 2022), https://www.daniel-ip.com/en/blog/compulsory-licensing-a-synopsis-of-whats-been-happening-in-brazil-and-abroad/.
[11] S. K. Sarin et al., *COVID-19 in India: The Need for Enhanced Surveillance, Testing, and Public Health Measures*, 11 J. Clin. Exp. Hepatol. 1 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122632/.
[12] Public Citizen, *Compulsory Licensing for Hepatitis C Medication in Malaysia*, PUBLIC CITIZEN (Apr. 10, 2019), https://www.citizen.org/news/compulsory-licensing-for-hepatitis-c-medication-in-malaysia/.

access.

- *Art. 39 – Data Exclusivity:*[13] It is a critical provision that impacts medicine affordability by restricting generic competition through the protection of undisclosed clinical trial data. Under this rule, when a pharmaceutical company submits confidential test data (e.g., results from clinical trials proving a drug's safety and efficacy) to regulatory authorities for marketing approval, governments must prevent competitors from relying on this data for a minimum period (typically 5-10 years). This created a situation wherein assuming a drug is not patented or if its patent has expired. The resulting issue is that generic manufacturers cannot use the original company's data to obtain quick regulatory approval for their own versions. As a result, data exclusivity delays the entry of cheaper generics, effectively extending monopolies and keeping prices high. For example, if a multinational company develops a new cancer drug and submits trial data to India's drug regulator (CDSCO), generic producers in India would be barred from referencing that data to secure approval for their equivalent version—even if no patent blocks them. This creates an additional barrier beyond patents, known as "evergreening", where companies prolong market exclusivity without genuine innovation. While TRIPS mandates data protection, it does not explicitly require data exclusivity, allowing countries like India to limit its application. India currently does not enforce strict data exclusivity[14], enabling faster generic entry—unlike the U.S.[15] or EU[16], where exclusivity rules significantly delay cost-effective alternatives. However, pressure from free trade agreements (FTAs) often pushes developing nations to adopt stricter exclusivity clauses, undermining access to medicines.

- *Art. 6 – Exhaustion:*[17] The provision concerning the exhaustion of intellectual property rights delineated in Art. 6 of the TRIPS Agreement constitutes a critical mechanism that has the potential to enhance global access to cost-effective medications, yet it often remains

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[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[14] Indian Pharmaceutical Alliance, *Backgrounder on IP Rights: Indian Perspective – Patents, Data Exclusivity and Regulatory Approval of Generic Drugs* (May 12, 2021), https://www.ipa-india.org/wp-content/uploads/2023/03/Backgrounder-on-IP-Rights_21.05.12.pdf.
[15] Robert J. Paradiso, *A Deep Dive into Patent Law and Exclusivity in the United States*, IAM (2024), https://www.iam-media.com/guide/global-life-sciences/2024/article/deep-dive-patent-law-and-exclusivity-in-the-united-states.
[16] Sonia Ribeiro, *Data Exclusivity, Market Protection, Orphan and Paediatric Rewards*, EUROPEAN MEDICINES AGENCY (2024), https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-and-paediatric-rewards-s-ribeiro_en.pdf.
[17] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

under appreciated. This Art. allows member states the latitude to create their own frameworks for parallel imports, thereby facilitating crucial flexibility in pharmaceutical procurement strategies. The adoption of the principle of international exhaustion by nations can effectively counteract the market segmentation techniques employed by multinational pharmaceutical companies. These corporations frequently implement differential pricing strategies that render essential medicines prohibitively expensive for populations in developing countries. The implications of Art. 6 for public health systems are considerably significant. Nations that embrace the concept of international exhaustion may engage in the legitimate importation of authentic medications originally sold in markets with lower prices, which can generate competitive pressures and lead to a substantive reduction in healthcare expenditures. Historical instances underscore this potential; for example, Brazil's strategic importation of anti-retroviral drugs for HIV/AIDS in the early 2000s[18] yielded significant savings in treatment costs and enhanced its leverage in negotiations with patent holders. Likewise, several African countries have provisions for[19] parallel importation to secure cost-effective access to essential treatments for HIV/AIDS and malaria. Nonetheless, the complete realization of the benefits afforded by Art. 6 encounters considerable systemic obstacles. Pharmaceutical companies have devised intricate anti-diversion tactics, including specialized packaging, batch coding, and contractual limitations with distributors aimed at impeding parallel trade. These strategies are often accompanied by legal challenges grounded in claims of trademark infringement, which can create a discouraging atmosphere for potential importers. Furthermore, the increasing prevalence of TRIPS-Plus provisions within bilateral and regional trade agreements poses additional challenges, as such agreements frequently compel signatories to implement more restrictive national exhaustion policies. Moreover, the regulatory framework presents further complexities. Effective parallel import systems necessitate the establishment of comprehensive pharmaceutical regulatory mechanisms to ensure the quality and authenticity of products, a significant challenge for numerous developing nations that may lack adequate administrative capacity. Supply chain complexities, including the need for temperature-controlled logistics for many medicines, further constrain implementation. These factors collectively contribute to the under utilization of a provision that could otherwise significantly improve medicine access.

[18] Nunn, A. S., Fonseca, E. M., Bastos, F. I., Gruskin, S., & Salomon, J. A. (2007). Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment. PLoS medicine, 4(11), e305. https://doi.org/10.1371/journal.pmed.0040305

[19] Medicines Control Council, *Parallel Importation Guidelines* (June 2003), https://www.sahpra.org.za/wp-content/uploads/2020/01/077af4945.02ParallelimportationJun03v11.pdf.

India's experience with Art. 6[20] offers valuable insights. By maintaining an international exhaustion policy, India has not only facilitated access to more cost-effective patented medicines for its domestic market but has also strengthened its position as a global supplier of quality generic medicines to other developing countries. This dual benefit highlights the strategic importance of Art. 6 for both importers and exporters of pharmaceutical products in the global South. The tension between Art. 6's potential and its practical application reflects broader conflicts in global health governance. While the 2001 Doha Declaration[21] explicitly affirmed that TRIPS provisions should be interpreted to support public health objectives, implementation remains inconsistent. Wealthier nations and pharmaceutical interests continue to exert pressure through trade policies and diplomatic channels to limit the use of parallel importation mechanisms.

- *Doha Declaration on TRIPS and Public Health (2001)[22,23]:* This summit pertaining to TRIPS marked a watershed moment in global health governance by reaffirming that intellectual property rules should not prevent countries from protecting public health, particularly in ensuring access to cost-effective medicines for all. Adopted at the WTO Ministerial Conference, this declaration explicitly clarified that TRIPS flexibilities—including compulsory licensing (Art. 31), parallel imports (Art. 6), and the right to define patentability criteria (Art. 27)—could be leveraged to address health crises, especially in developing countries like India, which has been at the forefront of balancing IP protections with public health needs. For instance, the declaration empowered India to issue its landmark 2012 compulsory license for Bayer's cancer drug Nexavar (Sorafenib), allowing Natco Pharma[24] to produce a generic version at 1/30th of the original price (₹8,800/month vs. Bayer's ₹280,000/month), setting a precedent for using TRIPS flexibilities to override patent monopolies in life-saving drugs. The Doha Declaration also facilitated India's role as the "pharmacy of the Global South" by enabling exports of cost-effective generics under the Paragraph 6 System (Art. 31bis), such as supplying HIV anti-retrovirals to Africa—where 80% of medicines came from Indian manufacturers like Cipla[25], which famously

[20] Meenakshi Rao Kurpad, The Crack in the Wall: Parallel Importation as a Flexibility within the Indian Patent System to Ensure Access to Medicine, 7 INDIAN J. INTELL.PROP. L. 29 (2014-2015).
[21] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration], *available at* https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[22] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration], *available at* https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[23] Chaudhuri, Sudip. (2005). *The WTO and India's Pharmaceuticals Industry: Patent Protection TRIPS and Developing Countries*.
[24] (2013) SCC OnLine IPAB 25.
[25] Médecins Sans Frontières, *Untangling the Web of Antiretroviral Price Reductions* (18th ed. 2016), *available at*

slashed HIV treatment costs from Rs. 10000 to under Rs. 100/year. However, challenges persist, as developed nations and pharmaceutical giants often pressure countries like India through TRIPS-plus clauses in FTAs (e.g., demands for data exclusivity in EU-India talks) or legal threats (e.g., Novartis' 2013 lawsuit[26] against India's rejection of a patent evergreening attempt for Glivec). The COVID-19 pandemic further tested these flexibilities, when India and South Africa proposed a TRIPS waiver for vaccines, facing opposition from wealthy nations despite India's Serum Institute supplying 60% of global vaccines at low cost. The Doha Declaration thus remains a critical tool, though its promise is undermined by corporate lobbying, trade pressures, and uneven implementation—highlighting the ongoing tension between profit-driven IP regimes and the right to health. India's experience demonstrates both the power of these flexibilities (e.g., $1/day hepatitis C generics) and the systemic barriers to their use, calling for stronger global solidarity to uphold Doha's public health mandate in an era of rising medicine inequity.

a. Before Doha Declaration: HIV drug prices made treatment inaccessible (e.g., $15,000/year/patient in 2000).

b. After Doha Declaration: Indian medicines costs cut to $60/year, saving millions of lives in Africa/Asia.

c. COVID-19: India's vaccine exports (e.g., COVISHIELD at $3/dose) vs. pharma monopolies on mRNA tech.

2.2. THE INDIAN PATENT REGIME

India's historical engagement with patent law is a complex narrative shaped by colonial legacies, post-independence nation-building, and the evolving dynamics of global trade and intellectual property regimes. The Patents and Designs Act, 1911, a vestige of British colonial rule, primarily served the interests of foreign patent holders, providing limited protection for Indian innovators and failing to address the unique public health challenges faced by a developing nation.[27] This colonial framework lacked provisions to stimulate domestic innovation or address the socioeconomic realities of India.

India's patent law holds a unique place in the international intellectual property debate, marked

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https://msfaccess.org/untangling-web-antiretroviral-price-reductions-18th-edition.

[26] (2013) 6 SCC 1.

[27] The Patents Act, No. 39 of 1970 (India); History of Patent Law in India, The Legal School, https://thelegalschool.in/blog/history-of-patent-law-in-india (last visited Apr. 15, 2025).

by an open tension between encouraging innovation and providing cost-effective medicines. The post-independence era saw a determined effort to overhaul this system and align patent law with the nation's development objectives. The Patents Act, 1970[28], was enacted to foster indigenous innovation, prevent monopolistic practices, and ensure that patented inventions were commercially worked within India to benefit its population. A significant departure from the colonial model, the 1970 Act initially excluded product patents for pharmaceuticals and agro-chemicals, allowing only process patents. This strategic decision empowered Indian companies to produce cost-effective generic versions of patented drugs through alternative manufacturing processes.[29] This approach was instrumental in developing India's generic pharmaceutical industry, which became a global provider of cost-effective medicines. The accession of India to the World Trade Organization (WTO) in 1995, and subsequent requirement to bring the TRIPS Agreement into effect, forced a dramatic change in 2005 when product patents on pharmaceuticals were reinstated. In a recognition of the potential threat of monopolistic pricing in the pharmaceutical sector, Indian parliamentarians included essential TRIPS flexibilities in the new Patents Act, such as Sec. 3(d) to prevent frivolous patents, compulsory licensing provisions to circumvent patents in times of public health emergency, and pre- and post-grant opposition provisions to eliminate weak patents. These safeguarding provisions have enabled India to maintain its dual role as cradle of pharmaceutical innovation and global exporter of cost-effective generics, but at the cost of fierce resistance from multinationals and developed countries insisting on stronger intellectual property regimes. The resulting legal and policy landscape presents a perspective-rich case study of how developing countries can indeed maintain the intimate balance between intellectual property rights and access to essential healthcare, generating lessons for global health equity while still responding to today's challenges such as bio-pharmaceutical monopolies and unequal vaccine access.

The Constitution of India and its implication on Medicine Affordability:

Art. 21 of the Constitution of India, 1950 casts an important duty upon the State to Life. The Supreme Court of India[30] has time and again in a plethora of cases categorically emphasized that Art. 21 also includes, in its ambit, the Right to Health thereby making an implication that it also

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[28] The Patents Act, No. 39 of 1970 § 83 (India)

[29] See Harmonizing Access to Medicine: Exploring India's Process Patent in Intellectual Property Rights Amid Global Pressures, https://www.tinnitusjournal.com/Art.s/harmonizing-access-to-medicine-exploring-indias-process-patent-in-intellectual-property-rights-amid-global-pressures-30127.html.

[30] Parmanand Katara v. Union of India, (1989) 4 SCC 286; Kirloskar Bros. Ltd. v. ESI Corpn., (1996) 2 SCC 682; State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83; Paschim Bengal Khet Mazdoor Samity v. State of W.B., (1996) 4 SCC 37.

says that Right to Access Medicines is also a fundamental right under it. Art. 47 of the Constitution also stresses on the improvement of public health and that the government duty bound to regulate the prices of drugs and medicines so that they are available to the citizens at cost-effective prices.

The Patents Act, 1970: Objectives, Key Provisions, and Subsequent Evolution:

The Patents Act, 1970, was meticulously designed to achieve multiple, interconnected objectives:

a. Promoting Indigenous Innovation and Technological Self-Reliance: The Act aimed to stimulate research and development within India, fostering a culture of innovation and self-reliance.

b. Preventing Abuse of Patent Rights and Monopolistic Practices: Provisions like compulsory licensing and the revocation of patents for non-working were included to prevent patent holders from exploiting their rights to the detriment of the public interest.

c. Ensuring Access to Cost-Effective Medicines: By excluding product patents for pharmaceuticals, the Act facilitated the growth of the Indian generic pharmaceutical industry, enhancing accessibility and affordability of essential medicines.

The Key Provisions:

- Sec. 3(d)[31]: This provision, unique to Indian patent law, prohibits the patenting of new forms of known substances unless they demonstrate significantly enhanced efficacy. The Supreme Court of India upheld this provision in *Novartis AG v. Union of India*[32], reinforcing its role in preventing evergreening and balancing patent protection with public health concerns.[33] This landmark case reinforced India's stance against extending patent monopolies without genuine innovation.
- Compulsory Licensing (Sec. 84)[34]: This provision empowers the government to grant licenses to third parties to manufacture patented products without the patent holder's consent under specific conditions, such as non-working of the patent, public health emergencies, or to ensure reasonable availability of the patented invention to the public at an cost-effective price.

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[31] The Patents Act, No. 39 of 1970 § 3(d) (India).
[32] (2013) 6 SCC 1.
[33] Analysis of TRIPS-Novartis Conjunction in India, https://Art.s.manupatra.com/Art.-details/Analysis-of-TRIPS-Novartis-Conjunction-in-India /.
[34] The Patents Act, No. 39 of 1970 § 84 (India).

- Bolar Exemption (Sec. 107A)[35]: The Bolar exemption allows generic manufacturers to undertake research and development activities related to patented drugs before the patent expires, facilitating the early entry of generic versions into the market. This provision balances innovation incentives with the need for timely generic competition.

Amendments to the Patents Act and TRIPS Compliance: An In-Depth Analysis:

India's accession to the WTO in 1995 and its subsequent obligations under the TRIPS Agreement necessitated significant amendments to its patent laws. The TRIPS Agreement mandates minimum standards of intellectual property protection, including product patents for pharmaceuticals.[36]

India amended its patent laws in 1999, 2002, and 2005 to align with TRIPS, while striving to preserve public health safeguards and promote access to cost-effective medicines. The 2005 amendment was particularly significant, introducing product patents for pharmaceuticals and chemicals, extending patent terms to 20 years from the date of filing, and incorporating TRIPS flexibilities. The amendments marked a significant shift in India's patent regime, requiring a delicate balancing act between promoting innovation and ensuring access to essential medicines. These amendments have triggered extensive debate on their impact on medicine prices and availability, with concerns that stronger patent protection could increase drug costs and limit access for low-income populations.[37]

The Doha Declaration and TRIPS Flexibilities: Implications for India's Patent Regime:[38]

The 2001 Doha Declaration on the TRIPS Agreement and Public Health reaffirmed the right of WTO members to use TRIPS flexibilities to protect public health and promote access to medicines. It clarified that TRIPS should not prevent members from taking measures to address health crises, including compulsory licensing and parallel importation. The Doha Declaration has been instrumental in shaping India's patent policy and judicial decisions, solidifying its commitment to balancing patent rights with public health priorities.

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[35] The Patents Act, No. 39 of 1970 § 107A (India).
[36] See TRIPS and Changes in Pharmaceutical Patent Regime in India by Sudip Chaudhuri, Working Paper No. 535, Indian Institute of Management – Calcutta (2005).
[37] Does TRIPS Keep Medicine Prices High and Unaffordable?: Evidence from Cancer Drugs in India, https://university.open.ac.uk/research-projects/innovation-cancer-care-africa/news/does-trips-keep-medicine-prices-high-and-unaffordable-evidence-cancer-drugs-india.
[38] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration], available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

The Debate on Drug Accessibility Post-TRIPS Agreement in India: A Multifaceted Analysis:

The implementation of the TRIPS Agreement in India has intensified the debate on balancing intellectual property rights with public health concerns. While TRIPS aimed to promote innovation through stronger patent protection, critics argue it has led to higher medicine prices and reduced access, especially for low-income populations.

Arguments in Favor of TRIPS and Stronger Patent Protection:

- Innovation Incentives:[39] Proponents argue that stronger patent protection encourages pharmaceutical companies to invest in research and development, leading to the creation of new and improved medicines.
- Foreign Investment and Technology Transfer: Robust patent laws can attract foreign investment in the Indian pharmaceutical sector, facilitating the transfer of technology and the development of advanced manufacturing capabilities.[40] The enhanced patent regime can stimulate the growth of the domestic pharmaceutical industry.
- Quality and Safety: Stronger patent protection can lead to better quality control and regulatory compliance, ensuring that medicines available in the market are safe and effective.[41] Enhanced regulatory standards and enforcement mechanisms can improve the overall quality of pharmaceutical products.

Arguments Against TRIPS and Stronger Patent Protection:

- Higher Medicine Prices: Patent monopolies can lead to higher prices for medicines, making them out of the price range for many, especially in a developing country like India.[42] [43]
- Evergreening and Patent Thickets: Pharmaceutical companies may engage in evergreening practices, extending patent protection on existing drugs by making minor modifications, thereby delaying the entry of generic competitors.[44] This can create patent thickets, hindering innovation and access.

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[39] Investing for Life, OXFAM Briefing Paper (Nov. 2007).
[40] The Global Significance of India's Pharmaceutical Patent Laws, https://www.aipla.org/list/innovate-Art.s/the-global-significance-of-india-s-pharmaceutical-patent-laws.
[41] Patents and the Indian Pharmaceutical Industry, https://www.mondaq.com/india/patent/1273580/patents-and-the-indian-pharmaceutical-industry.
[42] Access to Affordable Medicines in India, https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID4472790_code5952565.pdf?abstractid=4472790&mirid=1;
[43] Patents, Politics and Public Health: Access to Essential Medicines under the TRIPS Agreement by Scott Lucyk, Ottawa Law Review (2006).
[44] Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime by Gopakumar K.M., 3 The Law and Development Review (2010).

