THE NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES, KOCHI

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

ON THE TOPIC

CHALLENGES IN CROSS BORDER PATENT ENFORCEMENT: WITH SPECIAL REFERENCE TO THE PHARMACEUTICAL INDUSTRY

Under the Guidance and Supervision of

Dr. Athira P. S.

Assistant Professor

The National University of Advanced Legal Studies

Submitted by

Shimleel I. Thaiv

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CERTIFICATE

This is to certify that **Mr. SHIMLEEL I. THAIV**, Reg. No. **LM0224019** has submitted his Dissertation titled **"CHALLENGES IN CROSS BORDER PATENT ENFORCEMENT: WITH SPECIAL REFERENCE TO THE PHARMACEUTICAL INDUSTRY"**, in partial fulfilment of the requirement for the award of Degree of 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 him in original, bona fide and genuine.

Date: 28.05.2025
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DECLARATION

I declare that this dissertation titled, **"CHALLENGES IN CROSS BORDER PATENT ENFORCEMENT: WITH SPECIAL REFERENCE TO THE PHARMACEUTICAL INDUSTRY"** researched and submitted by me to the National University of Advanced Legal Studies, Kochi 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. ATHIRA P.S** is an original, bona fide work and it has been pursued for academic purposes. This work or any part 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: 28.05.2025
Place: Kochi

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PREFACE

This dissertation is the culmination of a year-long academic journey undertaken as part of the Master of Laws (LL.M.) program in International Trade Law at the National University of Advanced Legal Studies (NUALS), Kochi. It reflects a deep engagement with the pressing legal and policy challenges surrounding the enforcement of pharmaceutical patents in an increasingly globalized world.

The topic **"Challenges in Cross Border Patent Enforcement: With Special Reference to the Pharmaceutical Industry"** was chosen with a view to addressing one of the most complex intersections of international trade, public health, and intellectual property law. The pharmaceutical sector, being central to innovation and public welfare, presents unique legal dilemmas, particularly in developing economies like India. As cross-border transactions become the norm in pharmaceutical commerce, the absence of a harmonized international enforcement mechanism raises critical concerns about both innovation incentives and access to medicines.

This work attempts to bridge theory and practice by combining doctrinal legal analysis with comparative and policy-oriented perspectives. It draws upon Indian jurisprudence, international treaties such as TRIPS, and enforcement experiences in jurisdictions like the United States, European Union, and China. Particular attention is paid to India's unique position as a leading exporter of generic medicines and its balancing act between compliance with international obligations and domestic public health imperatives.

The research encapsulated in this dissertation owes much to the guidance and inspiration received throughout my academic journey. It is with a sense of humility and responsibility that I present this work-not merely as an academic exercise but as a small contribution to the evolving discourse on intellectual property law and equitable access to healthcare.

I hope this dissertation serves as a meaningful addition to the scholarship in this domain and provides a foundation for further inquiry and reform in cross-border patent enforcement.

LIST OF ABBREVIATIONS

Abbreviations	Definition
AG	Aktiengesellschaft (a German term for a corporation limited by shares)
AI	Artificial Intelligence
AIDS	Acquired Immunodeficiency Syndrome
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Organization
BRICS	Brazil, Russia, India, China, and South Africa
CBP	Customs and Border Protection (U.S.)
CJEU	Court of Justice of the European Union
COVAX	COVID-19 Vaccines Global Access Facility
COVID	Coronavirus Disease
DCGI	Drugs Controller General of India
DSB	Dispute Settlement Body (of the WTO)
EAPO	Eurasian Patent Organization
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FDA	Food and Drug Administration
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
INTERPOL	International Criminal Police Organization
ION	ION Geophysical Corporation
IP	Intellectual Property
IPAB	Intellectual Property Appellate Board
IPR	Intellectual Property Rights

ITC	International Trade Commission (U.S.)
OAPI	Organisation Africaine de la Propriété Intellectuelle
PCT	Patent Cooperation Treaty
SCC	Supreme Court Cases
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UPC	Unified Patent Court
US	United States
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CASES

1. *Novartis AG v. Union of India*, (2013) 6 SCC 1 (India).
2. *Bayer Corp. v. Union of India*, (2009) 41 PTC 634 (Del) (India).
3. *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory License Decision, Controller of Patents, India (2012).
4. *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, (2009) 40 PTC 125 (Del) (India).
5. *Merck Sharp & Dohme Corp. v. Glenmark Pharms. Ltd.*, (2015) 62 PTC 257 (Del) (India).
6. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972) (U.S.).
7. *WesternGeco LLC v. ION Geophysical Corp.*, 585 U.S. __ (2018) (U.S.).
8. *Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872 (9th Cir. 2012) (U.S.).
9. *Voda v. Cordis Corp.*, 476 F.3d 887 (Fed. Cir. 2007) (U.S.).
10. *Modi Entm't Network v. WSG Cricket Pte. Ltd.*, (2003) 4 SCC 341 (India).
11. *Huawei Techs. Co. v. Conversant Wireless Licensing SARL*, Supreme People's Court (China), 2019 (Anti-suit injunction case).
12. *Mittelbayerische v. Bayerische*, Case C-616/20, Judgment of the CJEU (2022).
13. *eBay Inc. v. MercExchange*, L.L.C., 547 U.S. 388 (2006).

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION

1.1 Introduction and Background

Patents are the cornerstone of innovation in the pharmaceutical industry, granting inventors exclusive rights to recoup the immense investments required for drug development.[1] While this system is intended to reward innovation, the global nature of pharmaceutical markets exposes a fundamental tension: patents are inherently territorial, enforceable only within the jurisdiction of grant.[2] There is no "world patent"; protection must be secured and enforced country by country, or through limited regional systems.[3] As the World Intellectual Property Organization notes, "patents are territorial rights, which means an invention is protected only in the countries or regions where a patent has been granted."[4]

This territoriality, once less problematic in an era of localized markets, now collides with the reality of transnational pharmaceutical supply chains. A single medicine may be invented in the United States, clinically tested in the European Union, manufactured in India or China, and sold worldwide.[5] Patent holders must therefore navigate a patchwork of national laws, often facing inconsistent outcomes and duplicative litigation.[6] The Paris Convention for the Protection of Industrial Property codifies the principle of national independence of patents, meaning that the grant or refusal of a patent in one country has no bearing on its status elsewhere.[7] This leads to divergent results, such as the anti-cancer drug imatinib (Gleevec) being patented in many countries but denied in India on public-interest grounds.[8]

Enforcement challenges are compounded when alleged infringement spans borders-for example, when manufacturing occurs in one country and export or sale in another. Courts are generally reluctant to adjudicate foreign patent rights, and most countries limit the reach of their patent statutes to domestic acts.[9] The result is a fragmented

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[1] Dreyfuss, Rochelle. The Costs of Cross-Border Patent Enforcement, 25 Fordham Intell. Prop. Media & Ent. L.J. 817, 820 (2015)

[2] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305

[3] Id

[4] World Intellectual Property Organization, What is a Patent?, WIPO Publication No. 450(E), at 4 (2020).

[5] Indian Patent Office, Annual Report 2022–23, at 17–19

[6] Shamnad Basheer & T. Prashant Reddy, The 'Indirect Infringement' Conundrum in Indian Patent Law, 14 J. Intell. Prop. L. & Prac. 1032, 1034–36 (2019)

[7] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305.

[8] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

[9] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972).

enforcement landscape, with patent holders and generic manufacturers alike facing uncertainty and complexity.

Recent years have seen incremental progress in bridging this gap, particularly in the European Union. The creation of the Unified Patent Court (UPC) and the EU unitary patent, effective June 2023, allows for centralized litigation and enforcement across multiple EU member states.[10] However, these innovations remain geographically confined and do not eliminate the fundamental territoriality of patent rights.

In sum, the pharmaceutical industry's globalized nature stands in stark contrast to the national boundaries of patent enforcement, setting the stage for the challenges and debates explored in this dissertation.

1.2 Statement of the Problem

This dissertation addresses the persistent challenge of enforcing patent rights across national borders, with a particular focus on the pharmaceutical sector. Although pharmaceutical commerce is inherently global, patent enforcement remains fundamentally territorial.[11] This disconnect gives rise to a series of legal and practical difficulties for patent holders, generic manufacturers, courts, and policymakers.

First, the lack of a unified international enforcement forum means that patent owners must litigate separately in each country where infringement is alleged.[12] This not only multiplies litigation costs and delays but also results in inconsistent outcomes: a patent may be upheld as valid and infringed in one jurisdiction, yet invalidated or unenforced in another.[13] The imatinib (Gleevec) case is illustrative-while the patent was enforceable in the United States and European Union, it was denied in India, enabling Indian firms to produce generics that might infringe abroad.[14] Such inconsistencies encourage strategic forum shopping and prolong legal uncertainty.