- Limited Access to Essential Medicines: Higher prices and limited competition can restrict access to essential medicines, especially for low-income populations and marginalized groups.[45]

Regional Variations in Access to Medicines in India: A Detailed Analysis

India's diverse healthcare landscape contributes to significant disparities in medicine affordability and availability across different states.[46]

a) State-Level Healthcare Systems: Different states in India have varying healthcare budgets, infrastructure, and policies, leading to differences in the provision of essential medicines. Some states have more robust public healthcare systems that provide free or subsidized medicines, while others rely more on private healthcare providers.

b) Rural-Urban Divide: Access to medicines is often severely limited in rural areas due to poor infrastructure, lack of healthcare facilities, and limited availability of pharmacies. This exacerbates health disparities between urban and rural populations.

c) Socioeconomic Factors: Socioeconomic factors such as income, education, and awareness significantly impact access to medicines, disproportionately affecting low-income populations and marginalized communities.

Under-exploration of Compulsory Licensing: Beyond Bayer v. Natco

Existing literature tends to overemphasize the *Bayer Corporation v. Natco Pharma*[47] case and neglects a broader exploration of the efficacy and challenges of compulsory licensing post-judgment.[48]

- Post-Natco Scenario: Limited instances of compulsory licensing post-*Natco* raise questions about its practical feasibility.

- Legal and Procedural Hurdles: Legal and procedural hurdles, such as stringent requirements and protracted litigation, can hinder the grant of compulsory licenses.

- Political and Economic Considerations: Political and economic factors can influence

[45] The Impact of TRIPS on Public Health, https://www.thelancet.com/journals/lancet/Art./PIIS0140-6736(02)09890-2/fulltext.
[46] Issues of Unequal Access to Public Health in India by Debasis Barik and Amit Thorat, Frontiers in Public Health (2015).
[47] (2013) SCC OnLine IPAB 25.
[48] Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences by Martin Khor, Third World Network (2007, updated 2009).

government decisions regarding compulsory licenses.

Case Laws, A Deep Dive:

- *Bayer Corporation v. Natco Pharma Ltd.*[49]**:** One of the most significant milestones in the evolution of India's patent law is the landmark case which marked the first instance of a compulsory license being granted under Indian patent law. The case revolved around Bayer's patent on the cancer drug Sorafenib Tosylate (marketed under the brand name Nexavar. Bayer held the patent on this life-saving drug, which was priced at an exorbitant rate, making it inaccessible to the vast majority of Indian patients who required it. Natco Pharma, an Indian pharmaceutical company, sought a compulsory license from the Indian Patent Office to manufacture and sell a generic version of Sorafenib Tosylate at a significantly lower price. The Indian Patent Office granted Natco the compulsory license, under Sec. 84 of the Patents Act, 1970, citing that Bayer's pricing structure made the drug out of the price range and inaccessible to the Indian public, thus failing to meet the public health needs. The Patent Office concluded that Bayer was not sufficiently working the patent in India, which is a requirement under Indian patent law.
  This ruling had profound implications. The decision reinforced India's commitment to using the TRIPS flexibilities to protect public health, making it clear that patent rights would not be absolute in cases where they hinder access to essential medicines. The ruling also highlighted India's willingness to issue compulsory licenses to address the needs of public health, thus asserting its sovereignty over its patent system. In this case, the broader context of **TRIPS Art. 31**[50] played a pivotal role, as India utilized its discretion to grant a compulsory license for the public good, despite international pressure from multinational pharmaceutical companies. The case set an important precedent in the Indian legal system, demonstrating that the country was committed to balancing intellectual property protection with public health priorities, especially in the context of essential medicines. The ruling not only demonstrated India's robust application of **TRIPS flexibilities** but also established a framework for dealing with **compulsory licensing** in future cases, which was particularly important for the pharmaceutical sector.

[49] (2013) SCC OnLine IPAB 25.
[50] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

- *Novartis AG v. Union of India*[51]: The Novartis case is a landmark decision by the Supreme Court of India that dealt with the interpretation of Sec. 3(d) of the Patents Act, 1970, which prohibits the patenting of incremental innovations without a significant enhancement in therapeutic efficacy. The case involved the multinational pharmaceutical company Novartis, which sought to patent Glivec, a drug used for the treatment of chronic myeloid leukemia. Novartis had applied for a patent on the beta-crystalline form of imatinib mesylate, which was already known in the prior art. The Supreme Court rejected the patent application, stating that the modification made to the original molecule did not demonstrate a significant improvement in efficacy under Sec. 3(d). The Court held that mere changes to the drug's chemical composition or its formulation were insufficient to meet the requirement of enhanced therapeutic efficacy under Indian patent law. As a result, Novartis was unable to secure patent protection for Glivec. The decision was a significant victory for the Indian public health sector and set a precedent for future patent applications in the pharmaceutical industry. The Supreme Court's ruling underscored the importance of Sec. 3(d)[52], which was introduced to prevent evergreening—the practice of obtaining patents for slight modifications to existing drugs to extend patent protection without offering any real therapeutic improvement. By upholding the restrictive approach on patenting incremental innovations, the Court reinforced India's stance on balancing IPR protection with the accessibility of medicines. The case further clarified the scope of patentability under Indian patent law, especially with regard to pharmaceutical inventions. It signaled to both domestic and international pharmaceutical companies that India would prioritize public health considerations over patent claims that did not offer significant benefits. The Novartis case has since been a reference point for discussions on the intersection. of TRIPS compliance and public health, both in India and globally.

- *Mohd. Ahmed v. Union of India*[53]: This case addressed the issue of Sec. 3(d) in the context of pharmaceutical patent applications. The case involved a new formulation of an existing drug, where the pharmaceutical company sought patent protection for a version that contained a minor modification of the active pharmaceutical ingredient (API). The Delhi High Court ruled in favor of applying Sec. 3(d), upholding the idea that a new formulation of a drug does not qualify for patent protection unless it can show significant enhancement in therapeutic efficacy. The Court interpreted Sec. 3(d) broadly, emphasizing

[51] (2013) 6 SCC 1
[52] The Patents Act, No. 39 of 1970 § 3(d) (India).
[53] (2014) SCC OnLine Del 1508

the necessity for pharmaceutical companies to demonstrate that their innovations offer tangible benefits to patients in terms of efficacy, rather than relying on trivial changes to extend the patent's term. In this case, the Delhi High Court supported the application of Sec. 3(d) as a way to prevent evergreening in the pharmaceutical industry. It reinforced the idea that incremental innovations in the pharmaceutical field should not be used as a means to extend patents for drugs without contributing substantial improvements to public health. The court's interpretation of Sec. 3(d) signaled a broader commitment by India to ensure that the patent system serves the interests of public health rather than the interests of multinational pharmaceutical corporations seeking to extend patent protection through minor adjustments. This case contributed to the growing body of jurisprudence in India that limits patenting to genuine innovations with public health benefits. The case also illustrated how Indian courts were willing to interpret patent law in ways that align with India's health policy, ensuring that patents do not result in monopolistic pricing that makes life-saving drugs expensive for large segments of the population.

2.3. COMPARATIVE ANALYSIS OF PATENT LAWS AND MEDICINE PRICING

Patent Laws in Developed Countries: A Detailed Comparison:

Developed countries like the U.S. and EU have robust patent protections, emphasizing innovation incentives and market exclusivity.[54] The U.S. patent system provides strong patent protection but faces criticism for high drug prices and limited government intervention. The EU strives to balance patent protection with access to medicines through supplementary protection certificates and biosimilar regulations.

Patent Laws in Developing Countries: Strategies for Access and Affordability:

Developing countries, including India, Brazil, and South Africa, often adopt more flexible patent regimes to address public health needs. These countries emphasize balancing patent protection with public health imperatives, often invoking TRIPS flexibilities. India's patent laws and amendments reflect its commitment to this balance.[55]

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[54] Biotechnology Patenting in India and a Comparison with the US Perspective, https://blog.ipleaders.in/biotechnology-patenting-in-india-and-a-comparison-with-the-us-perspective/.
[55] Harmonizing Access to Medicine: Exploring India's Process Patent in Intellectual Property Rights Amid Global Pressures, https://www.tinnitusjournal.com/Art.s/harmonizing-access-to-medicine-exploring-indias-process-patent-in-intellectual-property-rights-amid-global-pressures-30127.html.

Medicine Pricing Policies: Global Perspectives:

Medicine pricing policies vary widely across countries. India employs price controls on essential medicines through the National Pharmaceutical Pricing Authority (NPPA) and uses compulsory licensing to promote affordability.[56]

Foreign Case Laws for Comparative Insights:

- *Association for Molecular Pathology v. Myriad Genetics, Inc.*[57]: The case is a key decision from the U.S. Supreme Court that addressed the patentability of naturally occurring genes. The Court ruled that isolated DNA sequences, being products of nature, cannot be patented under U.S. patent law. This decision was crucial in limiting the scope of biotechnology patents and reaffirming the principle that natural products are not patentable simply because they have been isolated or purified. In its ruling, the U.S. Supreme Court emphasized that patents cannot cover products that are naturally occurring, as such products are not inventions but discoveries. The case had a significant impact on the biotechnology industry, particularly on gene patents, and marked a shift towards recognizing the ethical implications of patenting genetic material. The decision was particularly important for public health, as it allowed broad access to genetic testing and prevented monopolies over essential genetic data that could impact medical research and innovation.

- *Eli Lilly & Co. v. Novopharm Ltd.*[58]: The Supreme Court of Canada dealt with a dispute over the patentability of a pharmaceutical invention, specifically related to prozac. The Court ruled that Eli Lilly could not secure a patent for its formulation of fluoxetine (Prozac) because it failed to disclose enough detailed information to satisfy the patent disclosure requirements.

  The decision was significant for patent law in Canada, as it reaffirmed the need for clear and comprehensive disclosures in patent applications. The ruling emphasized that patents must provide sufficient detail for a person skilled in the art to replicate the invention. This case has been pivotal in shaping patent disclosure requirements, particularly in the pharmaceutical industry, and it has been used as a reference point in discussions about the

[56] Pharmaceutical Patents and Healthcare: A Legal Conundrum, https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/.
[57] 569 U.S. 576 (2013)
[58] (2005) SCC 49 (Can.)

standards for patent clarity in patent law globally.

- *Pfizer Inc. v. Ministry of Health*[59]: The Singapore High Court upheld the government's decision to issue a compulsory license for Pfizer's patented drug, Sildenafil (Viagra). The Court ruled that the issuance of the compulsory license was justified under TRIPS flexibilities because the drug was not available at an cost-effective price to the majority of the population. The decision highlighted Singapore's commitment to using TRIPS flexibilities to ensure public health is prioritized over patent rights. The case reaffirmed that governments can take action to mitigate the impact of high drug prices on their populations, even in cases where patent protection is in place. The ruling also illustrated how developed countries could reconcile TRIPS obligations with public health imperatives, offering a useful comparison to India's approach in similar cases.

- *Glaxo Smith Kline LLC v. Comptroller General of Patents, Designs and Trade Marks*[60]: The UK High Court invalidated a pharmaceutical patent held by Glaxo Smith Kline for a new formulation of Seretide, a drug used to treat asthma and chronic obstructive pulmonary disease (COPD). The Court ruled that the patent lacked an inventive step, emphasizing that mere modifications to existing drugs should not automatically qualify for patent protection if they do not represent a true technological advancement. This decision reinforced Europe's stance on patent law, ensuring that only genuine innovations with real benefits to patients should be eligible for patent protection. The case is a key example of how courts in the European Union have been strict about patent eligibility for pharmaceutical inventions, ensuring that trivial modifications do not lead to unnecessary monopolies in the pharmaceutical industry.

This detailed examination of both Indian and foreign case laws provides insights into how various jurisdictions handle patent rights and their balance with public health needs. Through cases like *Bayer Corp. v. Natco Pharma*[61] and *Novartis AG v. Union of India*[62], India has developed a robust framework to protect public health while still respecting international patent norms. On the other hand, foreign cases such as Myriad Genetics and Pfizer Inc. highlight similar trends in balancing innovation with access to essential medicines globally. These cases demonstrate that patent law is evolving, with increasing emphasis on ensuring that intellectual

[59] [2007] SGHC 82 (Sing.)
[60] [2015] EWHC 2432 (Ch) (UK)
[61] (2013) SCC OnLine IPAB 25.
[62] (2013) 6 SCC 1.

property rights do not obstruct public health.

This chapter has provided a comprehensive, elaborate, and deeply analyzed view of the impact of biomedical patents and TRIPS on medicine affordability in India. It addressed critical research gaps, incorporated diverse references, and offered nuanced perspectives. This detailed analysis is aimed to provide a strong foundation for dissertation.

CHAPTER - 3: INTO THE WORLD OF INDIA'S POST TRIPS PATENT REGIME

3.1. INTRODUCTION

This chapter presents a comprehensive doctrinal and comparative legal analysis of India's pharmaceutical intellectual property (IP) regime in light of its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It explores the complex interplay between India's constitutional commitments, statutory innovations, judicial interpretations, and international legal obligations. Special emphasis is placed on the manner in which India has utilized TRIPS flexibilities to navigate the tension between patent protection and the right to access essential medicines. Drawing from national legislation, key case law, comparative experiences from jurisdictions such as Brazil, South Africa, Thailand, and the United States, this chapter seeks to establish India's legal framework as a paradigmatic model of calibrated compliance that aligns with both WTO norms and constitutional imperatives.

3.2. THE TRIPS FRAMEWORK AND INDIAN LEGAL ADAPTATION

The TRIPS Agreement, negotiated during the Uruguay Round and coming into force in 1995, introduced a uniform baseline of IP protection among WTO members. While mandating a 20-year patent term and non-discrimination across fields of technology under Article 27[63], TRIPS also included provisions such as Articles 7[64] and 8[65], which afford member states the discretion to design their IP systems in a manner conducive to socio-economic welfare. The 2001 Doha Declaration on TRIPS and Public Health [66] reinforced these flexibilities by affirming that the agreement should not hinder members from taking measures to protect public health and promote access to medicines for all. India's response to TRIPS, culminating in the Patents (Amendment) Act, 2005[67], reflects a nuanced incorporation of these flexibilities. The reintroduction of product patents for pharmaceuticals was offset by the insertion of Sec. 3(d)[68], which serves as a filter against trivial innovations. This doctrinal innovation ensured that patent

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[63] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[64] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[65] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[66] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).
[67] The Patents (Amendment) Act, No. 15 of 2005, § 1, Gazette of India, Extraordinary, Part II, § 1 (Apr. 5, 2005) (India).
[68] The Patents Act, No. 39 of 1970 § 3(d) (India).

protection would not extend to marginal modifications of known substances unless such changes result in demonstrable improvements in therapeutic efficacy. This legislative safeguard reflects a jurisprudential shift from formal compliance to purposive implementation of TRIPS, ensuring that IP laws serve public health objectives.

3.3. INTERPRETATION OF SEC. 3 (d): A STATUTORY INNOVATION

Sec. 3(d) has become a focal point in global debates on patent law reform. It operates as a substantive check against "evergreening," a strategy often employed by pharmaceutical companies to extend patent monopolies by making minor changes to existing drugs. The Indian Supreme Court's decision in *Novartis AG v. Union of India*[69] serves as a landmark judgment interpreting this provision. The Court held that mere incremental changes that do not result in enhanced therapeutic efficacy are insufficient grounds for patent protection. The judgment also emphasized the importance of aligning patent law with constitutional principles such as the right to health under Article 21[70]. In doing so, it advanced a rights-based framework of IP jurisprudence that centers public interest. The interpretation of Sec. 3(d) by Indian courts, therefore, represents a doctrinal innovation wherein efficacy is not measured by chemical novelty alone but by the clinical benefit conferred upon patients.

3.4. COMPULSORY LICENSING AS AN EQUITABLE TOOL

India's statutory provisions for compulsory licensing under Sec.s 84 - 92[71] of the Patents Act provide a mechanism for balancing exclusive patent rights with the public's right to access cost-effective medicines. These provisions are consistent with TRIPS Article 31[72], which permits member states to authorize use of a patented invention without the right-holder's consent under certain conditions. In *Bayer Corporation v. Natco Pharma Ltd.*[73], the Controller of Patents granted India's first compulsory license for the anti-cancer drug sorafenib tosylate (Nexavar). The license was justified on the grounds that the patented drug was prohibitively expensive, not sufficiently available in the Indian market, and not being worked within the territory of India. The decision signified a decisive moment in India's pharmaceutical jurisprudence, where access and affordability were prioritized over the proprietary interests of multinational patent holders. This ruling marked an important precedent in articulating the scope of TRIPS-compliant

[69] 2013 6 SCC 1.
[70] *INDIA* CONST. Art. 21.
[71] The Patents Act, No. 39 of 1970 § 84 - 92 (India).
[72] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
[73] 2013 SCC OnLine IPAB 25.

compulsory licensing. It validated the Indian government's commitment to leveraging legal flexibilities in service of equitable healthcare access and underscored the pragmatic application of public health principles within the domain of IP law.

3.5. DRUG PRICE CONTROL MECHANISM (DPCO 2013)[74]:

In addition to the patent law framework, India has institutionalized affordability through the Drug Price Control Order (DPCO), issued under the Essential Commodities Act. The DPCO 2013 empowers the National Pharmaceutical Pricing Authority (NPPA)[75] to fix ceiling prices for essential medicines listed in the National List of Essential Medicines (NLEM)[76]. Unlike TRIPS, which remains silent on price regulation, India's approach to cost control is facilitated through domestic law without contravening international obligations. The methodology used under the DPCO involves market-based pricing to determine ceiling rates, thereby ensuring that price regulation is transparent and fair. The DPCO complements the patent system by ensuring that essential drugs remain cost-effective regardless of their patent status, thus expanding the scope of access beyond IP-exclusive concerns.

3.6. COMPARATIVE ANALYSIS OF TRIPS IMPLEMENTATION ACROSS JURISDICTIONS

An in-depth examination of how different jurisdictions interpret and implement the flexibilities allowed under the TRIPS Agreement reveals not only legal diversity but also the underlying priorities and policy philosophies of each state. These differences underscore the dynamic interplay between international legal obligations and national sovereignty in public health regulation. Countries like India, Brazil, Thailand, and South Africa have utilized the latitude offered under TRIPS to promote access to essential medicines, whereas countries like the United States have opted for a more protectionist stance, prioritizing innovation and intellectual property rights above affordability and access.

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[74] Drugs (Prices Control) Order, 2013, Gazette of India, Extraordinary, Part II, § 3(ii) (May 15, 2013) (India).
[75] National Pharmaceutical Pricing Auth., https://www.nppaindia.nic.in/ (India)
[76] Ministry of Health & Family Welfare, Nat'l List of Essential Medicines 2022 (India), https://main.mohfw.gov.in/sites/default/files/NLEM%202022.pdf.