Second, cross-border enforcement raises complex jurisdictional and procedural hurdles. Courts generally limit their authority to acts occurring within their territory and are reluctant to enforce foreign patent judgments with extraterritorial reach.[15] As a result, even a favourable ruling in one country does not guarantee relief elsewhere, and

[10] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[11] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305.
[12] Supra note 1
[13] Id
[14] Novartis AG v. Union of India, (2013) 6 SCC 1 (India)
[15] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972).

monetary damages or injunctions may not be recognized or enforced abroad.[16] Treaties like the Hague Judgments Convention further complicate matters by excluding intellectual property from their scope.[17]

Third, substantive differences in national patent laws and remedies exacerbate the problem. What qualifies as patentable or infringing in one country may not in another.[18] India's Section 3(d) of the Patents Act, for example, sets a higher bar for pharmaceutical patentability, while other countries may have broader compulsory licensing or research exemptions.[19] Enforcement strength also varies: some jurisdictions grant automatic injunctions for infringement, while others, such as India and the U.S. after *eBay v. MercExchange*, may limit injunctive relief to protect public health.[20]

Finally, these enforcement challenges have significant implications for public health and equity. Strong patent enforcement can impede the flow of affordable generics to low-income populations, while weak enforcement may undermine innovation incentives.[21] The global nature of pharmaceutical supply chains and divergent national exhaustion doctrines further complicate access to medicines and raise normative questions about the proper scope of patent rights.

In sum, the absence of a coherent and effective cross-border enforcement mechanism leaves patent holders navigating a fragmented system that often fails to provide timely or adequate protection, while also risking barriers to equitable access to medicines. This dissertation investigates these doctrinal, practical, and policy challenges, seeking pathways for reform and international cooperation.

1.3 Literature Review

The territorial nature of patent rights and the resulting challenges in cross-border enforcement have been the subject of extensive scholarly and legal analysis. The foundational principle that "patents are territorial rights" is well established in both international treaties and national laws, with the Paris Convention for the Protection of Industrial Property codifying the independence of patents granted in different

[16] Id
[17] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.
[18] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970).
[19] Id
[20] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).
[21] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317, 319–20 (2005).

countries.[22] Scholars have emphasized that this principle, while historically effective in less integrated markets, now creates significant friction in the context of globalized pharmaceutical innovation and trade.[23]

Territoriality and Its Implications

Early analyses, such as those by Bodenhausen and Cornish, underscore that the territorial limitation of patents was originally designed to respect national sovereignty and accommodate divergent policy priorities.[24] However, as Grosse Ruse-Khan notes, the globalization of pharmaceutical research, manufacturing, and distribution has exposed the inadequacy of purely national enforcement mechanisms.[25] The literature documents numerous instances where the same pharmaceutical patent is found valid and infringed in one jurisdiction but invalid or unenforceable in another, leading to legal uncertainty for both originator and generic companies.[26]

Cross-Border Enforcement: Judicial and Legislative Responses

Legal scholars have examined the difficulties patent holders face in pursuing infringers operating across multiple jurisdictions.[27] As summarized by Trimble, the lack of a "world patent" or international enforcement tribunal means that patent owners must initiate parallel litigation in each country where protection is sought.[28] This fragmentation is not only costly but also results in inconsistent judicial outcomes, as national courts apply their own laws and procedures.[29]

Recent years have seen courts and legislators' experiment with doctrines aimed at mitigating the rigidity of territoriality. For example, U.S. law was amended after the Supreme Court's decision in Deepsouth Packing Co. v. Laitram Corp. to extend liability for supplying components from the United States for assembly abroad.[30] Similarly, the U.S. Supreme Court in WesternGeco LLC v. ION Geophysical Corp. allowed for the

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[22] Paris Convention for the Protection of Industrial Property art. 4bis, Mar. 20, 1883, as revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305

[23] Rochelle C. Dreyfuss, The Territoriality of Patent Law, 19 Berkeley Tech. L.J. 753, 755–56 (2004)

[24] G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property 13–14 (1968); William R. Cornish, Intellectual Property: Patents, Copyright, Trademarks and Allied Rights 317–18 (8th ed. 2013).

[25] Henning Grosse Ruse-Khan, The Protection of Intellectual Property in International Law 236–39 (2016).

[26] Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. Int'l Econ. L. 469, 472–74 (2002).

[27] Graeme B. Dinwoodie, International Intellectual Property Litigation: A Vehicle for Reshaping Territoriality, 23 Fordham Int'l L.J. 1181, 1184–87 (2000).

[28] Marketa Trimble, Global Patents: Limits of Transnational Enforcement 27–31 (2012)

[29] Paul Torremans, Cross-Border Enforcement of Patent Rights, in Research Handbook on Cross-Border Enforcement of Intellectual Property 1, 3–6 (Paul Torremans ed., 2014).

[30] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972); 35 U.S.C. § 271(f).

recovery of foreign lost profits in certain circumstances, reflecting a willingness to address the extraterritorial effects of domestic infringement.[31] European legal scholarship has closely followed the development of the Unified Patent Court (UPC) and the EU unitary patent, noting that these innovations represent a significant, albeit regional, step toward supranational enforcement.[32]

International and Regional Harmonization Efforts

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been widely analysed for its role in harmonizing minimum standards of patent protection.[33] While TRIPS obligates members to provide effective enforcement mechanisms, it stops short of creating a cross-border enforcement process, leaving the task to national authorities.[34] The exclusion of intellectual property from the 2019 Hague Judgments Convention has been criticized in the literature as a missed opportunity to facilitate mutual recognition of patent judgments.[35]

Within the European Union, commentators such as Pila and Wadlow have highlighted the potential of the UPC to streamline enforcement and reduce the risk of divergent outcomes, although they caution that the system's effectiveness will depend on its uptake and the resolution of jurisdictional issues.[36] Outside Europe, the literature discusses tools such as Arrow declarations in the UK and anti-suit injunctions in the context of standard-essential patents as examples of courts grappling with transnational patent disputes.[37]

Pharmaceutical Industry Context

The pharmaceutical sector is frequently cited in the literature as a prime example of the challenges posed by territorial patent enforcement.[38] Studies by Sampat and Shadlen, as well as case analyses of disputes over drugs like imatinib (Gleevec), illustrate how public health considerations and national interests can lead to divergent patent

[31] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018)
[32] Justine Pila & Christopher Wadlow, The Unitary EU Patent System 105–09 (2015).
[33] 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.
[34] Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis 391–93 (4th ed. 2012).
[35] Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs, July 2, 1999, WIPO Pub. No. 227(E); see also Xandra Kramer, The Exclusion of IP from the Hague Judgments Convention, 16 J. Private Int'l L. 255, 256–58 (2020).
[36] Justine Pila & Christopher Wadlow, The Unitary EU Patent System 105–09 (2015)
[37] Lionel Bently et al., Intellectual Property Law 544–46 (6th ed. 2022)
[38] Bhaven N. Sampat & Kenneth C. Shadlen, Patent Politics: Life Sciences and Intellectual Property in Comparative Perspective 17–21 (2017).

outcomes.[39] The seizure of Indian generic medicines in transit through Europe has been the subject of both legal and policy critique, with scholars arguing that aggressive enforcement can undermine access to medicines and conflict with international trade norms.[40]

The literature thus reflects a consensus that the territoriality of patent rights, while foundational, is increasingly misaligned with the realities of global pharmaceutical markets.[41] While regional innovations such as the UPC offer partial solutions, the overall landscape remains fragmented, with significant implications for both innovation and access to medicines.

1.4 Objectives of the Study

This study sets out several interrelated objectives to address the problems outlined above:

1. To critically analyse the legal and practical challenges of enforcing pharmaceutical patents across national borders, with particular attention to how territoriality, jurisdictional limits, and divergent national laws impede effective and coherent enforcement.
2. To evaluate how current international, regional, and national legal frameworks address cross-border patent enforcement in the pharmaceutical sector, and to assess their impact on broader policy concerns such as access to medicines and public health.
3. To propose and assess potential legal and policy reforms-both domestic and international-that could improve the efficiency, fairness, and equity of cross-border pharmaceutical patent enforcement

1.5 Research Questions

To guide the inquiry, the dissertation is structured around several key research questions:

1. What are the principal legal and procedural challenges arising from the territorial enforcement of pharmaceutical patents in a globalized market?