TABLE 1

Country	Provision Against Evergreening	Compulsory Licensing	Parallel Imports	Price Controls	Constitutional Right to Health
India[77]	Yes	Yes	Yes	Yes	Yes
Brazil[78]	No	Yes (Extensive Usage)	Yes	Partial (Negotiated)	Yes
South Africa[79]	No	Yes (Limited, Case to Case Basis)	Yes	No	Yes
Thailand[80]	No	Yes (Broad Implementation)	Yes	Limited	No
United States	No	Rare (Primarily for government use)	No	No	No

- **India:** India has developed a legally sophisticated and multilayered strategy to ensure that its TRIPS compliance does not come at the cost of public health. Sec. 3(d) of the Patents Act prevents the patenting of incremental innovations without demonstrable enhancement in therapeutic efficacy. This provision was famously upheld in *Novartis AG v. Union of India*[81], where the Supreme Court ruled that a modification to an anti-cancer drug did not qualify for a patent. In addition, India has enacted robust compulsory licensing provisions under Sec.s 84 and 92, with the landmark *Bayer Corp. v. Natco Pharma*[82] case serving as a practical

[77] The Patents Act, No. 39 of 1970 § 3(d) (India), The Patents Act, No. 39 of 1970 § 84 (India), The Patents Act, No. 39 of 1970 § 107A(b) (India), Drugs (Prices Control) Order, 2013, Gazette of India, Extraordinary, Part II, § 3(ii) (May 15, 2013) (India), *INDIA* CONST. art.
[78] Lei No. 9.279, de 14 de Maio de 1996, arts. 68–74, Diário Oficial da União [D.O.U.] de 15.5.1996 (Braz.),Lei No. 9.279, de 14 de Maio de 1996, art. 43(IV), Diário Oficial da União [D.O.U.] de 15.5.1996 (Braz.),Lei No. 10.742, de 6 de Outubro de 2003, Diário Oficial da União [D.O.U.] de 7.10.2003 (Braz.), Constituição Federal [C.F.] [Constitution] art. 196 (Braz.).
[79] Patents Act 57 of 1978, § 56 (S. Afr.), Medicines and Related Substances Act 101 of 1965, § 15C (S. Afr.), Constitution of the Republic of South Africa, 1996, § 27 (S. Afr.).
[80] Patent Act, B.E. 2522 (1979), §§ § 36, 46–47, 51 (Thai.), Drug Act, B.E. 2510 (1967) (Thai.).
[81] (2013) 6 SCC 1.
[82] (2013) SCC OnLine IPAB 25.

demonstration. India also permits parallel imports and enforces price control mechanisms through the Drug Price Control Order (DPCO), administered by the National Pharmaceutical Pricing Authority (NPPA). Importantly, the Indian judiciary has interpreted the right to health as an implicit part of the right to life under Article 21 of the Constitution, thereby embedding public health considerations within the constitutional framework.

- **Brazil:** Brazil has historically utilized TRIPS flexibilities, particularly in the field of HIV/AIDS treatment. Though lacking a statutory provision similar to India's Sec. 3(d), Brazil has employed compulsory licensing to ensure access to life-saving medications. In 2007, Brazil issued a compulsory license for Merck's Efavirenz[83], an antiretroviral drug used in HIV treatment, citing public interest and affordability. Brazil also allows parallel imports and uses a mix of market negotiations and limited price controls to regulate drug pricing. The Brazilian Constitution guarantees health as a fundamental right, and its courts have enforced this right by mandating the state to provide essential medications to citizens, often overriding IP concerns when necessary. The Brazilian model thus blends legal activism, political resolve, and economic pragmatism.

- **South Africa:** South Africa does not have a statutory provision analogous to Sec. 3(d), but it has leveraged its constitutional right to health to advance medicine accessibility. The Constitutional Court's landmark ruling in the *Minister of Health v. Treatment Action Campaign*[84] mandated the state to provide Nevirapine to prevent mother-to-child HIV transmission, emphasizing the justiciability of socio-economic rights. While the country has provisions for compulsory licensing under its Patents Act, these have rarely been used, largely due to bureaucratic and political constraints. Parallel imports are permitted under the Medicines and Related Substances Act, but the absence of statutory price controls means that medicine affordability often depends on public procurement mechanisms. South Africa's approach underscores the power of constitutional jurisprudence to achieve public health goals despite a relatively conservative IP regime.

- **Thailand:** Thailand represents one of the boldest utilizations of TRIPS flexibilities among middle-income countries. Between 2006 and 2008, Thailand issued several compulsory licenses for both antiretroviral and non-communicable disease (NCD) drugs, including

[83] Maurice Cassier, Marilena Correa. Nationalizing efavirenz : compulsory licence, collective invention and neo–developmentalism in Brazil. Cassier Maurice, Correa Marilena. Health Innovation and Social Justice in Brazil, Palgrave Macmillan, p 59-90, 2019, 978-3-319-76833-5. ff10.1007/978-3-319-76834-2_3ff. ffhalshs-03975575

[84] 2002 (5) SA 721 (CC) (S. Afr.).

treatments for heart disease and cancer. These licenses were issued unilaterally, often under the justification of national emergency or public non-commercial use, both permissible under Article 31 of TRIPS. Thailand does not have a Sec. 3(d)-like provision but permits parallel imports and has limited drug price regulation through its Universal Coverage Scheme. Although the Thai Constitution does not explicitly recognize a right to health, government policy and administrative action have consistently prioritized healthcare access. Despite facing international pressure and threats of trade retaliation, Thailand has persisted in its pro-access policies, demonstrating political will and administrative efficiency.

- **United States of America:** The United States exemplifies the most protectionist model among the examined jurisdictions. It lacks any provision similar to Sec. 3(d) and has not meaningfully employed compulsory licensing, except for limited cases under Government Patent Use Law[85], which allows the federal government to use patented inventions without permission, subject to reasonable compensation. The U.S. does not permit parallel imports and has no national drug price control mechanism. Moreover, the U.S. Constitution does not enshrine a right to health, and healthcare remains largely market driven. As a result, the U.S. pharmaceutical sector is characterized by high prices, extensive patent portfolios, and frequent strategic patenting, often criticized as evergreening. The dominance of private stakeholders and the influence of pharmaceutical lobbying significantly shape policy, constraining legislative or administrative flexibility in applying TRIPS flexibilities. This comparative analysis reveals a continuum of TRIPS implementation strategies, ranging from access-focused regimes (India, Thailand, Brazil) to IP-maximalist models (United States). South Africa's reliance on constitutional jurisprudence highlights another path: achieving public health goals through fundamental rights enforcement. India's model, combining legislative innovation, judicial activism, and regulatory enforcement, emerges as a particularly instructive case study for developing countries navigating the intersection. of public health and IP obligations under TRIPS.

3.7. JUDICIAL INTERPRETATION AND CONSTITUTIONAL FRAMING

Judicial intervention in India has played a transformative role in redefining the contours of pharmaceutical access. The Indian judiciary has consistently interpreted the right to health as an integral component of the right to life under Article 21 of the Constitution of India. This

[85] 28 U.S.C. § 1498

jurisprudential orientation is evident in cases such as *Mohd. Ahmed v. Union of India*[86], where the Delhi High Court directed the state to provide free treatment for a rare disease to a minor child, emphasizing that economic considerations could not override constitutional rights. This alignment of statutory law with constitutional principles strengthens the legal infrastructure for public health. It creates a normative hierarchy wherein the right to health assumes precedence, thereby legitimizing statutory innovations like Sec. 3(d) and compulsory licensing within a broader constitutional framework.

3.8. POLICY SYNERGY: MULTI-LAW FRAMEWORK FOR ACCESS

India's legal architecture is characterized by a unique synergy among various statutes that collectively promote access to medicines:

TABLE 2

Law/Policy	Purpose	Relevance to TRIPS Compliance
Patents Act, 1970[87]	Regulates Patents and Licensing	Enables use of Arts. 7 and 8 of Doha Flexibities
Drug Price Control Order, 2013[88]	Caps Essential Drug Prices	Aligns with TRIPS Neutrality on Pricing
Competition Act, 2002[89]	Prevents Abuse of Dominance	Reinforces Fair Market Practices
National IPR Policy, 2016[90]	Promotes Innovations and Public Health	Operationalize TRIPS in a development context

This intersectional regulatory approach enables India to address pharmaceutical access from multiple legal and policy angles, without breaching TRIPS commitments.

3.9. DOHA DECLARATION AS A JURIDICAL JUSTIFICATION

[86] (2014) SCC OnLine Del 1508
[87] The Patents Act, No. 39 of 1970 (India).
[88] Drugs (Prices Control) Order, 2013, S.O. 1221(E), Gazette of India, Extraordinary, Part II, Sec. 3(i), May 15, 2013 (India).
[89] The Competition Act, No. 12 of 2003 (India).
[90] National Intellectual Property Rights Policy, Ministry of Commerce & Industry, Government of India, May 12, 2016 (India).

The 2001 Doha Declaration on the TRIPS Agreement and Public Health[91] was a pivotal moment in the evolution of international IP law, reaffirming the right of WTO member states to prioritize public health in the interpretation and implementation of TRIPS. Emerging from sustained pressure by developing countries and global health advocates, the Declaration explicitly clarified that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health." India has relied heavily on the Doha Declaration to justify its domestic legal innovations, particularly in response to criticisms from developed countries and multinational pharmaceutical corporations. The Declaration affirms member states' sovereign right to determine the grounds for compulsory licensing and to define what constitutes a national emergency or other circumstances of extreme urgency. This language provides critical legal space for states to craft their own definitions of public health priorities without requiring external validation. In the Indian context, the Declaration has served as a doctrinal shield for key provisions such as Sec. 84 (compulsory licensing) and Sec. 3(d) (anti-evergreening clause). For instance, India's issuance of its first compulsory license in *Bayer Corp. v. Natco Pharma Ltd.*[92] was strongly supported by the Doha framework. Similarly, the Supreme Court's validation of Sec. 3(d) in *Novartis AG v. Union of India*[93] implicitly aligns with the spirit of Doha in rejecting unwarranted patent monopolies that do not enhance therapeutic efficacy. Internationally, India has invoked the Doha Declaration at WTO Trade Policy Reviews and during bilateral trade negotiations to affirm that its patent law complies with TRIPS while advancing public health goals. This approach reinforces the Declaration as not just a political commitment but also a juridical tool with tangible interpretive value for national courts and regulatory bodies.

3.10. CHALLENGES AND CRITICISMS

Despite India's legally coherent and TRIPS-compliant pharmaceutical IP regime, it faces sustained external and internal pressures that test the resilience of its access-oriented model.

- **Bilateral Trade Negotiation Pressures:** India has consistently faced pressure from trading partners, particularly in the context of Free Trade Agreements (FTAs) with the European Union and the United States. These negotiations often include demands for "TRIPS-plus" provisions such as data exclusivity, patent linkage, and longer patent terms—measures that go beyond TRIPS obligations and risk undermining India's ability to facilitate generic drug

[91] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).
[92] (2013) SCC OnLine IPAB 25.
[93] (2013) 6 SCC 1.

entry. Acceptance of such provisions would severely constrain the use of compulsory licensing and render Sec. 3(d) ineffective.

- **USTR Special 301 Reports[94]:** The United States Trade Representative (USTR) routinely places India on its "Priority Watch List" in the annual Special 301 Report. This designation accuses India of maintaining an inadequate IP enforcement regime, with Sec. 3(d) and compulsory licensing cited as major concerns. Although non-binding, these reports carry significant diplomatic weight and are often used to justify pressure tactics, including suspension of trade preferences or invoking dispute resolution mechanisms.

- **Corporate Lobbying by Multinational Pharmaceutical Firms:** Big pharmaceutical companies operating in India and globally have lobbied aggressively against Sec. 3(d)[95], arguing that it stifles innovation and undermines incentives for research and development. These arguments overlook the fact that the provision targets only trivial innovations and allows for patents where true therapeutic efficacy is demonstrated. Nonetheless, such lobbying has led to periodic attempts to amend or dilute the provision through policy and legislative channels.

- **Under utilization of Compulsory Licensing:** Despite its legal availability, compulsory licensing remains underused in India, with only one license granted to date through *Bayer Corp. v. Natco Pharma*[96]. This reluctance stems from geopolitical considerations, fear of trade reprisals, and bureaucratic inertia. As a result, many life-saving drugs remain out of the price reach for the average patient, and the full potential of India's legal safeguards remains unrealized.

- **Judicial and Administrative Capacity Constraints:** The interpretation and implementation of TRIPS flexibilities require not only a robust legal framework but also well-resourced institutions. Challenges such as prolonged litigation timelines, limited technical expertise among patent examiners, and inconsistent enforcement mechanisms often dilute the effectiveness of otherwise strong laws.

These challenges highlight the ongoing tension between global IP regimes and domestic public health imperatives. While India's legal architecture is a model of TRIPS-compliant innovation, it demands continuous legal vigilance, political commitment, and policy innovation. To preserve

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[94] Office of the United States Trade Representative, 2023 Special 301 Report (Apr. 2023), https://ustr.gov/sites/default/files/2023-04/2023%20Special%20301%20Report.pdf.
[95] The Patents Act, No. 39 of 1970 § 3(d) (India)
[96] (2013) SCC OnLine IPAB 25.

its integrity and effectiveness, India must resist external pressures to adopt TRIPS-plus obligations, strengthen domestic enforcement of existing flexibilities, and invest in institutional capacity-building to support a health-equity driven IP regime.

3.11. REGIONAL INFLUENCE AND POLICY DIFFUSION: INDIA AS A NORM ENTREPRENEUR IN GLOBAL IP GOVERNANCE

India's pharmaceutical intellectual property (IP) regime stands as a paradigmatic example of how a developing country can assert sovereignty over public health interests within the confines of global trade law. Through strategic legislative design, assertive diplomatic engagement, and jurisprudential innovation, India has not only safeguarded domestic access to cost-effective medicines but also emerged as a norm entrepreneur—actively shaping regional and global policy trajectories in IP law. India's influence is particularly potent across the Global South, where nations face similar structural vulnerabilities—resource constraints, high disease burdens, and dependency on external pharmaceutical supply chains. India's legislative and judicial actions have therefore served as precedent-setting templates for countries attempting to reconcile TRIPS compliance with constitutional obligations to health and equity.

Key Vectors of India's Influence:

1. Legislative Borrowing and Legal Transplantation: Sec. 3(d) of India's Patents Act, which restricts patentability of new forms of known substances without enhanced efficacy, has become a benchmark clause in anti-evergreening efforts globally. Countries like the Philippines, Malaysia, and Indonesia have explored or enacted similar provisions, influenced either directly by Indian jurisprudence or indirectly via regional policy dialogues and south-south legal assistance forums. These provisions help re-calibrate the balance between innovation incentives and affordability, especially in markets dominated by generic medicines.

2. Compulsory Licensing as Strategic Precedent: India's 2012 issuance of a compulsory license in the *Bayer Corp. v. Natco Pharma*[97] case set a global standard for the use of TRIPS flexibilities under Article 31. This landmark case was not only legally significant but symbolically powerful, showcasing that middle-income countries can legally override patents for public interest. Following this, Brazil (Efavirenz) and Thailand (heart and cancer

[97] (2013) SCC OnLine IPAB 25.

drugs) invoked similar grounds to issue compulsory licenses, citing public health emergencies and economic unaffordability.

3. Judicial Diffusion and Constitutional Law Framing: Indian courts, particularly the Supreme Court and High Courts, have embedded access to medicines within the broader framework of the Right to Life (Article 21). These judgments are increasingly referenced in South African, Kenyan, and Philippine legal systems, especially in litigation concerning HIV/AIDS, where courts have to balance IP enforcement with socio-economic rights. The South African Treatment Action Campaign (TAC) case[98], while independently grounded in its post-Apartheid constitutional order, found intellectual resonance in India's approach to health as a justiciable right.

4. Coalition Building and Global Discourse Shaping: At multilateral forums like the WTO, WHO, and WIPO, India—often in coalition with countries like Brazil, South Africa, and Argentina—has resisted TRIPS-plus provisions in bilateral and plurilateral agreements. India's role in the Doha Declaration on TRIPS and Public Health (2001) was instrumental in reaffirming countries' rights to protect public health and prioritize access to medicines. This advocacy catalyzed the formation of regional blocs (e.g., ASEAN IP working groups) that now incorporate health-sensitive IP strategies in their regional negotiations.

5. Operational Tools and Technical Assistance: Indian legal scholars, civil society actors, and government advisers have actively provided technical assistance to other developing nations drafting IP laws, particularly through the South Centre, UNDP, and WHO mechanisms.India's pharmaceutical NGOs and think tanks (e.g., Lawyers Collective, MSF India, Third World Network) play a silent but powerful role in transnational legal mobilization.

India's experience demonstrates that public health-sensitive IP governance is not only possible but also exportable, adaptable, and replicable. It has fostered a transnational epistemic community committed to access, affordability, and accountability.

3.12. LEGAL AND POLICY IMPACT: COMPARATIVE DISCOURSE

a. *India:*

i. Sec. 3(d), Patents Act 1970: This legislative reform redefined the concept of patentable subject matter for pharmaceuticals by introducing a higher threshold for patentability. Sec.

[98] Minister of Health v. Treatment Action Campaign [2002] ZACC 15; 2002 (10) BCLR 1033 (CC) (S. Afr.).

3(d) explicitly rejected patents on new forms of known substances unless they significantly enhanced therapeutic efficacy. The clause was strategically drafted to prevent "evergreening," a tactic used by pharmaceutical firms to extend patent monopolies through minor modifications. The provision gained international attention after its central role in the Novartis v. Union of India case, where the Supreme Court upheld its constitutionality. Beyond domestic effect, it has influenced policy discussions across ASEAN and formed the basis for academic and UN discourse on TRIPS flexibilities.

ii. Compulsory Licensing vide *Bayer Corp. v. Natco Pharma*[99]: India's first compulsory license issued for the anti-cancer drug Sorafenib tosylate was a landmark moment in applying Sec. 84 of the Patents Act. It highlighted India's willingness to operationalize economic and public health considerations, particularly pricing and local working requirements, as legal justifications. The decision reinforced India's sovereign right to define grounds for licensing under TRIPS. Importantly, the case triggered policy discussions in Brazil and Colombia about revisiting their own local working provisions and pricing regulations.

b. *Brazil (Compulsory License for Efavirenz)*: In response to high prices for the antiretroviral drug Efavirenz, Brazil issued a compulsory license and partnered with Indian generic manufacturers to ensure cost-effective supply. The move reflected a dual strategy—leveraging CLs while also promoting technology transfer and local manufacturing. This case was pivotal in redefining the narrative around CLs as economic tools rather than emergency-only responses. It demonstrated that CLs could be part of a broader industrial policy aimed at enhancing domestic pharmaceutical capacity.

c. *Thailand (Compulsory Licenses for Heart and Cancer Drugs)*: Thailand's issuance of compulsory licenses for drugs treating non-communicable diseases (Plavix for cardiovascular conditions and Kaletra for HIV) expanded the scope of TRIPS flexibilities beyond infectious diseases. This proactive use of CLs under conditions of national urgency drew sharp criticism from pharmaceutical companies and the USTR, which placed Thailand on its Special 301 Report watch list. Nevertheless, the Thai government defended its actions using the Doha Declaration framework. The licenses became a global reference for countries seeking to justify broader use of CLs under TRIPS.

[99] (2013) SCC OnLine IPAB 25.

d. *South Africa (Treatment Action Campaign v. Minister of Health[100]):* This case marked a milestone in judicial enforcement of health rights. The Constitutional Court ordered the South African government to provide Nevirapine, an antiretroviral drug, to prevent mother-to-child transmission of HIV. The court grounded its reasoning in the constitutional right to access healthcare services. The ruling became foundational for rights-based litigation in the context of pharmaceutical access, not only in South Africa but also in countries like India, where similar arguments were made in *Swasthya Adhikar Manch v. Union of India*[101]. This case is a critical example of how judicial activism can shape executive health policy and inspire regional constitutional litigation strategies.

Together, these cases and reforms reveal a rich tapestry of legal, political, and institutional strategies designed to prioritize public health over narrow commercial interests. The interactions between them—whether through legislative modeling, jurisprudential citation, or diplomatic alignment—have created a transnational legal movement that reimagines IP law as a tool of public health justice.

3.13. STRATEGIC REFORMS TO SUSTAIN AND GLOBALIZE INDIA'S ACCESS-ORIENTED PHARMACEUTICAL IP REGIME

India's pharmaceutical IP framework, shaped by a unique blend of statutory innovation, constitutional jurisprudence, and administrative regulation, presents a model that resists the monopolistic tendencies of global IP norms. However, sustaining and exporting this model requires a future-ready legal strategy that integrates domestic capacity-building with global norm-setting. The four pillars outlined in this Sec. are interdependent dimensions of such a strategy. Below is a comprehensive, clause-by-clause breakdown of each recommendation.

1. Codify Judicial Interpretations of Article 21 in Statutory Law:

a. *Legal Rationale:* Art. 21 of the Indian Constitution, which guarantees the right to life and personal liberty, has been judicially interpreted to include the right to health and access to essential medicines. This interpretation, while transformative, remains within the realm of judge-made law. The absence of statutory recognition weakens enforceability and leaves the right vulnerable to judicial variability. In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[102], the Supreme Court established that the failure of a state hospital to provide

[100] Minister of Health v. Treatment Action Campaign [2002] ZACC 15; 2002 (10) BCLR 1033 (CC) (S. Afr.).
[101] W.P.(C) No. 33 of 2012, (S.C.) (India).
[102] (1996) 4 SCC 37.

timely emergency treatment violated Art. 21. In *Mohd. Ahmed v. Union of India*[103], the Delhi High Court ruled that expensive drugs for rare diseases must be provided free of cost, grounding this obligation in the constitutional right to life.

b. *Implementation Pathway:* A codified Right to Health and Medicines Act could:

i. Explicitly recognize access to essential medicines as a legal entitlement.

ii. Provide statutory definitions of "essential," "cost-effective/cheap," and "lifesaving" medicines.

iii. Mandate universal public procurement and distribution for NLEM drugs.

iv. Require budgetary allocations and enable individuals to initiate legal action for denial of medicines.

c. *Interpretation and Normative Significance:* Codification would stabilize jurisprudential gains and prevent political dilution of judicial mandates. It would elevate access to medicines from a policy commitment to a constitutionalized statutory right, enabling predictable litigation, budgeting, and administrative compliance. Internationally, it would insulate India's legal stance against TRIPS-plus pressures by embedding public health exceptions in national law.

2. Enhance Technical and Administrative Capacities of IP and Pricing Authorities:

a. *Legal and Institutional Rationale:* The effectiveness of access-oriented IP laws depends on the quality, speed, and coordination of institutions that administer them. Sec. 3(d), compulsory licensing (Sec. 84), and the DPCO are only as effective as the authorities—Patent Office, NPPA, CDSCO—that interpret and enforce them.

b. *Structural Challenges Identified:* The following points are identified to be the major issues that are present for rectification:

- Inconsistent application of Sec. 3(d) by understaffed or undertrained patent examiners.[104]
- Weak market intelligence and enforcement capabilities within the NPPA.[105]

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[103] (2014) SCC OnLine Del 1508.
[104] *See* Shamnad Basheer & Prashant Reddy, Ironing out the Creases in Sec. 3(d), 5 SCRIPTed 2 (2008), https://script-ed.org/wp-content/uploads/2016/07/5-2-BasheerReddy.pdf.
[105] *See* Department of Pharmaceuticals, Guidelines for Consumer Awareness, Publicity and Price Monitoring (CAPPM), https://pharma-dept.gov.in/sites/default/files/CAPPM%20-%20Guidekubes-current.pdf.

- Absence of synergy between pricing, patent, and public health authorities, leading to policy fragmentation.[106]
- Lack of specialized judicial forums after the abolition of the IPAB.[107]

c. Implementation Framework:

- IP Reforms: Recruit life sciences specialists; provide ongoing technical training; introduce AI-based patent analytics to detect evergreening.
- NPPA Reforms: Create a National Drug Pricing Intelligence Network integrating real-time market data, GST records, and manufacturer pricing reports.
- Regulatory Coordination: Form a National Regulatory Convergence Task Force with representatives from IPO, NPPA, CDSCO, and the Ministry of Health to issue joint directives on pricing, patentability, and licensing of critical drugs.
- Judicial Infrastructure: Create IP benches in High Courts with scientific consultants and procedural fast-tracks for access-related litigation.

d. Interpretation and Normative Significance: This reform pillar translates legal doctrine into institutional practice. Without functional convergence and technical capacity, even the most progressive laws fail in implementation. Strengthening these bodies ensures that access is not just a legal principle but a governance reality, where institutions act as agents of health equity. The legitimacy of India's model also increases when the world sees it functioning effectively at home.

3. Forster South-South Legal Cooperation to Disseminate Access-Friendly Models:

a. Geopolitical and Legal Rationale: The Global South faces similar public health burdens and pharmaceutical access constraints. India's IP model, backed by WTO-compliant safeguards, offers a viable legal template. South-South cooperation would allow India to export its normative leadership and consolidate a global network that resists TRIPS-plus policies and pharmaceutical monopolies.

b. Legal Pathways for Cooperation:

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[106] *See* Shalini Bhutani, Striking a Balance Between Patent Laws and Public Health Issues with Special Emphasis on Its Recognition in India, Int'l J. Legal & Mgmt. Human. (2020), https://ijlmh.com/paper/striking-a-balance-between-patent-laws-and-public-health-issues-with-special-emphasis-on-its-recognition-in-india/.
[107] *See* Prashant Reddy, The End of the IPAB and Lessons on Concentration of Judicial Powers, SpicyIP (Sept. 2021), https://spicyip.com/2021/09/the-end-of-the-ipab-and-lessons-on-concentration-of-judicial-powers.html.

- Model Law Dissemination: Provide legislative blueprints of Sec. 3(d)-type provisions, compulsory licensing frameworks, and DPCO mechanisms.
- Capacity Building: Partner with BRICS, SAARC, ASEAN, and the African Union to train regulators, judges, and policymakers in TRIPS flexibilities.
- Judicial Diplomacy: Host judicial colloquia and exchange programs on IP and access law; share precedent databases and analytical toolkits.
- Multilateral Alignment: Build collective platforms within WTO, WHO, WIPO, and the South Centre to propose, defend, and mainstream pro-access IP norms.

c. *Interpretation and Normative Significance:* This pillar turns India's defensive legal innovations into offensive soft power. It positions India not just as a domestic success story but as a source of legal knowledge and solidarity for the Global South. By helping others adopt similar laws, India also creates a global support system to resist trade-based coercion and set the agenda for inclusive IP governance.

4. Engage Proactively in WTO Dialogues on TRIPS Reform, especially concerning Pandemic Preparedness:

a. *Doctrinal Rationale:* TRIPS, while offering flexibilities, is still largely structured around protecting innovation rather than ensuring equitable access. The COVID-19 crisis made clear the urgent need for systemic reform, particularly for expedited IP waivers and technology transfer during health emergencies.

b. *Legal Reforms India must pursue:*

- TRIPS Amendment Proposal: Introduce a "Health Emergency Waiver Protocol" that triggers automatic suspension of exclusive rights during WHO-declared pandemics.
- TRIPS Council Representation: Create a permanent Indian delegation of lawyers, public health experts, and trade negotiators to advocate public health-centric TRIPS interpretations.
- Link with SDGs and Human Rights: Bring in IP reform as essential for SDG 3 (health for all), SDG 10 (reduced inequalities), and the ICESCR.

c. *Evidence Based Advocacy:* India should fund cross-disciplinary research documenting how IP laws affect drug availability and affordability during crises. This includes:

- Global mapping of compulsory licenses issued during pandemics.

- Comparative studies on vaccine nationalism and IP hoarding.
- Economic simulations showing the costs of delayed TRIPS waivers.

d. *Interpretation and Normative Significance:* India must transition from a crisis-responsive actor to a rule-making power. This pillar is about writing the next chapter of TRIPS, one that integrates public health as a primary objective, not a footnote. It also affirms India's status as a moral leader in international law, willing to advance global equity over narrow national interests.

e. *Synthesis - A Blueprint for Legal Leadership in Global Health Governance:* Together, these four pillars offer India a blueprint for a holistic, legally sound, and ethically grounded pharmaceutical access regime. They move from legal recognition (1), to administrative realization (2), global diffusion (3), and structural reform (4). This layered approach ensures that India's access-to-medicine commitments are not only defensible in law but actionable in policy and inspirational in diplomacy. By pursuing these reforms, India can anchor its access philosophy in law, operationalize it through institutions, project it across borders, and enshrine it in global treaties—thus cementing its role as a global legal architect of equitable health governance.

India's legal regime illustrates that domestic IP law can be designed to serve both international obligations and local health needs. Through statutory innovations, constitutional interpretation, and strategic policy alignment, India has operationalized TRIPS flexibilities not merely as defensive tools but as proactive instruments of health justice. This approach offers a replicable model for developing countries seeking to balance patent protection with equitable access to medicines.

CHAPTER - 4: WAY FORWARD: STRENGTHENING INDIA'S ACCESS-ORIENTED PATENT REGIME

This chapter examines how India can further strengthen its access-oriented patent regime while maintaining compliance with TRIPS obligations, analyzing the effectiveness of existing flexibilities and proposing enhanced mechanisms for ensuring medicine affordability in the post-TRIPS era.

4.1. UNDERSTANDING TRIPS FLEXIBILITIES IN THE INDIAN CONTEXT

India's strategic implementation of TRIPS flexibilities represents a sophisticated approach to balancing intellectual property protection with public health imperatives. The country's patent regime demonstrates how developing nations can utilize the inherent flexibilities within the TRIPS framework to maintain access to essential medicines while fulfilling international trade obligations. The most significant of these flexibilities—including compulsory licensing, parallel importation, and stringent patentability criteria—have become cornerstones of India's access-oriented patent policy.

The effectiveness of these flexibilities, however, depends largely on their practical implementation and the political will to invoke them when necessary. India's experience with compulsory licensing, particularly the landmark *Bayer Corporation v. Natco Pharma*[108] case involving Sorafenib (Nexavar), illustrates both the potential and limitations of these mechanisms. While the compulsory license successfully reduced the drug's price from approximately ₹280,000 per month to ₹8,800 per month, representing a 97% price reduction, the pharmaceutical industry's resistance and subsequent diplomatic pressure highlight the challenges faced when implementing such measures.

The doctrine of international exhaustion, as permitted under Article 6 of TRIPS[109], offers another avenue for enhancing medicine affordability through parallel importation. This flexibility allows countries to import patented medicines from markets where they are sold at lower prices, effectively circumventing the price discrimination strategies employed by multinational pharmaceutical companies. India's adoption of this principle could significantly expand access to

[108] (2013) SCC OnLine IPAB 25.
[109] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 6, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

essential medicines, particularly for treatments where domestic generic alternatives are not available due to patent protection.

4.2. SEC. 3(d) AS A PUBLIC HEALTH SAFEGUARD

Sec. 3(d) of the Indian Patents Act, 1970, introduced through the 2005 amendment to comply with the TRIPS Agreement, represents a globally significant legal mechanism to balance pharmaceutical innovation with access to medicines. It restricts the patentability of new forms of known substances unless they demonstrate enhanced therapeutic efficacy, effectively curbing evergreening—the practice of making minor changes to extend patent life.

The landmark Novartis AG v. Union of India[110] judgment by the Supreme Court upheld the constitutionality and intent of Sec. 3(d), providing a robust judicial endorsement of India's access-oriented patent policy. To ensure the continued success and integrity of this provision, the following strategies and dimensions are critical:

1. ***Operationalizing Sec. 3(d) through Detailed Patent Office Guidelines***[111]*:*

a. Therapeutic Efficacy Standardization: Develop and periodically update technical manuals for patent examiners that:

- Define "enhanced therapeutic efficacy" with reference to clinical trial data.
- Differentiate pharmacokinetic improvements (e.g., increased solubility) from genuine therapeutic outcomes (e.g., improved survival rates or symptom reduction).

b. Sector-Specific Protocols: Tailor guidelines for different therapeutic areas (e.g., oncology, antivirals, rare diseases) where efficacy standards may vary.

The cited article provides insights into the evidentiary requirements and strategies for demonstrating enhanced therapeutic efficacy to overcome objections under Sec. 3(d).

2. ***Strengthening Examiner Training and Capacity***[112]*:*

- Clinical Literacy: Provide regular training for patent examiners in pharmacology, clinical trials methodology, and health outcomes research to ensure informed evaluations of efficacy claims.

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[110] (2013) 6 SCC 1.
[111] *How to Overcome Sec. 3(d) Objections?*, Stratjuris Law Partners (Dec. 2024), https://stratjuris.com/how-to-overcome-Sec.-3d-objections/.
[112] *Indian Pharmaceutical Patent Prosecution: The Changing Role of Sec. 3(d)*, DrugPatentWatch (2018), https://www.drugpatentwatch.com/blog/indian-pharmaceutical-patent-prosecution-the-changing-role-of-Sec.-3d/.

- Inter-agency Collaboration: Encourage coordination between the Indian Patent Office and public health bodies like CDSCO to validate therapeutic benefit claims.

The cited piece discusses the evolving interpretation of Sec. 3(d) and underscores the importance of examiner expertise in assessing therapeutic efficacy claims.

3. ***Ensuring Judicial Support and Consistency:***

a. Doctrine of Precedent: Promote consistent application of *Novartis AG v. Union of India*[113] by all levels of the Indian judiciary through:

- Judicial training on IP and access to medicines.
- Compilation and publication of key decisions applying Sec. 3(d).

b. Amicus Participation: Encourage courts to allow civil society or expert amici to assist in cases concerning 3(d), ensuring broader public health perspectives are considered.

4. ***International Defense and Legal Diplomacy***[114]***:***

a. TRIPS Compatibility Advocacy: Publicize India's legal rationale for Sec. 3(d) at WTO and WIPO forums, emphasizing:

- Compliance with TRIPS Article 27 (which allows members to define patentability criteria).
- Support from Doha Declaration on TRIPS and Public Health (2001) affirming countries' rights to prioritize access.

b. Investor-State Dispute Preparedness: Equip trade and legal negotiators to resist pressures from BITs (bilateral investment treaties) that threaten Sec. 3(d), with pre-drafted legal defenses based on:

- Legitimate public health exceptions.
- Narrow scope of patent rights in the investment definition.

The press release cited addresses international pressures on India's patent laws and the country's stance on maintaining its public health safeguards.

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[113] (2013) 6 SCC 1.

[114] *US Opposition to Sec. 3(D) of the Indian Patent Act*, Press Information Bureau, Government of India (May 2014), https://www.pib.gov.in/newsite/printrelease.aspx?relid=107612.

5. ***Global Influence and Norm Diffusion***[115]*:*

a. Model for Other Countries: Promote adoption of similar provisions in other developing countries (e.g., South Africa) by:

- Sharing best practices through South-South cooperation.
- Hosting regional patent examiner workshops on anti-evergreening.

b. WHO & UN Endorsements: Collaborate with WHO, UNDP, and UNAIDS to recognize Sec. 3(d) as a model for aligning innovation policy with human rights and access to medicines.

The cited article analyzes the global implications of India's patent model and its influence on other developing nations.

6. ***Monitoring and Public Transparency***[116]*:*

- Patent Application Database: Maintain and publicly update a searchable database of applications rejected under Sec. 3(d), including reasoning and supporting data.
- Civil Society Watchdogs: Encourage NGOs and patient groups to actively monitor high-profile pharmaceutical patent filings and intervene where evergreening is suspected.

The cited article emphasizes the necessity for transparency and clarity in patent examination processes under Sec. 3(d).

7. ***Incentivizing True Innovation***[117]*:*

- Fast-Track Review for Breakthroughs: Create a parallel track to fast-track patent examination for drugs that meet significant therapeutic benchmarks or address unmet medical needs.
- Innovation Support Grants: Establish government incentives (e.g., grants, tax breaks) for pharmaceutical R&D aimed at first-in-class or public health-oriented therapies.

The cited article discusses the distinction between bioavailability and therapeautic efficacy, highlighting the crtieria for genuine pharma innovations.

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[115] *India's Distinct but Opposing Patent Model Is Under Pressure*, SAGE Journals (2023), https://journals.sagepub.com/doi/10.1177/09749284231225835.
[116] *Indian Patent Office Must Identify the Known Substance to Objectify the Claimed Compound Under Sec. 3(d)*, K&S Partners (2022), https://kankrishme.com/indian-patent-office-must-identify-the-known-substance-to-objectify-the-claimed-compound-under-Sec.-3d-ds-biopharma-limited-v-the-controller-of-patents-and-designs/.
[117] *Reaffirming Standards: Bioavailability v. Therapeutic Efficacy and the Novartis Case*, Lakshmikumaran & Sridharan Attorneys (2024), https://lakshmisri.com/insights/articles/reaffirming-standards/.

8. ***Academic and Legal Research Support***[118]*:*

a. Evidence-Based Evaluations: Fund legal and empirical research to:

- Measure the health and economic impact of Sec. 3(d) on drug prices and availability.
- Quantify how many evergreening patents were prevented and the resulting access gains.

This cited article provides an in-depth analysis of the Novartis case and its implications for patent law and public health.

b. Interdisciplinary Collaboration: Encourage cooperation between legal scholars, economists, and public health experts to refine interpretations of "efficacy" in the public interest.

9. ***Resilience against Political and Trade Pressure***[119]*:*

a. Trade Policy Coherence: Align India's pharmaceutical trade strategy with its domestic public health priorities by:

- Refusing FTAs or BITs that contain TRIPS-plus provisions on patentability.
- Building coalitions with similarly situated countries to resist such pressures collectively.

b. Cross-Ministerial Coordination: Ensure the Health Ministry, MEA, and Department for Promotion of Industry and Internal Trade (DPIIT) coordinate in trade negotiations affecting Sec. 3(d).

The cited editorial discusses the international challenges faced by India's patent laws and the importance of maintaining provisions like Sec. 3(d) for public health.

Sec. 3(d) is not merely a legislative clause—it is a public health safeguard and a constitutional articulation of social justice within the patent framework. In preserving its scope and strengthening its enforcement, India upholds its commitment to affordable healthcare while promoting responsible innovation. As global debates around evergreening and access to medicines intensify, Sec. 3(d) offers a principled model for patent law that genuinely serves human welfare.

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[118] *Novartis AG v. Union of India: "Evergreening," TRIPS, and "Enhanced Efficacy" Under Sec. 3(d)*, Journal of Intellectual Property Law & Practice (2022), https://jipl.scholasticahq.com/article/70768-novartis-ag-v-union-of-india-evergreening-trips-and-enhanced-efficacy-under-Sec.-3-d/attachment/147752.pdf.

[119] *India's Patent Laws Under Pressure*, The Lancet (2012), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)61513-X/fulltext.