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[39] Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act 2005, 1 Indian J. L. & Tech. 15, 19–21 (2005).
[40] Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 326–28 (2d ed. 2020).
[41] Rochelle C. Dreyfuss, The Territoriality of Patent Law, 19 Berkeley Tech. L.J. 753, 755–56 (2004).

2. How do inconsistencies in national patent enforcement frameworks affect innovation incentives and access to medicines?
3. What gaps exist in current international and regional frameworks for addressing cross-border patent disputes in the pharmaceutical sector?
4. What reforms could harmonize enforcement mechanisms while balancing patent protection and public health priorities?

1.6 Hypothesis

The fragmented nature of cross-border patent enforcement mechanisms creates significant legal and procedural challenges for the pharmaceutical industry, resulting in inefficiencies that hinder innovation and restrict equitable access to medicines.

1.7 Chapterization

Chapter 1: Introduction

This chapter introduces the theme of cross-border patent enforcement, highlights the problem statement, reviews the relevant literature, and outlines the research objectives, questions, and methodology.

Chapter 2: Cross-Border Patent Enforcement: Legal and Procedural Challenges

This chapter examines the principle of territoriality, the Indian patent regime, and compares enforcement frameworks in the US, EU, and China, highlighting key legal and procedural obstacles.

Chapter 3: Reforming Cross-Border Pharmaceutical Patent Enforcement: Indian Perspectives and Global Pathways

The chapter analyses India’s policy stance, evaluates global reform efforts, and explores legal reforms and cooperative strategies to improve enforcement while safeguarding access to medicines.

Chapter 4: Emerging Challenges and Future Trajectories in Cross-Border Pharmaceutical Patent Enforcement

It discusses evolving global trends, technological disruptions, and ethical dilemmas in patent enforcement, with a focus on India's strategic role in shaping equitable international frameworks.

Chapter 5: Conclusion Synthesizing the Cross-Border Patent Enforcement Dilemma: An Indian Perspective on Global Challenges and Pathways Forward

This final chapter summarizes findings, revisits the hypothesis, reflects on research limitations, and proposes forward-looking recommendations to balance patent rights and public health priorities.

CHAPTER 2: CROSS-BORDER PATENT ENFORCEMENT: LEGAL AND PROCEDURAL CHALLENGES

2.1 Introduction

The pharmaceutical industry stands at the intersection of science, commerce, and law, driven by innovation yet shaped fundamentally by the legal architecture of intellectual property rights. Patents, in particular, are the lifeblood of pharmaceutical innovation, granting inventors a time-limited monopoly in exchange for public disclosure of their inventions. This monopoly is intended to incentivize the enormous investment required to develop new medicines, a process that often takes over a decade and costs billions of dollars. The rationale is straightforward: without the promise of exclusive rights, few companies would risk the resources needed to bring life-saving drugs to market.[42]

Yet, the very nature of pharmaceutical innovation and commerce is global. New medicines are developed in one country, clinically tested and licensed in others, manufactured in still others, and ultimately distributed to patients worldwide.[43] This internationalization of the pharmaceutical supply chain is especially pronounced in India, which has emerged as a global hub for generic drug manufacturing and is often referred to as the "pharmacy of the developing world."[44] Indian pharmaceutical companies supply affordable medicines not only to the domestic market but also to developing and developed countries alike, making India central to global access-to-medicines debates.[45]

However, the legal framework governing patents is fundamentally territorial. As codified in the Paris Convention for the Protection of Industrial Property, "patents applied for in the various countries of the Union shall be independent of patents obtained for the same invention in other countries of the Union."[46] This principle means that a patent granted in India gives its owner rights only within India; a U.S. patent is enforceable only in the United States, and so on.[47] The World Intellectual Property Organization (WIPO) emphasizes that "patents are territorial rights, which means an

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[42] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[43] Shamnad Basheer, Compulsory Licensing in India: A Silver Bullet for Access to Medicines?, 1 Indian J. L. & Tech. 1, 3 (2012).
[44] Id. at 2.
[45] Id.; see also Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317, 319–20 (2005).
[46] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305.
[47] The Patents Act, No. 39 of 1970, § 48, India Code (1970); 35 U.S.C. § 271(a) (2022).

invention is protected only in the countries or regions where a patent has been granted." There is no such thing as a "world patent" with universal effect, and no international court or authority with the power to enforce patents globally.[48]