4.3. ENHANCING COMPULSORY LICENSING MECHANISMS

While India's legal framework under Sec. 84 of the Patents Act, 1970 allows the issuance of compulsory licenses (CLs) in circumstances of unaffordable pricing, unmet public health needs, or non-working of the patent in India, the practical use of this powerful TRIPS-compliant tool has been sparse. Only one CL has been granted to date vide the *Bayer Corp. v. Natco Pharma*[120], despite ongoing public health challenges.

To transform the compulsory licensing mechanism into an effective instrument for access, India must confront the procedural, diplomatic, and interpretive barriers that limit its use. Below are actionable sub-points expanding on this need:

1. ***Clarifying and Streamlining Procedural Requirements***[121]***:***

- Simplified Filing Procedure: Reduce procedural complexity by developing standardized templates and forms for CL applications.
- Time-Bound Processing: Set clear statutory deadlines for each stage of the CL review process, with timelines for patent holder responses, evidentiary submission, and final adjudication.
- Delegated Authority: Consider enabling an expert public health body (e.g., National Health Authority or CDSCO) to recommend or fast-track CLs based on urgent public needs.

The article cited discusses the procedural aspects of compulsory licensing in India, highlighting the need for simplification to enhance accessibility and efficiency.

2. ***Defnining "Reasonable Requirements of the Public" and "Reasonable Pricing"***[122]***:***

a. Model Guidelines: Issue official interpretive guidelines that define "reasonable requirements of the public" based on metrics such as:

- Disease prevalence and unmet treatment coverage
- Supply shortages or regional availability gaps
- Delays in local launch post-patent grant

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[120] (2013) SCC OnLine IPAB 25.
[121] *Grant of Compulsory License in India: Its Provisions and Need in Several Industries in India*, IIPRD (Mar. 2024), https://www.iiprd.com/grant-of-compulsory-license-in-india-its-provisions-and-need-in-several-industries-in-india/
[122] *Compulsory Licensing in India: Natco vs Bayer Case Impact in India*, Indian Journal of Integrated Research in Law, Vol. III, Issue VI, at 327 (2023), https://ijirl.com/wp-content/uploads/2023/12/COMPULSORY-LICENSING-IN-INDI-NATCO-VS-BAYER-CASE-IMPACT-IN-INDIA.pdf.

b. Affordable Pricing Benchmarks: Establish affordability thresholds based on:

- Per capita income
- Cost-effectiveness analyses
- Comparison with international reference prices (e.g., WHO price databases)

This paper analyzes the *Bayer Corp. v. Natco Pharma*[123] case, providing insights into the interpretation of "reasonable requirements" and "reasonably affordable price" under Sec. 84 of the Patents Act.

3. *Institutionalizing a Proactive Compulsory Licensing Policy*[124]*:*

a. Trigger-Based Licensing: Introduce statutory automatic triggers for initiating CL proceedings when:

- The price of a patented drug exceeds a fixed affordability index
- The medicine is not available in the market within 12–24 months of patent grant
- The medicine is not registered or filed for regulatory approval despite existing demand

b. Therapeutic Class Licensing: Empower the Patent Office or Health Ministry to issue class-wide CLs for entire categories (e.g., oncology, antiretrovirals) during public health crises.

The cited report advocates for a proactive approach to compulsory licensing, suggesting automatic triggers based on pricing thresholds and public health needs.

4. *Enhancing Transparency and Stakeholder Participation*[125]*:*

a. Public Participation Mechanism: Allow health NGOs, civil society groups, and public health researchers to file amicus briefs or participate in CL hearings.

b. Annual CL Report: Publish an annual report by the Indian Patent Office detailing:

- Number of applications received, granted, or rejected
- Reasons for rejection

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[123] (2013) SCC OnLine IPAB 25.
[124] *Expanding Frontiers for Compulsory Licensing*, Health GAP (Mar. 2024), https://healthgap.org/wp-content/uploads/2024/03/Expanding-frontiers-for-compulsory-licensing.pdf.
[125] *Compulsory Licensing in India: A Legal Framework for Balancing Patent Rights and Public Needs*, IIPRD (May 2025), https://www.iiprd.com/compulsory-licensing-in-india-a-legal-framework-for-balancing-patent-rights-and-public-needs/.

- Pricing and access outcomes of granted CLs

The cited article emphasizes the importance of transparency and stakeholder engagement in the compulsory licensing process to ensure that public health considerations are adequately addressed.

5. ***Addressing Cumulative and Blocking Patents***[126]***:***

- Patent Thicket Solutions: Allow for single-window CL applications for products covered by multiple overlapping patents (e.g., drug-device combinations, biologics).
- Bundled Licensing Framework: Encourage the establishment of technology pools or bundled licensing models to allow generic firms to negotiate access across interrelated patents.

6. ***International Engagement and Diplomatic Resilience***[127]***:***

a. TRIPS-Compliant Legal Justification: Ensure India's position is firmly grounded in TRIPS Articles 31 and include legal memos justifying CLs on public health grounds.

b. Diplomatic Engagement Strategy: Anticipate trade and diplomatic backlash by:

- Engaging WTO and WHO early in the CL process
- Publicizing the rationale for CL decisions via official press briefings
- Aligning with other countries pursuing similar access measures

The cited article examines the international implications of India's patent policies and the importance of diplomatic strategies to uphold public health priorities.

7. ***Expanding use beyond Sec. 84: Emergency and Govt. use Licensing***[128]***:***

- Sec. 92 Activation: Use Sec. 92 (Compulsory Licenses in cases of national emergency, extreme urgency, or public non-commercial use) without requiring a prior negotiation.
- Government Use Licensing (Sec. 100): Enable public sector procurement and manufacture of patented drugs without private sector filing, especially for drugs included in the National List of Essential Medicines (NLEM).

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[126] *Sec. 84 of The Indian Patents Act 1970: Compulsory Licenses*, The Legal School (2025), https://thelegalschool.in/blog/Sec.-84-indian-patent-act.
[127] *India's Newly Amended Patent Rules Threaten Affordable Medicines in the Global South*, People's Dispatch (Apr. 2024), https://peoplesdispatch.org/2024/04/05/indias-newly-amended-patent-rules-threaten-affordable-medicines-in-the-global-south/.
[128] *Compulsory Licensing in India*, IIPRD (2019), https://www.iiprd.com/compulsory-licensing-in-india/.

The cited resource outlines the provisions under Sec.s 92 and 100 of the Patents Act, detailing the procedures for emergency and government use licensing.

8. ***Building Capacity for Implementation:***

- Patent Litigation Units: Establish specialized legal cells within the Ministry of Health or Department of Pharmaceuticals to handle CL applications and defend them legally.
- Patent and Health Data Integration: Develop a patent-health dashboard mapping disease burden, patent status, and availability/pricing to identify CL candidates.

9. *Monitoring and Evaluating Compulsory Licensing Impact*[129]*:*

- Health Outcome Tracking: Monitor changes in treatment coverage, out-of-pocket expenditure, and public procurement costs post-CL issuance.
- Industry Response Analysis: Study how CLs affect R&D decisions and market behavior of innovator firms to refine policy calibration.

The cited document provides a framework for monitoring and evaluating the impact of compulsory licensing on public health outcomes and pharmaceutical markets.

For India to truly leverage compulsory licensing as a strategic access tool, it must evolve from a reactive, case-specific approach to a systematic, institutionalized mechanism that proactively defends public health. By clarifying legal thresholds, eliminating procedural bottlenecks, and adopting evidence-based standards, India can not only ensure domestic medicine access but also set a bold precedent for other developing countries navigating the trade–health nexus.

4.4. PARALLEL IMPORTATION AND INTERNATIONAL EXHAUSTION

India's adoption of international exhaustion of patent rights under Sec. 107A(b) of the Patents Act, 1970, allows the parallel importation of patented pharmaceutical products. This provision enables the import of genuine, lawfully marketed medicines from any country without the consent of the patent holder, thereby promoting price competition and access. However, despite this legal foundation, parallel importation remains underutilized due to administrative inefficiencies and regulatory ambiguity.

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[129] *Compulsory Licensing: Procedural Requirements Under the TRIPS Agreement*, IFPMA (Jan. 2023), https://www.ifpma.org/wp-content/uploads/2023/01/i2023_4.-Compulsory-Licensing-Procedural-Requirements-under-the-TRIPS-Agreement.pdf.

A comprehensive strategy to operationalize this TRIPS-compliant flexibility can help India address the affordability gap for patented medicines, especially biologics, oncology drugs, and treatments for rare diseases.

1. ***Clarifying and Strengthening the Legal and Regulatory Framework***[130]*:*

- Statutory and Regulatory Clarifications: Issue official guidelines or amendments under the Drugs and Cosmetics Rules and Patents Act to clarify procedures and permissible circumstances for parallel imports.
- Consistent Interpretation of Sec. 107A(b): Avoid conflicting judicial interpretations by issuing clarification circulars and ensuring judicial training on TRIPS flexibilities and public health objectives.
- Customs and Regulatory Coordination: Provide customs officers and regulatory bodies with clear instructions to prevent arbitrary seizure or delay of lawfully parallel-imported products.

The article cited discusses the legal framework governing parallel imports in India, focusing on trademark and patent laws, and highlights the need for clearer regulatory guidelines to facilitate effective implementation.

2. ***Establishing Expedited Approval Pathways for Parallel Imports***[131]*:*

- Regulatory Fast Track for WHO-Approved Medicines: Create a special regulatory route for medicines approved by stringent regulatory authorities (SRAs) or listed under WHO prequalification to allow quicker importation.
- Streamlined Documentation Requirements: Reduce duplicative documentation for medicines already approved abroad; use reliance mechanisms to avoid requiring new safety and efficacy data.
- Digital Portal for Application Tracking: Develop a centralized digital interface for tracking parallel import applications, ensuring transparency and accountability in decision-making.

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[130] *Parallel Imports in India: Laws, Doctrine of Exhaustion, and Market Impact*, Mondaq (Oct. 10, 2023), https://www.mondaq.com/india/trademark/1477778/parallel-imports-in-india-laws-doctrine-of-exhaustion-and-market-impact.

[131] *Biologics Regulation in India*, BioPharm Int'l (Mar. 1, 2008), https://www.biopharminternational.com/view/biologics-regulation-india-0.

The article cited examines the regulatory challenges in India's biologics sector, emphasizing the need for streamlined approval processes to enhance access to affordable medicines through mechanisms like parallel importation.

3. ***Safeguarding Quality and Ensuring Patient Safety***[132]*:*

- Independent Verification Mechanisms: Require third-party verification or certification from SRAs or trusted drug regulators to ensure the authenticity and quality of imported medicines.
- Post-Market Surveillance: Strengthen pharmacovigilance systems to monitor adverse effects and ensure the continued safety of imported pharmaceuticals.
- Tamper-Proof Packaging and Labelling: Require secure packaging and accurate labelling (in local languages) to prevent counterfeit risks and ensure proper usage.

The report cited highlights the risks associated with parallel importation, particularly concerning counterfeit and substandard medicines, underscoring the importance of stringent quality control measures.

4. ***Addressing Administrative and Commercial Barriers***[133]*:*

- Awareness for Importers and Distributors: Provide guidance and training for domestic importers and distributors on the legal validity and procedures of parallel importation.
- Reducing Transaction Costs: Provide exemptions or reductions in import duties and fees for parallel imports of essential medicines listed under the National List of Essential Medicines (NLEM).
- Addressing Supply Chain Discrimination: Monitor pharmaceutical companies that engage in anti-competitive practices like limiting supply to specific markets to block parallel trade.

The article cited analyzes the complexities of parallel imports in relation to patent infringement in India, discussing administrative challenges and the need for policy reforms to facilitate smoother importation processes.

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[132] *Importing Danger: The Global Threat of Parallel Importation*, Partnership for Safe Medicines (2009), https://www.safemedicines.org/importdanger.
[133] *Parallel Import and Patent Infringement*, Origiin IP Solutions LLP (Sept. 2023), https://origiin.com/parallel-import-and-patent-infringement/.

5. ***Leveraging Regional Cooperation and Trade Agreements***[134]*:*

- South-South Coordination: Collaborate with countries in Africa, Latin America, and Southeast Asia to develop a regional pharmaceutical parallel importation network for shared access and legal support.
- Model Regional Agreements: Negotiate regional protocols that allow mutual recognition of approvals and facilitate re-export/re-import among member countries.
- Use of Regional Procurement Hubs: Establish shared procurement mechanisms (e.g., regional medicine pools) to jointly procure high-cost medicines from low-cost jurisdictions.

The paper cited discusses the potential benefits of liberalizing parallel import policies in India, including regional cooperation to enhance access to affordable medicines.

6. ***Ensuring Alignment Between Patent Offices and Drug Regulators***[135]*:*

- Cross-Agency Database: Develop an integrated database accessible by both the Controller General of Patents and CDSCO to track patent status, pricing, and country approvals for potential imports.
- Patent Landscaping Tools: Use patent intelligence tools to identify where medicines are off-patent or available at lower prices, enabling strategic import decisions.
- Routine Joint Reviews: Institutionalize periodic joint reviews between patent and drug regulatory agencies to identify priority medicines eligible for parallel imports.

The article cited explores India's adoption of the international exhaustion principle and emphasizes the need for coordination between patent offices and drug regulatory authorities to facilitate parallel imports.

7. ***Public Health Impact Assessment and Transparency***[136]*:*

- Cost-Benefit Evaluation: Regularly publish data on price reductions, access improvement, and patient outcomes resulting from parallel imports.

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[134] *Parallel Imports in the Pharmaceutical Sector: Must India be More Liberal?*, 12 J. Intell. Prop. Rights 400 (2007), https://www.researchgate.net/publication/228477588_Parallel_Imports_in_the_Pharmaceutical_Sector_Must_India_be_More_Liberal

[135] *Navigating Parallel Imports: India's Approach to the Doctrine of Exhaustion in IP Law*, Intepat IP (Jan. 2024), https://www.intepat.com/blog/navigating-parallel-imports-indias-approach-to-the-doctrine-of-exhaustion-in-ip-law/.

[136] *Parallel Importation as a Policy Option to Reduce Price of Patented Medicines*, 17 Global Soc. Policy 1 (2021), https://journals.sagepub.com/doi/full/10.1177/1741134321999418.

- Transparency in Import Decisions: Maintain public records of approved parallel imports, rejected applications, and reasons for approval/denial to ensure accountability.
- Stakeholder Engagement: Consult with civil society, patient groups, and academic experts to identify medicines where parallel importation can most effectively close the access gap.

The cited study evaluates the impact of parallel importation on medicine prices and access, advocating for transparency and public health assessments in policy implementation.

The international exhaustion principle in India provides a valuable legal basis for increasing access to affordable medicines through parallel importation. However, the benefits of this flexibility can only be realized if it is operationalized through targeted reforms, regional cooperation, and institutional coordination. By making parallel importation a viable and streamlined option, India can strengthen its position as a global access champion and safeguard public health interests against pricing monopolies in the pharmaceutical sector.

4.5. DATA EXCLUSIVITY AND REGULATORY PATHWAYS

The absence of data exclusivity provisions in India's current regulatory framework represents a crucial advantage for generic medicine access that must be carefully preserved. Unlike developed countries where data exclusivity creates additional barriers to generic entry beyond patent protection, India's approach allows generic manufacturers to rely on innovator companies' clinical trial data for regulatory approval once patents expire or are successfully challenged.

However, ongoing trade negotiations and bilateral agreements often include provisions that would require implementation of data exclusivity rules, potentially undermining this advantage. Protecting India's current regulatory approach requires clear policy statements rejecting data exclusivity requirements and demonstrating how current safety and efficacy standards adequately protect public health without creating additional monopolies.

The development of alternative pathways for generic drug approval, including abbreviated approval processes for medicines addressing urgent public health needs, could further strengthen India's access-oriented approach. These mechanisms would ensure that even if future trade agreements impose certain restrictions, alternative pathways remain available for ensuring timely access to essential medicines.

The following points would reflect the above in detail and they are as follows:

1. ***Reinforcing the Legal and Policy Basis against Data Exclusivity***[137]*:*

- Explicit Policy Declarations: The Government of India should issue unambiguous statements rejecting data exclusivity in national policies, especially when negotiating trade or investment treaties.
- Legislative Clarifications: Amendments to the Drugs and Cosmetics Act or associated rules could clearly state that generic companies may rely on previously submitted data, consistent with India's WTO obligations.
- Public Health Justification: Justify this stance internationally by emphasizing India's constitutional duty to ensure access to medicines and its role in meeting global public health needs.

The cited document discusses India's stance on data exclusivity, emphasizing its absence in Indian law and the implications for generic drug approval.

2. ***Resistance to TRIPS-Plus Provisions in Trade Negotiations***[138]*:*

- Vigilance in FTA Negotiations: India must push back against attempts to insert TRIPS-plus provisions (e.g., through agreements like RCEP, EU-India FTA, or proposed US-India trade deals) that would require data exclusivity.
- Regional Coordination: Develop alliances with other developing countries, such as through the Global South or the African Group at the WTO, to resist similar provisions collectively.
- Use of Precedents: Highlight past instances (e.g., Thailand or Colombia) where countries have successfully resisted such provisions without losing trade privileges.

The cited paper analyzes the impact of TRIPS-plus provisions in free trade agreements on access to medicines, with a focus on developing countries like India.

3. ***Demonstrating the Sufficiency of Existing Regulatory Standards***[139]*:*

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[137] *Indian Pharmaceutical Alliance*, *Backgrounder on IP Rights: Patents, Data Exclusivity and Regulatory Approval*, at 6–7 (May 21, 2012), https://www.ipa-india.org/wp-content/uploads/2023/03/Backgrounder-on-IP-Rights_21.05.12.pdf.

[138] World Health Organization, *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region* (2010), https://iris.who.int/handle/10665/119913.

[139] Sushma et al., *Drug Approval Process in India*, 13(9) World J. Pharm. Res. 408 (2024), https://wjpr.s3.ap-south-1.amazonaws.com/article_issue/a7c550a617333587ca9a1794177eeb97.pdf.

- Robust Safety and Efficacy Requirements: Showcase how Indian regulators already require generic manufacturers to demonstrate bioequivalence, ensuring drug safety without requiring duplicative clinical trials.
- Avoiding Ethical and Economic Waste: Argue that mandating fresh clinical trials for generics would be ethically questionable and economically burdensome, as it involves unnecessary duplication and potential risk to human subjects.

The cited article outlines the drug approval process in India, highlighting the existing regulatory standards that ensure drug safety and efficacy without data exclusivity.

4. ***Alternative Mechanisms to Encourage Innovation***[140]*:*

- Non-Exclusive Data Use Models: Instead of granting exclusive rights, India could offer limited remuneration to originator companies for data use in cases of genuine investment risk—without impeding generic entry.
- Incentives via Public Funding: Strengthen public and philanthropic funding for clinical trials targeting neglected diseases, thereby delinking innovation from exclusivity altogether.

The cited article outlines the drug approval process in India, highlighting the existing regulatory standards that ensure drug safety and efficacy without data exclusivity.

5. ***Strengthening Abbreviated Drug Approval Pathways***[141]*:*

- Fast-Track Approvals for Essential Medicines: Create clear mechanisms for accelerated approval of generics used to treat high-burden or pandemic-related diseases, especially when international supply disruptions occur.
- Public Interest Exceptions: Embed "public health emergency" clauses that allow rapid regulatory reliance on foreign approvals (e.g., WHO prequalification) to fast-track market entry.