The consequences of this territoriality are profound, especially in the pharmaceutical sector. In an era of transnational supply chains and cross-border commerce, the fragmentation of patent rights creates significant enforcement challenges.[49] A pharmaceutical company seeking to protect its innovation must obtain and enforce patents in every country where it seeks protection, and must initiate separate legal proceedings in each jurisdiction where infringement occurs.[50] This process is costly, time-consuming, and fraught with the risk of inconsistent outcomes.[51] For example, a drug patent may be upheld in one country but invalidated or denied in another, as famously occurred with the cancer drug imatinib (Gleevec), whose patent was refused in India on public interest grounds despite being granted in many other jurisdictions.[52]

The difficulties are compounded when infringing conduct itself crosses borders. Modern pharmaceutical production often involves multiple countries: active pharmaceutical ingredients (APIs) may be manufactured in India, formulated in China, packaged in Europe, and shipped to markets worldwide.[53] Infringers may exploit this fragmentation by splitting infringing acts across jurisdictions, making it difficult for patent holders to obtain effective relief.[54] National courts are generally reluctant to adjudicate infringement of foreign patents, both out of respect for sovereignty and due to practical difficulties in applying foreign law.[55] As the U.S. Supreme Court has observed, U.S. patent law "makes no claim to extraterritorial effect; these laws do not, and were not intended to, operate beyond the limits of the United States."[56] Indian courts have taken a similar approach, emphasizing the independence and territoriality of Indian patents.[57]

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[48] Supra note 1 at 817, 820.
[49] Paul Torremans, Cross-Border Patent Litigation in Europe: Forum Shopping and Parallel Litigation, 44 IIC 1, 2–3 (2013)
[50] Id
[51] Id
[52] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[53] Supra note 6 at.1032, 1033–34.
[54] Id
[55] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007).
[56] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972).
[57] Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672

Efforts to address these challenges at the international level have been only partially successful. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization, harmonizes minimum standards for patent protection and obligates member states to provide effective enforcement mechanisms.[58] However, TRIPS does not create any international enforcement tribunal or cross-border enforcement mechanism; enforcement remains firmly within the domain of national courts and authorities.[59] Attempts to facilitate cross-border enforcement of intellectual property rights through instruments such as the Hague Judgments Convention have foundered on the lack of consensus, with IP judgments explicitly excluded from the Convention's scope.[60]

Regional initiatives, most notably in the European Union, have made greater strides. The creation of the Unified Patent Court (UPC) and the EU unitary patent regime allows for centralized enforcement of patents across multiple EU member states, reducing the need for duplicative litigation and the risk of inconsistent judgments.[61] Recent decisions of the Court of Justice of the European Union (CJEU) have further clarified the circumstances under which a single national court may exercise jurisdiction over cross-border patent disputes within the EU.[62] However, these innovations remain geographically confined and are not directly replicable in other regions, including South Asia.[63]

For India, the challenges of cross-border patent enforcement are particularly acute. As a major exporter of generic medicines, India has been at the centre of high-profile disputes over the seizure of Indian generics in transit through Europe and over the grant of compulsory licenses for essential medicines.[64] Indian law, as embodied in the Patents Act, 1970, and interpreted by the courts, reflects a careful balance between the protection of patent rights and the imperative of ensuring access to affordable medicines-a balance that is closely scrutinized both domestically and internationally.[65]

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[58] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 1, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[59] Id. art. 1(1)
[60] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.
[61] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[62] Case C-616/20, Mittelbayerische v. Bayerische, ECLI:EU:C:2025:123 (CJEU 2025).
[63] Supra note 1 at 817, 820.
[64] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)
[65] The Patents Act, 1970, § 84; Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India).

This chapter undertakes a comprehensive analysis of the legal frameworks governing cross-border patent enforcement in the pharmaceutical sector. It begins by tracing the historical and doctrinal foundations of the territoriality principle in patent law, as reflected in international treaties and national statutes. It then examines the Indian legal framework in detail, including statutory provisions, judicial decisions, and border enforcement measures. Comparative perspectives from the United States, European Union, and China are considered, highlighting both best practices and pitfalls. The chapter further analyses the mechanisms available for addressing cross-border infringement, including contributory infringement, anti-suit injunctions, and customs enforcement. Finally, it assesses the challenges and gaps in the current system, with particular attention to the tension between effective enforcement and access to medicines. The analysis is grounded in Indian law and practice but is situated within the broader context of international and comparative legal developments, with the aim of identifying pathways toward a more effective and equitable system of cross-border patent enforcement in the pharmaceutical sector.