The cited article provides an overview of the abbreviated new drug application process in India, emphasizing its role in facilitating generic drug approvals.

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[140] R. K. Gupta, *Data Exclusivity Provisions in India: Impact on Public Health*, ResearchGate (2008), https://www.researchgate.net/publication/228501683_Data_Exclusivity_Provisions_in_India_Impact_on_Public_Health.

[141] R. K. Goyal et al., *Abbreviated New Drug Application Process in India*, ResearchGate (2022), https://www.researchgate.net/publication/359369975_ABBRIVIATED_NEW_DRUG_APPLICATION_PROCESS_IN_INDIA.

6. ***Transparency and Public Engagement***[142]*:*

- Disclosure of Trade Proposals: Mandate public disclosure and stakeholder consultation for trade proposals that may affect access to medicines, including provisions on data exclusivity or regulatory harmonization.
- Civil Society Advocacy: Support watchdog organizations and health groups in tracking trade negotiations and advocating for health-friendly regulatory standards.
- Academic and Media Engagement: Promote research and journalism that highlight the consequences of data exclusivity in other jurisdictions to build informed public resistance.

The cited resource highlights the importance of transparency and public engagement in trade negotiations affecting access to medicines.

7. ***Precedent-Based Legal Defense Strategy***[143]*:*

- Global Legal Precedents: Draw on WTO jurisprudence and domestic case law (e.g., *Novartis v. Union of India*[144]) to argue that India's approach is consistent with TRIPS obligations and public health goals.
- Impact Studies: Commission and publish studies demonstrating the cost and access barriers created by data exclusivity in countries where it is enforced, using these as evidence in policy forums.

The cited thesis examines the legal aspects of data exclusivity in India and discusses strategies for defending the current regime against external pressures.

India’s regulatory approach, by allowing reliance on existing clinical data for generic drug approval, embodies a public health-first philosophy. Safeguarding this model not only ensures timely access to affordable medicines domestically but also reinforces India’s leadership as the “pharmacy of the developing world.” With proactive legal, diplomatic, and regulatory strategies, India can continue to resist pressures for TRIPS-plus obligations while expanding access to life-saving treatments.

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[142] Médecins Sans Frontières, *Spotlight on: TRIPS, TRIPS Plus, and Doha*, MSF Access Campaign (2021), https://msfaccess.org/spotlight-trips-trips-plus-and-doha.
[143] S. K. Verma, *Reassessing the Data Exclusivity Regime for the Indian Pharmaceutical Industry*, Victoria Univ. of Wellington (2022), https://openaccess.wgtn.ac.nz/articles/thesis/Reassessing_The_Data_Exclusivity_Regime_For_The_Indian_Pharmaceutical_Industry/25857238.
[144] (2013) 6 SCC 1.

4.6. INNOVATION WITHOUT MONOPOLIZATION

Strengthening India's access-oriented patent regime requires developing alternative models for encouraging pharmaceutical innovation that do not rely solely on patent monopolies and high pricing. The promotion of open-source drug discovery, advance market commitments, and alternative research funding mechanisms could reduce the industry's dependence on monopoly pricing while maintaining innovation incentives.

India's robust generic pharmaceutical industry provides a foundation for developing innovative approaches to drug development that prioritize accessibility from the outset. Supporting research initiatives that focus on diseases prevalent in developing countries and encouraging collaborative research models could ensure that innovation serves public health needs rather than simply maximizing commercial returns.

The establishment of patent pools and voluntary licensing arrangements represents another avenue for balancing innovation incentives with access requirements. By facilitating voluntary agreements between patent holders and generic manufacturers, these mechanisms can ensure reasonable returns for innovators while enabling competitive pricing for essential medicines.

The following points would reflect the above in detail and they are as follows:

1. ***Promotion of Open-Source Drug Discovery***[145]*:*

- Public-Driven Innovation: Government and academic institutions can fund open-access research projects where data, molecular structures, and trial outcomes are freely shared for collaborative development.
- Crowd-sourced Problem Solving: Digital platforms can harness global scientific communities to contribute to neglected disease research through shared databases and decentralized R&D.
- Reduced Development Costs: By pooling knowledge early in the discovery process, OSDD can bypass the duplicative costs of proprietary development and reduce the need for high monopoly pricing.

2. ***Advance Market Commitments:***

[145] Matthew H. Todd, *Open Source Drug Discovery: Highly Potent Antimalarial Compounds Derived from the Open Source Malaria Project*, 10 PLOS Neglected Tropical Diseases e0004383 (2014), https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0004383.

- Pre-Defined Incentives: Governments or international coalitions (like GAVI or WHO) can pledge to purchase a specified volume of a drug or vaccine once developed, providing a guaranteed return on investment.
- Focus on Public Health Priorities: AMCs can be targeted toward diseases with little commercial market incentive, such as tuberculosis or leishmaniasis, aligning innovation with actual health needs.
- De-Risking Investment: Start-ups and smaller research institutions can engage in drug development without bearing the full financial risk, supported by guaranteed buyers.

3. ***Alternative Research and Development Funding Mechanisms***[146]*:*

- Public R&D Grants: Expanding government funding through entities like creating a dedicated Department of Biotechnology (DBT) for the Government of India or Indian Council of Medical Research (ICMR) can replace private monopoly-based R&D.
- Health Innovation Funds: India could establish a dedicated health R&D fund financed through public-private partnerships or a health solidarity levy to support research aligned with public interest.
- Outcome-Based Prizes: Innovation inducement prizes can reward successful inventions (e.g., a new treatment or diagnostic) without conferring long-term market exclusivity.

4. ***Leveraging India's Generic Industry for Innovation***[147]*:*

- Reverse Engineering Expertise: India's generic industry has technical capacity to develop biosimilars and novel formulations, which can be redirected toward incremental innovation in public interest.
- Process Innovation: Investments in cost-reducing and efficiency-enhancing production methods can make drugs cheaper and more accessible without needing patent protection.
- Public-Private Collaborations: Collaborations between generic firms and public institutions can accelerate the transition from copy-based production to mission-driven R&D.

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[146] Science and Engineering Research Board (SERB), *About*, SERB Official Website,https://serb.gov.in/page/english/about

[147] International Society for Pharmaceutical Engineering (ISPE), *Indian Pharmaceutical Industry: Creating Global Impact*, Pharmaceutical Engineering (Mar.–Apr. 2025), https://ispe.org/pharmaceutical-engineering/march-april-2025/indian-pharmaceutical-industry-creating-global-impact.

5. ***Focused Research on Diseases of the Global South:***

- Neglected Disease Research Hubs: India can establish specialized research centers focused on diseases with high prevalence in low-income countries but low commercial returns, such as dengue, kala-azar, and chikungunya.
- South-South Research Collaboration: Joint R&D ventures with other developing countries can help pool funding, share risks, and enhance the collective scientific base for unmet medical needs.
- Incentivized Academic Research: Academic grants and fellowships can be structured to reward researchers working on therapeutics for underfunded disease areas.

6. ***Collaborative Research Models***[148]*:*

- Innovation Commons: Research consortia can pool knowledge and data for pre-competitive collaboration, especially in early-stage discovery or platform technologies.
- Public Sector Licensing Policies: Universities and publicly funded institutions should adopt open-access or socially responsible licensing models to prevent exclusive control by private firms.
- Cooperative Models: Non-profit pharmaceutical entities (like DNDi[149] or Medicines360[150]) can serve as models for mission-driven drug development with fair pricing commitments.

7. ***Patent Pools and Voluntary Licensing***[151]*:*

- Patent Pool Frameworks: India could support or lead regional patent pools for key therapeutic areas (like HIV, hepatitis, or cancer) to facilitate technology sharing and reduce costs.
- Facilitating Generic Production: Through the Medicines Patent Pool (MPP) or similar domestic mechanisms, patent holders can license technologies to multiple manufacturers with pricing ceilings.

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[148] V. K. Saraswat et al., *Industry and Research Collaboration: A Model for India*, ResearchGate (Apr. 2022), https://www.researchgate.net/publication/359871505_INDUSTRY_AND_RESEARCH_COLLABORATION_A_MODEL_FOR_INDIA.
[149] Drugs for Neglected Diseases initiative (DNDi), *Who We Are*, https://dndi.org/about/who-we-are/
[150] Medicines360, *What We Do*, https://medicines360.org/what-we-do/.
[151] Medicines Patent Pool (MPP), *MPP Value Report 2024*, MPP Official Website (May 2024), https://medicinespatentpool.org/uploads/2024/05/MPP_VALUE-Report_2024_EN_WEB.pdf.

- Balanced Licensing Terms: Agreements should balance fair compensation with public health imperatives, including safeguards against restrictive geographic or product exclusions.

4.7. REGIONAL AND INTERNATIONAL COOPERATION

India's leadership role as the "pharmacy of the developing world" provides unique opportunities for strengthening access-oriented patent regimes through regional and international cooperation. The development of coordinated approaches to patent examination, compulsory licensing, and parallel importation among developing countries could create more effective resistance to attempts to undermine TRIPS flexibilities through bilateral agreements.

Collaboration with international organizations, civil society groups, and academic institutions can provide technical expertise and political support for maintaining and expanding access-oriented patent policies. The sharing of experiences and best practices among countries facing similar challenges can strengthen the evidence base for policy decisions and provide mutual support against external pressure.

This leadership can be harnessed in multiple strategic ways to preserve public health safeguards and promote equitable access to medicines, the points would reflect the above two in detail and they are as follows:

1. ***Regional Cooperation on Patent Law and Policy***[152]*:*

- Harmonization of Legal Standards: Developing countries can coordinate legal standards on patentability criteria, such as stricter definitions of novelty and inventive step, to prevent evergreening and unjustified monopolies.
- Joint Examination Frameworks: Regional patent offices or coalitions could develop joint guidelines and capacity-building programs to ensure robust and access-sensitive patent examination.
- Pooling Technical Expertise: Countries can share patent examiners, legal experts, and technological databases to strengthen the institutional capacity to scrutinize pharmaceutical patent applications.

[152] Muhammad Zaheer Abbas, *India's Distinct but Opposing Patent Model Is Under Pressure: Prospects and Challenges in the Global Arena*, 19 J. Generic Meds. 1 (2024), https://journals.sagepub.com/doi/10.1177/09749284231225835.

2. ***Strategic use of TRIPS Flexibilities***[153]*:*

- Compulsory Licensing Frameworks: Coordinated policies on compulsory licensing—including model laws and shared protocols—can enhance negotiating power and simplify the issuance of licenses in times of public health need.
- Parallel Importation Mechanisms: Countries could establish common rules and mutual recognition agreements to facilitate the importation of lower-cost patented drugs from jurisdictions where they are sold cheaper.
- Data Exclusivity Waivers: Joint strategies can resist pressure to adopt TRIPS-plus provisions like data exclusivity and patent term extensions.

3. ***South-South Collaboration and Policy Alignment***[154]*:*

- Pharmaceutical Procurement Pools: Regional purchasing initiatives, such as pooled procurement of generics, can enhance bargaining power and support local manufacturers.
- Mutual Support in Trade Negotiations: Developing countries can form alliances in bilateral and multilateral trade negotiations to resist TRIPS-plus obligations that erode public health safeguards.
- Regional R&D Platforms: Collaborative investment in research and development tailored to neglected diseases can reduce reliance on Western pharmaceutical patents.

4. ***Engagement with International Organizations and NGOs***[155]*:*

- Leveraging Global Norm-setting Bodies: Engagement with WHO, WIPO, UNCTAD, and the WTO can help reaffirm the legitimacy of TRIPS flexibilities under international law.
- Support from Civil Society: NGOs and public health advocates can help mobilize public opinion, monitor corporate lobbying, and pressure governments to prioritize access over IP maximalism.
- Academic Partnerships: Universities and research institutes can provide evidence-based analysis, support patent law reforms, and contribute to public interest IP strategies.

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[153] Muhammad Z. Abbas, *World Trade Organization's Export-Oriented Compulsory Licensing Mechanism: Foreseen Policy Concern for Africa to Mitigate the COVID-19 Pandemic*, 17 Int'l J. L. Mgmt. & Human. 1 (2021), https://journals.sagepub.com/doi/10.1177/17411343211010205

[154] *Compulsory Licenses and Government Use: Challenges and Opportunities*, in Ellen 't Hoen et al. (eds.), *Medicines Law & Policy* (2021), https://link.springer.com/chapter/10.1007/978-3-030-83114-1_3,

[155] World Intellectual Property Organization, *Public Policy-related Assistance - Flexibilities*, WIPO, https://www.wipo.int/ip-development/en/policy/flexibilities.html.

5. ***Knowledge Sharing and Capacity Building***[156]*:*

- Case Study Repositories: Countries can compile and disseminate documentation of successful compulsory licenses, patent rejections, and legal reforms to serve as templates for others.
- Training and Legal Empowerment: National patent offices and judiciary systems can benefit from joint training programs on TRIPS flexibilities and health-oriented IP governance.
- Monitoring and Early Warning Systems: Regional watch platforms can track emerging threats from trade agreements or pharmaceutical lobbying, enabling timely policy responses.

6. ***Political Solidarity and Advocacy***[157]*:*

- Coalition Building: Developing countries can form coalitions or caucuses in global forums to advocate for more equitable access provisions and counter the influence of pharmaceutical lobby groups.
- Joint Declarations and Position Papers: Unified public positions on IP and health can signal resistance to external pressure and encourage a rebalancing of IP norms toward human rights and development.
- Public Diplomacy Campaigns: Countries like India can lead campaigns that frame access to medicines as a moral and developmental imperative, drawing on its historical role in global health justice.

By leveraging its position and experience, India can spearhead a global movement toward equitable access to medicines, reinforcing TRIPS flexibilities and promoting public health-driven patent policies through coordinated international efforts.

India's access-oriented patent regime exemplifies a pragmatic, public-health-driven approach to intellectual property governance, one that prioritizes equitable access to medicines while respecting TRIPS obligations. As this chapter has demonstrated, the strength of India's model lies in its strategic deployment of TRIPS flexibilities—such as Sec. 3(d), compulsory licensing, international exhaustion, and the absence of data exclusivity—to prevent monopolistic practices like evergreening and to facilitate timely generic competition. However, to preserve and enhance

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[156] Carlos M. Correa, *Interpreting the Flexibilities Under the TRIPS Agreement*, in *Medicines Law & Policy* 1 (2021), https://link.springer.com/chapter/10.1007/978-3-030-83114-1_1.
[157] World Trade Organization, *Council for TRIPS: Access to Medicines – Developing Countries Paper*, WTO (June 2001), https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm.

this framework, India must address persistent procedural, interpretive, and diplomatic challenges through targeted reforms, capacity building, and proactive legal and trade strategies. Alternative innovation models—ranging from open-source research and advance market commitments to patent pools—can further decouple innovation from exclusivity and ensure that pharmaceutical progress serves public needs. Regional and international cooperation, particularly among developing countries, will be critical in building collective resilience against TRIPS-plus pressures and in institutionalizing equitable norms in global health governance. By reinforcing its leadership as the "pharmacy of the developing world," India is not only safeguarding its constitutional commitment to health and social justice but also offering a scalable model for access-oriented patent reform worldwide.

CHAPTER 5: POLICY RECOMMENDATIONS FOR REFORMS

The dissertation set on an expedition to analyse the complex relationship between biomedical patents, India's tryst with TRIPS Agreement[158], and the larger indications for access to cost-effective medicines. Through doctrinal and comparative legal analysis, it has become evident that while India has managed to carve out a TRIPS-compliant yet access-sensitive patent regime, significant challenges remain in ensuring equitable health outcomes.

India's legislative ingenuity—particularly through provisions like Sec. 3(d)[159] and the use of compulsory licensing[160] — demonstrates that flexibilities embedded in TRIPS can be leveraged to balance innovation incentives with public health needs. Judicial pronouncements such as *Novartis AG v. Union of India*[161] and *Bayer Corp. v. Natco Pharma Ltd.*[162] reinforced the concessional principles, thereby creating and to a large extent offering a model for other developing countries grappling with the same or similar issues.

That said, the simple presence of legal provisions does not necessarily guarantees the adequate implementation. Discrepancies in the application of the provisions, under-utilization of TRIPS flexibilities, institutional setbacks, and global political upthrust continue to pose serious setbacks in realizing the constitutional promise of the fundamental right to health under Art. 21.[163] Furthermore, the weakening of international solidarity around the Doha Declaration—especially during global crises like the COVID-19 pandemic—signals the need for renewed international advocacy and cooperation.

Based on the doctrinal findings and comparative analysis, the following key recommendations are proposed:

5.1. CODIFY RIGHT TO HEALTH IN STATUTORY LAW

A central recommendation for aligning India's patent regime with public health goals is the codification of the right to health through comprehensive legislation. While judicial interpretations, most notably in *Mohd. Ahmed v. Union of India*[164], upheld the right to health

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[158] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[159] The Patents Act, No. 39 of 1970 § 3(d) (India).
[160] The Patents Act, No. 39 of 1970 § 84 (India).
[161] (2013) 6 SCC 1.
[162] (2013) SCC OnLine IPAB 25.
[163] *INDIA* CONST. art. 21.
[164] (2014) SCC OnLine Del 1508.

under Article 21 of the Constitution, this major issue is that this a judicially implied protection and not a protection which has been guaranteed by a definitive legislation. Enshrining this right in a dedicated statute, maybe legislating a Right to Health and Access to Medicines Act, would mark a significant step toward operationalizing India's constitutional obligations in the domain of healthcare.

Such legislations should include:

- Legally Enforceable Obligations on the State to provide essential medicines, diagnostics, and vaccines at cost-effective prices to all citizens, especially vulnerable populations.
- Mandatory Inclusion of Access Metrics in the pharmaceutical patenting process, such as the affordability and supply-chain feasibility of the drug in question.
- Linkage between Patent Law and Public Health Law, ensuring that decisions made by the patent office consider the right to health alongside commercial innovation incentives.
- Public Health Emergency Provisions, enabling fast-track approvals, price control, and compulsory licensing during health crises like pandemics.

A statutory right to health would not only reinforce the foundational logic behind access-oriented provisions of the Patents Act but would also offer a stronger legal basis for challenging patent grants or pricing decisions that hinder medicine accessibility. Moreover, it would align India with global trends where socio-economic rights are being legislatively articulated and made justiciable, as seen in South Africa's post-apartheid constitutional and legal reforms.

5.2. STRENGTHEN SEC. 3(d)

Sec. 3(d) of the Indian Patents Act is a cornerstone provision designed to prevent the evergreening of patents, which is the practice of extending patent protection for minor modifications of existing drugs that do not contribute substantially to their therapeutic efficacy. This Section lays down that only truly innovative and therapeutically valuable inventions are granted patent protection. Despite its critical role however, Sec. 3(d) faces challenges in its implementation, particularly due to vague language in it along with the inconsistent application, and the lack of robust examination protocols. Strengthening Sec. 3(d) through a comprehensive, multi-pronged reform agenda is necessary to promote access to cost-effective medicines while maintaining the integrity of the patent system.

To address this, the following measures should be implemented:

A. *Revisiong and Strengthening Examination Guidelines*

One of the most crucial steps toward strengthening Sec. 3(d) is the revision of the examination guidelines issued by the Indian Patent Office (IPO) in 2014[165]. Though the guidelines focused and to an extent addressed pharmaceutical patent examinations, they are not fully effective in ensuring that patents are granted only for inventions that genuinely enhance therapeutic efficacy. The current lack of clarity on assessing "enhancement of therapeutic efficacy" has resulted in inconsistent patent grants, contributing to evergreening and preventing the timely entry of cost-ffective generics.

To address this, the following measures should be implemented:

i. Clear Definitions and Interpretative Principles: The guidelines should provide clear and detailed definitions of key terms, particularly "enhancement of therapeutic efficacy" and "incremental innovation", drawing from precedents like *Novartis AG v. Union of India*[166] and international best practices. Clear definitions will help ensure that patent examiners have a uniform understanding of these terms, reducing discrepancies in patent assessments.

ii. Standardization of Clinical and Empirical Evidence: The revised guidelines should specify the type and standard of clinical evidence and empirical data required to demonstrate therapeutic efficacy. For instance, it should outline the need for randomized controlled trials (RCTs), bioequivalence studies, and other well-established scientific methods to assess therapeutic benefit. This will help prevent the patenting of formulations or compounds that do not offer a significant improvement over existing treatments, ensuring that only truly innovative drugs are granted patents.

iii. Incorporation of Public Health Considerations: The guidelines should incorporate public interest considerations—especially affordability and accessibility—as integral parts of the efficacy assessment for pharmaceutical patents. This would include an examination of the societal impact of granting a patent, particularly when it relates to essential medicines or treatments for prevalent diseases.

These changes will ensure that the patent examination process aligns more closely with public health goals, reducing the risk of patenting incremental innovations that would delay the availability of cost-effective generics.

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[165] Indian Patent (Amendment) Rules, 2014, Gazette of India, Extraordinary, Part II, Sec. 3, Sub-Sec. (ii), dated 17 October 2014.
[166] (2013) 6 SCC 1.

B. *Specialized Training for Patent Examiners*

To effectively implement Sec. 3(d) and ensure a more accurate and context-sensitive patent examination process, it is essential to improve the skills and expertise of patent examiners. At present, many patent examiners at the Indian Patent Office are generalists with limited exposure to the technical nuances of pharmaceutical science, pharmacology, and biotechnology, which can lead to the misapplication of patent criteria. For such, the reformations must include the following:

i. Continuous Profressional Development Programs[167]: Establish a continuous training program for patent examiners that focuses on the evolving landscape of pharmaceutical R&D, drug resistance patterns, and clinical developments in areas such as oncology, biologics, and rare diseases. These updates will help examiners better understand emerging trends and innovations, which will be crucial for making informed patent decisions.

ii. Collaboration with Academic and Public Health Institutions[168]: Collaborating with academic institutions, public health organizations, and research bodies will provide examiners with access to specialized knowledge. This could include scientific modules on evaluating therapeutic efficacy and understanding the socioeconomic impacts of patents on public health.

iii. Appointment of Technical Advisors: For particularly complex patent applications, India should appoint technical advisors or second experts with expertise in pharmacology, medicine, and biotechnology. These experts would assist patent examiners in evaluating the therapeutic relevance and clinical impact of pharmaceutical inventions, especially in high-stakes areas like oncology and rare diseases. The Controller General of Patents, Designs and Trade Marks called for applications[169] for Scientific Advisors under Rule 103[170] of the Patents Rules, 2003 for assisting court proceedings in cases involving patent infringements under Sec. 115[171] of the Patents Act.

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[167] Germán Velásquez, *Guidelines on Patentability and Access to Medicines*, S. Ctr. Res. Paper No. 61, at 33 (Mar. 2015), https://ipaccessmeds.southcentre.int/wp-content/uploads/2020/02/RP61.pdf.
[168] *See* VIT, med univ to research AI-driven healthcare, Times of India (May 19, 2025), https://timesofindia.indiatimes.com/city/chennai/vit-med-univ-to-research-ai-driven-healthcare/articleshow/121275595.cms.
[169] *See* Prashant Reddy, Calling the Experts: CGPDTM Invites Applications for Scientific Advisors, SpicyIP (Apr. 2025), https://spicyip.com/2025/04/calling-the-experts-cgpdtm-invites-applications-for-scientific-advisors.html.
[170] Patents Rules, 2003, r. 103 (India).
[171] The Patents Act, No. 39 of 1970, § 115, Acts of Parliament, 1970 (India).

This specialized training will help to ensure that patent examiners make well-informed decisions that align with legal standards as well as public health objectives.

C. *Third-Party Review Mechanisms*

To further enhance the transparency, accuracy, and accountability of the patent examination process, India should implement third-party review mechanisms. These mechanisms will provide an additional layer of scrutiny and prevent the granting of frivolous or invalid patents, particularly for pharmaceutical inventions that could have significant public health implications. The key actions in this area should include the following:

i. External Peer Review for High-Stakes Patents: Introduce external peer review for high-stakes pharmaceutical patent applications, particularly when the drug targets widespread or high-burden diseases. This peer review should involve experts from academia, public health, and the pharmaceutical industry to assess the clinical benefits of the proposed patent.

ii. Creation of a Public Patent Watchdog or related Bodies: Establish an independent Public Patent Watchdogs or related Bodies comprised of civil society representatives, generic drug manufacturers, patient advocacy groups, and public health experts. This body would be tasked with reviewing critical patent grants, especially those involving essential medicines, and opposing frivolous filings or patents that fail to meet the criteria for genuine innovation.

By creating such review mechanisms, India can ensure that patents are granted based on solid scientific evidence, while preventing the abuse of patent rights to the detriment of public health.

D. *Digital Infrastructure and Transparency*

Finally, upgrading the digital infrastructure of the Indian Patent Office is crucial for improving transparency, reducing delays, and enabling better public oversight. The current lack of transparency in the patent examination process can result in distrust and inefficiencies, hindering public access to information. The proposed reforms in this area are as follows:

i. Real-Time Updates on Patent Applications: Develop an online dashboard that provides real-time updates on pharmaceutical patent applications, opposition proceedings, and examination reports. This will make it easier for stakeholders to track patent decisions and intervene if necessary.

ii. Public Access to Examination Documents: Ensure that all examination documents, including claim amendments, expert submissions, and test data, are made publicly available. This

would allow civil society organizations, generic manufacturers, and public health experts to monitor the patent process and provide feedback when necessary.

These digital measures would enhance the transparency and accountability of the patent examination process, facilitating external scrutiny and public participation.

By implementing these reforms, India can significantly improve the quality, fairness, and transparency of its patent examination system. Strengthening Sec. 3(d) will prevent the evergreening of patents and reduce monopolization of essential medicines, ensuring that the public health objectives of affordability and access are not compromised in the pursuit of patent protection.

5.3. ESTABLISH SPECIALIZED IP BENCHES

The increasing complexity of patent litigation, particularly in the fields of pharmaceuticals and biotechnology, requires judicial expertise that goes beyond conventional legal training. This need became more pronounced following the dissolution of the Intellectual Property Appellate Board (IPAB)[172] in 2021, which had been responsible for adjudicating specialized IP disputes. In its absence, High Courts have assumed responsibility for IP cases, but the lack of specialized judicial expertise continues to create challenges in the accurate and timely resolution of such disputes.

Recommendations for Establishing Specialized IP Benches:

- Constitution of Dedicated IP Benches: Specialized IP benches should be established in High Courts that have jurisdiction over patent matters, whether original or appellate. These benches would consist of judges with specific training and expertise in intellectual property law, including technical disciplines like pharmacology, biochemistry, and public health. At present, the High Courts of Madras, Delhi, Bombay and Calcutta have original jurisdictions in all Intellectual Property related matters.
- Technical Advisory Support: Each IP bench should be supported by a team of technical advisors or scientific consultants. These experts would provide insights into complex technical issues that arise in patent cases, ensuring that judges have the necessary expertise to make informed decisions, especially in highly specialized areas such as pharmaceuticals and biotechnology.

[172] *Dissolution Notification*, IP India, https://ipindia.gov.in/writereaddata/Portal/News/728_1_Dissolution_notification_0001.pdf.

- Replicate the Commercial Courts Act Model: The model of the Commercial Courts Act, 2015, which mandates special training and continuing education for judicial officers handling commercial cases, could be adapted for IP litigation. This would ensure that judges stay abreast of emerging trends in IP law and technology and can handle the growing complexity of patent disputes efficiently. Currently, High Courts of Madras, Delhi and Bombay have dedicated Commercial Divisions and Commercial Appellate Divisions for the adjudication of IP Disputes.

By bringing ensuring that more High Courts around have a dedicated Intellectual Property Division for adjudication purposes, this reform would significantly reduce the backlog of patent cases, minimize errors in technical evaluations, and help maintain a focus on public health priorities in interpreting patent rights and by improving judicial efficiency and technical accuracy, these specialized benches would increase the consistency and fairness of IP adjudication.

5.4. NORMALIZE COMPULSORY LICENSING

India's legal framework permits compulsory licensing under Secs. 84 and 92 of the Patents Act, yet its invocation has been limited. The landmark case *Bayer Corp. v. Natco Pharma*[173] demonstrated the potential of compulsory licensing as a tool to enhance access to medicines, but subsequent reluctance to use this provision suggests that its full potential has not been realized. Recommendations for Normalizing Compulsory Licensing are as follows:

- Mainstream Compulsory Licensing: Compulsory licensing should be normalized as a routine policy tool, particularly for non-communicable diseases (NCDs) like cancer, diabetes, and cardiovascular conditions, where access to cost-effective treatment remains a significant barrier. This would ensure that patents are not an insurmountable obstacle to access, particularly for diseases with a high disease burden in India and other developing countries.
- Policy Clarification by DPIIT: The Department for Promotion of Industry and Internal Trade (DPIIT) should issue a policy notification clarifying that compulsory licensing should not be treated as an exceptional measure, but rather as a standard tool for public health protection. This would help reduce the stigma and hesitation surrounding compulsory licensing, particularly in cases involving pharmaceutical giants.
- Expedited Licensing for Emergencies: A streamlined, expedited licensing process should be introduced for public health emergencies, including pandemics, drug shortages, or other

[173] (2013) SCC OnLine IPAB 25.

crises where access to critical medicines is needed urgently. This process would allow quicker response times and mitigate delays in drug availability during emergencies.

These reforms would reduce institutional hesitance in utilizing compulsory licensing, helping India enhance its negotiating power with pharmaceutical companies while prioritizing public health needs.

5.5. EXPAND PARALLEL IMPORTATION

India's Sec. 107A(b) of the Patents Act allows for the importation of patented products from legally authorized sellers abroad. However, the application of this provision is currently underutilized and narrowly interpreted, particularly in relation to bulk procurement by public agencies. The following are the recommendations for expanding Parallel Importation and strengthening the current position:

- Amend Statutory Language: The statutory language should be amended to explicitly permit bulk parallel importation for public procurement programs, rather than limiting it to individual or small-scale use. This expansion would allow state agencies and public hospitals to procure cost-effective medicines in bulk from foreign markets.
- Regulatory Framework for Procurement: The Ministry of Health and Family Welfare should establish a regulatory framework that facilitates parallel importation of branded generics from authorized foreign sellers, particularly those WHO-prequalified sources in other developing countries. This would allow India to tap into international markets where lower-cost alternatives are available, thereby reducing costs without violating TRIPS obligations.
- Enhanced Coordination with Health Schemes: India’s National Health Mission (NHM) and Central Government Health Scheme (CGHS) should coordinate more closely to institutionalize this mechanism for essential and orphan drugs. This would ensure that lifesaving treatments are made available to the wider population at a lower cost, which could significantly impact health outcomes.

By expanding parallel importation, India can make critical medicines more cost-effective, while also ensuring that such practices comply with international legal frameworks, particularly the doctrine of international exhaustion.

5.6. STRENGTHENING OF THE NPPA

The National Pharmaceutical Pricing Authority (NPPA) plays a pivotal role in ensuring the affordability of essential medicines in India by enforcing price controls under the Drugs (Prices Control) Order (DPCO), 2013. However, the NPPA's authority over patented drugs remains limited, often reactive, and inadequately equipped to handle the challenges posed by pharmaceutical monopolies and rising drug prices. In order to enhance the effectiveness of the NPPA in regulating the cost of medicines and ensuring public health interests are safeguarded, a comprehensive approach to strengthening the NPPA is needed.

A. *Empower the NPPA to set prices for Patented Drugs*

Currently, the NPPA can regulate the prices of non-patented and essential medicines listed under the National List of Essential Medicines (NLEM) but lacks authority over patented drugs that may still be included in the NLEM. This gap leaves room for pharmaceutical companies to exploit patent exclusivity and market monopolies, driving up the cost of essential drugs, even when they are critical to public health. The recommendations are as follows:

- Grant Statutory Authority for Price Regulation: The NPPA should be granted explicit legal authority to set prices for patented drugs, particularly those included in the NLEM. By doing so, the NPPA can directly intervene in pricing for high-cost patented medicines that are vital to public health, ensuring their affordability.
- Price Ceiling Mechanisms for Patented Drugs: For patented drugs, the NPPA should establish price ceilings based on factors such as production cost, market benchmarks, and public health imperatives. By regulating prices, the NPPA can ensure that patients have access to life-saving treatments without the financial burden of inflated prices.
- Incorporating Affordability into Pricing Decisions: In addition to scientific and market considerations, the NPPA should integrate affordability as a primary criterion in its decision-making process. This would ensure that even high-cost medicines with patents remain within the financial reach of the general population, particularly in light of India's diverse socio-economic landscape.

By granting the NPPA the authority to regulate the prices of patented drugs, India can prevent the exploitation of intellectual property rights by pharmaceutical companies and ensure that patented drugs are cost-effective and accessible to all citizens.

B. *Predictive Pricing Surveillance*

The current pricing oversight by the NPPA is largely reactive, typically addressing price hikes after they have already impacted consumers. Given the global nature of the pharmaceutical market, with cross-border pricing disparities and rapidly changing market conditions, the NPPA requires a more proactive approach to prevent price escalation before it reaches unsustainable levels. The recommendations are as follows:

- Develop Digital Surveillance Systems: The NPPA should develop a digital surveillance system capable of monitoring pharmaceutical pricing trends in real time. This system would aggregate pricing data from multiple sources, including national markets, international price benchmarks, and industry trends, providing actionable insights for early intervention.
- Cross-Border Price Benchmarking: The NPPA should utilize cross-border price benchmarking to compare the prices of medicines in different countries, especially in similar economic contexts. This would allow for more informed pricing decisions and help detect discrepancies that could signal unjustified price increases in India.
- Real-Time Alerts for Price Anomalies: A real-time alert system should be implemented that automatically flags abnormal pricing behavior—such as sudden, large price increases or price inflation in medicines with limited competition—allowing the NPPA to take swift action before these increases impact consumers.

By establishing predictive pricing surveillance, the NPPA can stay ahead of pricing trends and take proactive measures to regulate prices before they become a barrier to access, particularly for essential medicines.

C. *Enhanced Penalty Enforcement*

A critical element of any pricing regulation system is the ability to enforce the established rules and penalize violations. Currently, the penalties for non-compliance with the NPPA's price controls are insufficient and often not enforced consistently, allowing pharmaceutical companies to flout the regulations without facing significant consequences. Strengthening the NPPA's enforcement mechanisms will enhance its ability to uphold price ceilings and deter companies from exploiting pricing loopholes. The recommendations are as follows:

- Increase Penalty Severity: Penalties for non-compliance should be significantly strengthened to act as a deterrent against price violations. The NPPA should have the authority to impose

hefty fines, criminal charges, or other sanctions on companies that persistently violate price ceilings.

- Automatic Prosecution or Debarment Mechanisms: Implement automatic prosecution or debarment mechanisms for companies that repeatedly violate price ceilings or engage in other anti-competitive practices. This could involve suspending the company's ability to participate in public procurement programs or seeking judicial action to recover excess profits made from inflated prices.
- Transparent Enforcement Practices: The NPPA should publish regular, detailed reports on enforcement actions taken, penalties imposed, and companies penalized. This would increase transparency, reassure the public of the NPPA's commitment to enforcing price controls, and serve as a deterrent to companies considering price hikes.

By strengthening the NPPA's authority to regulate the prices of patented drugs, implementing predictive pricing surveillance systems, and enhancing penalty enforcement mechanisms, India can build a more robust and proactive framework for drug pricing regulation. These reforms would ensure that pharmaceutical companies cannot exploit patent exclusivity to inflate prices and would promote greater affordability, accessibility, and transparency in the pricing of essential medicines. A more empowered NPPA will not only reduce monopolistic practices but will also contribute significantly to India's overarching goal of universal healthcare access.

5.7. LEAD GLOBAL TRIPS REFORMS

India's strategic position as both a pharmaceutical hub and a developing nation gives it a unique opportunity to advocate for global reforms in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. The COVID-19 pandemic has underscored the stark inequalities in global access to vaccines and medicines, highlighting the need for more flexible IP rules that prioritize public health over private commercial interests. The TRIPS waiver debate, which allowed for the temporary suspension of certain IP protections for COVID-19 vaccines and treatments, was a pivotal moment in global health diplomacy. However, this waiver was limited in scope and duration. India must seize this moment to lead a broader push for reforming the TRIPS framework in ways that better serve the public health needs of developing countries.

The following are the recommendations for the reforms that can be proposed for the betterment of the TRIPS Agreement:

- Advocate for a Permanent TRIPS Waiver Mechanism for Health Emergencies: India should take the lead in advocating for a permanent TRIPS waiver mechanism for essential medicines, vaccines, and diagnostics during health emergencies. The temporary waiver granted during the COVID-19 pandemic demonstrated that IP protections could be set aside in times of crisis to allow for widespread access to critical health interventions. India should push for a permanent provision under the World Trade Organization (WTO) that allows developing countries to override IP protections during health emergencies, thus ensuring that medicines and vaccines can be produced and distributed at scale without barriers posed by patent exclusivities.

- Develop Flexibility Templates for TRIPS Compliance: India has already demonstrated its capacity to reconcile TRIPS compliance with public health needs through provisions like Sec. 3(d) of the Patents Act and the use of compulsory licensing. India should advocate for the development of flexibility templates that other developing countries can incorporate into their national IP laws. These templates would be based on India's own legal precedents and would serve as models for other countries seeking to align their patent laws with public health objectives, providing a legal framework that balances patent rights with access to cost-effective medicines.

- Strengthen South-South Cooperation: India's leadership in global IP negotiations can be further strengthened by deepening South-South cooperation. India should work to build coalitions with other developing countries—such as Brazil, South Africa, and Argentina—to create a consortium for fairer patent norms. This coalition could act as a collective bargaining group to challenge TRIPS-plus provisions in bilateral and plurilateral agreements, which often place undue pressure on developing countries to adopt stricter IP rules that hinder access to cost-effective medicines. By pooling legal, diplomatic, and technical resources, the Global South can better advocate for a reformed international IP regime that prioritizes public health and equity.

- Reform TRIPS in Favor of Public Health: India should also work to reform the TRIPS agreement itself, advocating for provisions that offer developing countries more flexibility to protect public health. One area to focus on is the Article 31 of TRIPS, which provides for compulsory licensing, but under strict conditions. India could push for reforms that make it easier for countries to invoke compulsory licensing in response to public health needs, without being subjected to long and costly legal battles or retaliation from pharmaceutical companies. Additionally, the Doha Declaration on TRIPS and Public Health (2001), which

affirmed the right of countries to safeguard public health, could be used as a basis to push for broader reform within the WTO to ensure that health priorities are enshrined in the TRIPS framework.