2.2 The Territoriality Principle in Patent Law

The territoriality principle is the cornerstone of modern patent law, dictating that patent rights are confined to the jurisdiction that grants them. This section explores the historical development of this principle, its codification in international legal instruments, and its practical implementation in key jurisdictions, with a focus on pharmaceuticals.

Historical Origins

The concept that patent rights are territorial-enforceable only within the boundaries of the granting state-emerged from the doctrine of national sovereignty and the historical evolution of patent systems. Early forms of patent protection were royal privileges or monopolies granted by sovereigns, such as the English Crown's "letters patent" in the 15th and 16th centuries, which conferred exclusive rights to inventors or favoured individuals within the realm.[66]

By the 19th century, as industrialization accelerated and inventions began to have commercial value across borders, nations developed their own statutory patent regimes. The lack of harmonization meant that an inventor seeking protection in multiple

[66] Brad Sherman & Lionel Bently, The Making of Modern Intellectual Property Law 70–74 (1999)

countries had to apply separately in each.[67] The independence of national patents was not just a practical necessity but a legal doctrine: each patent grant was an act of sovereign authority, and the rights conferred were strictly limited to the territory of the granting state.[68]

This principle was reinforced by the prevailing view that the state had both the right and the obligation to determine the scope, duration, and enforceability of patents within its borders, reflecting local economic priorities, public policy, and legal traditions.[69] Early attempts to secure cross-border protection, such as bilateral treaties, recognized but did not fundamentally alter the territorial character of patents.[70]

The territoriality doctrine also reflected concerns about extraterritoriality and comity. Courts were (and remain) reluctant to apply their patent laws to acts committed abroad, both out of respect for other nations' sovereignty and due to the practical difficulties of enforcing judgments in foreign jurisdictions.[71] As the U.S. Supreme Court famously declared, "the right conferred by a patent under our law is confined to the United States and its territories, and infringement of this right cannot be predicated on acts wholly done in a foreign country."[72]

In sum, the territoriality principle originated as a natural outgrowth of the sovereign power of states and the practical realities of enforcing exclusive rights in a world of distinct legal systems.

Codification in International Treaties

The territorial nature of patents was formally codified in the first major multilateral treaty on industrial property: the **Paris Convention for the Protection of Industrial Property** (1883). Article 4bis (1) of the Paris Convention provides:

"Patents applied for in the various countries of the Union shall be independent of patents obtained for the same invention in other countries of the Union."[73]

This "independence clause" enshrines the idea that each national patent grant is autonomous: the grant, refusal, or invalidation of a patent in one country has no legal effect on the status of corresponding patents in other countries.[74]

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[67] Supra note 1 at 817, 820–21.
[68] Id
[69] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022)
[70] Supra note 49 at 1, 2–3.
[71] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007)
[72] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972)
[73] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305.
[74] Id

The Paris Convention also introduced the right of priority, allowing inventors to file in multiple countries based on an initial application, but did not create any system of global or automatically recognized patents.[75] The Convention's approach reflected both the practicalities and the political realities of the late 19th century, when sovereignty and national economic interests were paramount.

The **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, which came into force in 1995 as part of the World Trade Organization (WTO) framework, further harmonized substantive standards for patent protection. Article 28 of TRIPS confers exclusive rights on patent holders, but Article 1(1) makes clear that:

"Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[76]

Thus, while TRIPS sets minimum standards for patentability, term, and enforcement, it does not alter the territorial character of patents. Enforcement remains a matter for national courts and authorities.[77]

Other international instruments, such as the **Patent Cooperation Treaty (PCT)**, facilitate the process of seeking patents in multiple countries through a single application, but do not create a "world patent" or cross-border enforcement mechanism.[78] The PCT streamlines filing but ultimately results in a bundle of national or regional patents, each subject to local examination and enforcement.[79]

Attempts to create international mechanisms for the recognition and enforcement of patent judgments have met with limited success. The **Hague Conference on Private International Law** adopted the 2019 **Hague Judgments Convention** to facilitate the recognition and enforcement of foreign civil judgments, but explicitly excluded intellectual property matters, including patents, from its scope due to lack of consensus.[80] This exclusion perpetuates the need for duplicative litigation in each jurisdiction where a patent is asserted.