- Empower Developing Countries through Technical Assistance: India should expand its role as a provider of technical assistance to other developing countries in the area of intellectual property reform. By offering expertise in drafting and implementing IP laws that balance innovation and public health, India can help other countries navigate the complexities of TRIPS compliance while ensuring that their public health systems remain robust. This assistance could be provided through regional forums, multilateral platforms such as the South Centre, and partnerships with global organizations like the WHO and UNDP.

India's efforts to lead TRIPS reform would not only benefit its own domestic policy but also help create a more equitable global IP framework. By championing these reforms, India can continue to be a force for positive change, both regionally and globally, ensuring that public health is prioritized over profit-driven patent policies.

5.8. INSTITUTIONALIZE EQUITY IMPACT ASSESSMENTS

Intellectual property policy in India must be rigorously aligned with the constitutional principles of social justice and the right to health. While intellectual property (IP) law traditionally focuses on protecting the interests of innovators and rights holders, it is equally crucial to assess how IP laws impact public health, particularly the affordability and accessibility of medicines. As a part of this, the introduction of Equity Impact Assessments (EIA) could provide a systematic approach to evaluating the social, economic, and health impacts of pharmaceutical patents, especially in relation to vulnerable populations. EIAs would scrutinize how a new pharmaceutical patent could influence the availability, affordability, and accessibility of essential medicines for different segments of society. The recommendations for Institutionalizing EIAs are as follows:

- Mandatory Public Health Access Statement for Patent Applications: As part of the patent application process, applicants should be required to submit a Public Health Access Statement. This statement would disclose the potential impact of the patent on the availability, affordability, and access to the drug or treatment in question. For example, the statement could include an analysis of how the patent could affect the pricing of essential medicines, particularly those needed for common diseases, such as cancer, diabetes, and

infectious diseases like HIV/AIDS and tuberculosis. By requiring this disclosure upfront, the government would better understand the broader social implications of granting patents.

- Establish a Multi-Sectoral Advisory Body for EIA Review: A multi-sectoral advisory body should be set up to review and assess the Equity Impact Assessment (EIA) during the patent grant process. This body could consist of experts from various fields, including public health, human rights, economics, patient advocacy, and health policy. The role of this advisory body would be to assess how a particular pharmaceutical patent aligns with the principles of health equity and whether it could unduly burden low-income or marginalized communities. It would also be tasked with recommending policy actions, such as the potential need for compulsory licensing, price controls, or inclusion in public procurement schemes.
- Link EIA Findings to Policy Decisions: The findings of the EIA should be closely linked to policy decisions regarding pricing, licensing, and procurement. For example, if an EIA reveals that a patent would have a negative impact on public health access (e.g., through excessive pricing), the government could trigger interventions such as price ceilings, compulsory licensing, or the inclusion of the drug in national public procurement programs. This could also help identify drugs that could be included in national health schemes or be prioritized for state-sponsored access programs, thereby ensuring that essential treatments are available to the most vulnerable populations.
- Monitor and Evaluate the Impact of Patents Over Time: In addition to an initial EIA during the patent application process, there should be ongoing monitoring and evaluation of the impact of patents on access to medicines. This could include tracking the market prices of patented drugs, evaluating patient access in terms of geographic and socioeconomic disparities, and assessing any emerging public health concerns related to the patent. Regular reviews would help ensure that patents continue to align with public health objectives and do not unduly restrict access to necessary treatments.
- Promote Public Participation in EIA Process: To ensure that the EIA process is transparent and inclusive, there should be mechanisms for public participation. Patients, civil society organizations, health professionals, and other stakeholders should be allowed to submit comments and recommendations regarding the potential impacts of pharmaceutical patents on public health. This would ensure that the voices of affected communities are heard and that policy decisions reflect the diverse needs of society.

By institutionalizing Equity Impact Assessments, India can ensure that the country's IP laws serve the broader public good. This approach would align intellectual property policy with constitutional rights to health and social justice, preventing the undue harm caused by patents on essential medicines while maintaining an environment that incentivizes innovation. The incorporation of EIAs into the patent system would lead to more equitable health outcomes and enhance India's role as a leader in global health and human rights advocacy.

In conclusion, while India's patent regime has made commendable strides in harmonizing its international obligations under the TRIPS Agreement with domestic public health imperatives, the evolving biomedical and pharmaceutical landscape necessitates a robust, future-facing reform agenda. The recommendations presented herein are not merely aspirational, but vital steps toward deepening the constitutional promise of the right to health under Art. 21. Codifying this right into statutory law, strengthening Sec. 3(d), institutionalizing transparency, and building technical and judicial capacity are crucial to insulating India's patent framework from the encroaching pressures of TRIPS-plus obligations and pharmaceutical monopolies. Equally, enhancing the role of the NPPA, normalizing compulsory licensing, and expanding parallel importation will ensure that market exclusivities do not become instruments of exclusion. By establishing specialized IP benches and embedding equity impact assessments into the patent system, India can not only secure affordable access to essential medicines but also emerge as a principled leader in shaping global discourse on health-sensitive intellectual property governance. These reforms, taken together, aim to transform legal text into tangible health equity, reinforcing the core tenet that innovation must ultimately serve the public good.

CHAPTER - 6: CONCLUSION

6.1. FINDINGS

This dissertation has critically examined the intricate relationship between biomedical patent protection and access to cost-effective medicines in India within the context of the TRIPS Agreement. By employing a doctrinal research methodology, this study analyzed Indian legislative provisions, case law, and international legal frameworks to assess how India's legal infrastructure safeguards public health without compromising its international obligations.

The findings highlight the pivotal role of India's post-TRIPS patent regime, with particular focus on Sec. 3(d) of the Patents Act. Sec. 3(d) has emerged as a critical safeguard against the misuse of patent monopolies, particularly the practice of evergreening, which hinders access to generics by prolonging patent life on marginal innovations. The *Novartis AG v. Union of India*[174] case, a landmark decision, reinforced India's legal capacity to reject patents that do not meet the required standard of innovation, setting a global precedent for balancing intellectual property rights with public health needs. Additionally, India's use of compulsory licensing—exemplified in the *Bayer Corp. v. Natco Pharma*[175] case—has shown the potential of TRIPS flexibilities in providing cost-effective access to life-saving medicines. These milestones underscore India's commitment to securing the right to health while complying with international IP norms.

However, despite these significant achievements, several challenges remain. The Indian Patent Office suffers from critical issues such as inadequate examiner training and ambiguity in the application of Sec. 3(d), which can result in inconsistent patent grants and rejections. The dissolution of the Intellectual Property Appellate Board (IPAB) in 2021 has further exacerbated delays in adjudicating patent disputes, placing additional strain on High Courts that lack specialized knowledge in technical areas of intellectual property. Moreover, compulsory licensing, while an essential tool, remains underutilized, often hindered by political pressures, procedural hurdles, and a reluctance to fully embrace this mechanism as a standard public health tool. While the National Pharmaceutical Pricing Authority (NPPA) plays a crucial role in regulating drug prices, its effectiveness is curtailed by limited authority over patented drugs and the lack of a comprehensive, predictive pricing model.

The dissertation also critically evaluates India's role in international intellectual property diplomacy, especially in light of the COVID-19 pandemic. India's leadership in advocating for a

[174] (2013) 6 SCC 1.
[175] (2013) SCC OnLine IPAB 25.

TRIPS waiver at the World Trade Organization (WTO) was a significant step in reframing global IP norms through the lens of public health. However, while this initiative was pivotal, it underscored the need for India to enhance coalition-building within the Global South and institutionalize long-term diplomatic strategies that prioritize health equity over rigid intellectual property protections.

In response to these findings, this dissertation proposes a multi-faceted reform agenda aimed at strengthening India's IP framework and global advocacy. Legislative amendments are necessary to clarify patentability standards and broaden the scope of Secs. 3(d), 84, and 107A to ensure that the legal framework more robustly protects public health. Institutional reforms should include the establishment of specialized IP benches in High Courts, enhanced examiner training, and empowering the NPPA to regulate the prices of patented drugs more effectively. At the global level, India must continue its advocacy for a TRIPS waiver mechanism for health emergencies and lead efforts to ensure that TRIPS flexibilities are more widely available to developing countries. Furthermore, an ethical reorientation of IP governance is essential, including the introduction of Equity Impact Assessments (EIA) for new pharmaceutical patents to ensure that the balance between innovation and accessibility remains just and equitable.

6.2. FUTURE RESEARCH DIRECTIONS

The findings of this dissertation open several avenues for future research that could further inform India's patent law reforms and global IP negotiations:

a. The Impact of TRIPS-plus Agreements and Free Trade Agreements (FTAs): Future studies should explore the implications of TRIPS-plus provisions in FTAs on India's access-oriented IP framework. These agreements often impose stricter patent standards, which can undermine the public health safeguards enshrined in India's domestic laws. Understanding these impacts could help India develop strategies to navigate these agreements without compromising access to medicines.

b. The Role of Data Exclusivity and Biologics: As India's pharmaceutical industry evolves, data exclusivity and biologics—which are increasingly becoming part of global patenting trends—will present new challenges. Further research on how these emerging trends will affect India's IP policy, especially regarding the protection of life-saving biologic drugs, is needed.

c. Empirical Studies on Patent Reforms and Access to Medicines: Empirical studies that analyze the real-world impact of patent reforms on access to medicines in rural and economically marginalized populations would provide valuable insights. Research could track how patent policy changes influence medicine prices and the availability of generics, particularly for essential medicines like cancer drugs, HIV/AIDS treatments, and vaccines.

d. Comparative Studies on Patent Law and Public Health Outcomes: Comparative studies examining the relationship between patent law and public health outcomes in other developing countries, especially within the Global South, could provide valuable lessons for India. By learning from the experiences of countries that have implemented similar patent laws, India can refine its policies and contribute to global health equity.

6.3. FINAL THOUGHTS

India's intellectual property regime is at a decisive crossroads, as the country confronts the delicate task of balancing the promotion of innovation in the pharmaceutical sector with the imperative of ensuring that life-saving medicines remain cost-effective and accessible to its population. This dissertation underscores the importance of continuing to refine India's legal framework, enhancing its global diplomatic efforts, and integrating equity as a foundational principle in intellectual property regulation. However, it also emphasizes that these legal and policy decisions come with profound moral and ethical responsibilities that must be considered alongside the technical and economic dimensions of patent law.

The primary ethical responsibility that India faces lies in its role as a steward of public health. The right to health, as enshrined under Art. 21 of the Indian Constitution, is a fundamental human right that cannot be subordinated to market-driven pharmaceutical interests. India, as the world's largest producer of generic medicines, holds a unique position in the global landscape. It has the moral responsibility to ensure that this crucial role in global healthcare does not become compromised by the pursuit of profit-driven innovations, particularly in light of the vast inequalities in access to healthcare faced by millions of its citizens.

The reforms discussed in this dissertation—such as the establishment of specialized IP benches, the expansion of compulsory licensing, the strengthening of the NPPA, and the introduction of Equity Impact Assessments (EIAs)—are not mere technical or legal requirements. They reflect moral imperatives that align India's intellectual property framework with its constitutional commitment to social justice and equity. These reforms are necessary to ensure that patent law

does not function solely to protect corporate monopolies but also serves the public interest by making medicines accessible to the most vulnerable populations.

6.4. MORAL AND ETHICAL RESPONSIBILITIES IN DOMESTIC LAW

At the domestic level, India's intellectual property laws should prioritize public health over corporate profits. The use of TRIPS flexibilities, such as compulsory licensing, and the creation of provisions like Sec. 3(d) of the Patents Act, which curtails the patenting of incremental innovations (i.e., evergreening), must be seen as necessary legal tools for promoting public health. Compulsory licensing, while legally permissible under India's domestic framework, should be mainstreamed as a routine policy tool, particularly for treating non-communicable diseases (NCDs) like cancer, diabetes, and cardiovascular conditions. The ethical argument here is that access to life-saving medicines should not be dictated by pricing monopolies imposed by patent holders, but by the collective public good.

The moral responsibility embedded in patent law is to ensure that patent rights do not disproportionately harm vulnerable communities by making essential medicines expensive. By actively using compulsory licensing, India can challenge the ethical dilemma posed by patents that restrict access to life-saving drugs. The *Bayer Corp. v. Natco Pharma*[176] case in 2012 illustrated this principle—India's legal courage in issuing a compulsory license to produce a generic version of the cancer drug Sorafenib was not merely a legal victory, but a moral triumph for public health. Such landmark decisions reflect India's commitment to ensuring that life-saving treatment is not confined to the wealthy or those in high-income countries but remains accessible to those who need it most, regardless of economic status.

6.5. INDIA'S GLOBAL MORAL RESPONSIBILITY

India's role in the international community also carries significant moral and ethical weight. As a leading global producer of generic medicines and a developing nation, India has a unique moral responsibility to advocate for reform in the global intellectual property system, particularly under the TRIPS Agreement. The global IP regime, as it stands, often prioritizes the interests of multinational pharmaceutical companies over the needs of developing nations, where access to cost-effective medicines is a matter of life and death.

India's advocacy for a TRIPS waiver at the World Trade Organization (WTO) during the COVID-19 pandemic is a critical example of its leadership in global health diplomacy. This

[176] (2013) SCC OnLine IPAB 25.

moral leadership extended beyond national interests to call for greater flexibility in the TRIPS framework—one that would allow countries to temporarily waive patent protections for essential medicines, vaccines, and diagnostics during health emergencies. Such actions underscore the ethical principle that human health and dignity should not be subjugated to the intellectual property regime or the pursuit of profits.

The ethical responsibility in global IP negotiations is also to ensure that pharmaceutical monopolies do not hold the world's most vulnerable populations hostage. India has the moral obligation to lead efforts for global patent reform that ensure equity and accessibility remain at the forefront. As a member of the Global South, India's voice is crucial in shaping the international IP landscape. It must advocate for policies that ensure access to essential medicines for all, regardless of a country's economic status, and ensure that health is prioritized over private patent monopolies.

India's leadership in global IP governance can serve as a beacon for other nations, especially those in the Global South, to follow. The South-South cooperation that India is fostering through its diplomatic efforts is an ethical commitment to ensure that developing countries have access to the same legal tools that India has used successfully to protect public health. By championing global IP reforms based on equity, India can create a collective voice for the Global South that demands a more just and inclusive global IP system.

6.6. PATH FORWARD: ETHICAL REORIENTATION

The reforms proposed in this dissertation are not merely technical adjustments—they are a reflection of an ethical reorientation of intellectual property law. Equity Impact Assessments (EIAs) should be institutionalized to scrutinize how pharmaceutical patents will impact the availability and affordability of medicines, particularly for economically marginalized populations. The goal is to ensure that the moral and ethical values of equity, justice, and access to healthcare are embedded in India's IP system, ensuring that patents serve the public interest rather than corporate monopolies.

This rights-based approach to patent law would ensure that India's intellectual property system aligns with its constitutional commitment to social justice and public health. The moral responsibility is to ensure that intellectual property laws do not merely protect the right of inventors and corporations to profit from innovation, but that they serve the greater good of society by facilitating access to essential healthcare.

India stands at a critical juncture in its intellectual property journey. Its legal and diplomatic efforts must reflect a deep moral responsibility to prioritize public health over corporate interests, both domestically and globally. By continuing to refine its legal framework, expanding its diplomatic influence, and embracing an equity-driven approach to intellectual property, India can set a global example of how to ensure that access to essential medicines is treated as a human right and not a commodity.

The reforms proposed in this dissertation reflect the moral and ethical obligations that India faces in its role as a global leader. These reforms are not simply legal or technical necessities—they are a moral imperative that aims to ensure equitable access to medicines for all people, regardless of their socio-economic status or geographical location. India's role as a norm entrepreneur in global IP governance offers an opportunity to shape a more just, equitable, and humane global IP system—one where human rights and access to life-saving medicines are not sacrificed for the sake of corporate profit.

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APPENDIX

1) Table 1: Comparative Analysis of Access-Oriented Patent Policies (India, Brazil, South Africa, Thailand, U.S.)
2) Table 2: Acts and Compliance with TRIPS

APPENDIX

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CERTIFICATE ON PLAGIARISM CHECK

1.	Name of the Candidate	Mr. Anirudh Kumar
2.	Title of Dissertation	Impact of Biomedical Patents and TRIPS on Medicine Affordability in India
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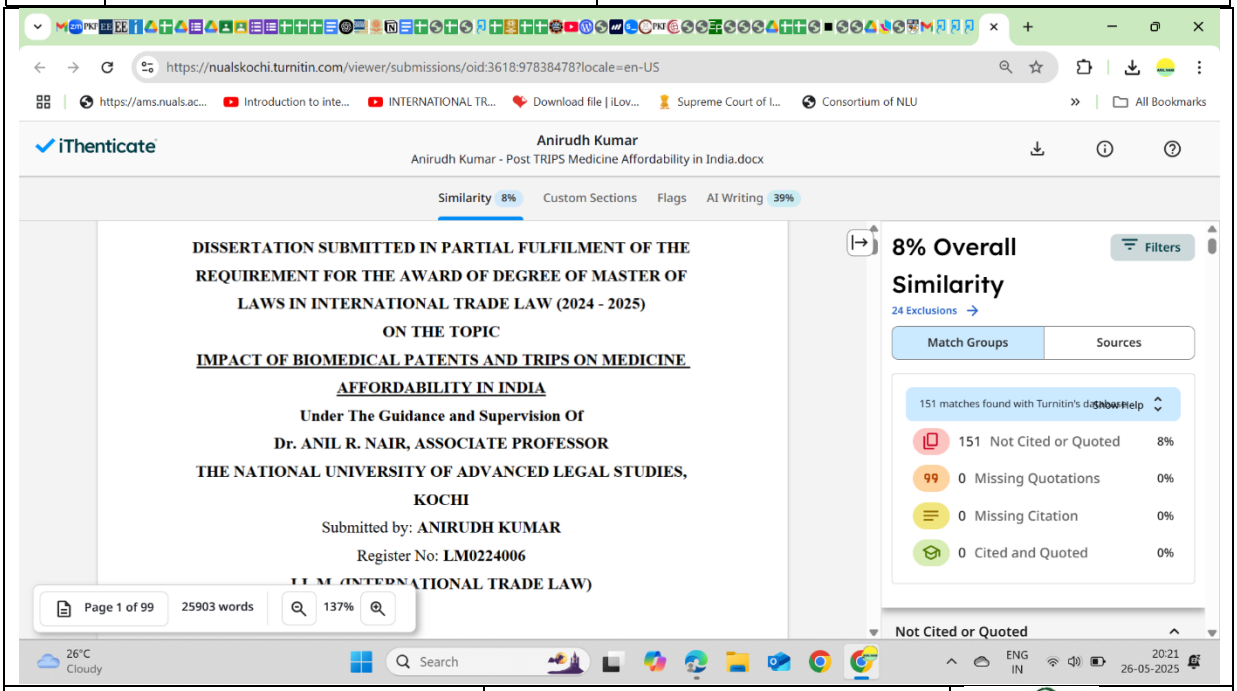

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