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[75] Id. art. 4.
[76] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1(1), Apr. 15, 1994, 1869 U.N.T.S. 299.
[77] Id. art. 28.
[78] Patent Cooperation Treaty art. 3, June 19, 1970, 1160 U.N.T.S. 231.
[79] id
[80] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019

In summary, international treaties have harmonized certain aspects of patent law but have consistently reaffirmed the territoriality principle, leaving enforcement fragmented and jurisdiction-specific.

National Implementation: A Comparative Overview

While the territoriality principle is universal, its implementation varies across jurisdictions. This section examines how key countries-India, the United States, the European Union, and China-have incorporated and operationalized the doctrine in their patent laws, with particular attention to pharmaceuticals.

A. India

India's patent regime, governed by the **Patents Act, 1970**, is firmly grounded in the principle of territoriality. Section 48 of the Act grants the patentee "the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India."[81] The exclusive rights are thus strictly limited to acts occurring within Indian territory.

Indian courts have consistently upheld this principle. In **Bayer Corporation v. Union of India**, the Delhi High Court held that export of a patented product from India constitutes "use" within India and may amount to infringement if the patent is in force in India.[82] However, the court emphasized that Indian courts cannot adjudicate infringement of foreign patents.[83] The Indian regime does not recognize contributory or indirect infringement occurring wholly outside India, nor does it provide for the enforcement of foreign patent judgments.[84] Enforcement is strictly national, and remedies are available only for acts committed within India.

B. United States

The U.S. Patent Act, codified at **35 U.S.C.**, also embodies the territoriality principle. Section 271(a) provides that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."[85]

Historically, U.S. courts took a strict approach, refusing to find infringement where any essential element occurred abroad.[86] However, Congress amended the law after

[81] The Patents Act, No. 39 of 1970, § 48, India Code (1970)
[82] Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672.
[83] Id
[84]Supra note 6 at 1032, 1034.
[85] 35 U.S.C. § 271(a) (2022).
[86] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972)

the **Deepsouth Packing Co. v. Laitram Corp.** decision to add Section 271(f), which imposes liability for supplying components from the U.S. for assembly abroad.[87] The Supreme Court has also recognized, in limited circumstances, the possibility of awarding damages for certain foreign sales lost due to domestic infringement, to prevent defendants from evading liability by offshoring parts of their operations.[88] Nonetheless, U.S. courts generally refuse to adjudicate infringement of foreign patents, citing comity and practical difficulties in applying foreign law.[89]

C. European Union

The European patent system is unique in that it overlays national systems with regional mechanisms. Under the **European Patent Convention (EPC)**, a "European patent" is granted centrally but results in a bundle of national patents, each enforceable only in its designated state.[90]

The EU has recently introduced the **Unified Patent Court (UPC)** and the **unitary patent** (effective June 2023), which allow for centralized enforcement of patents across participating member states.[91] The UPC can issue injunctions and award damages effective in all member states, reducing the need for duplicative litigation. However, validity challenges remain within the purview of national authorities for non-unitary patents, and the system is geographically limited to participating EU countries.[92]

The **Brussels I Regulation (Recast)** and recent CJEU jurisprudence permit, under certain conditions, a single EU court to hear infringement claims involving multiple national patents, provided the defendant is domiciled in the forum and the validity of foreign patents is not at issue.[93]

D. China

China's patent law, as amended in 2020, is also strictly territorial. Article 2 of the **Patent Law of the People's Republic of China** provides that only acts occurring within Chinese territory can infringe a Chinese patent.[94] Recent amendments have strengthened enforcement mechanisms, including punitive damages and improved border measures, but the basic territorial limitation remains.[95] Chinese courts have

[87] Id; 35 U.S.C. § 271(f)
[88] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).
[89] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007).
[90] European Patent Convention art. 2, Oct. 5, 1973, 1065 U.N.T.S. 199.
[91] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1
[92] Mittelbayerische v. Bayerische, ECLI:EU:C:2025:123 (CJEU 2025).
[93] Id
[94] Patent Law of the People's Republic of China art. 2 (2020).
[95] id

begun to issue anti-suit injunctions in global patent disputes, reflecting a more assertive approach to cross-border issues, but these are procedural innovations rather than substantive extensions of patent rights.[96]

2.3 The Indian Legal Framework

India's approach to patent law is shaped by its unique socio-economic context, constitutional imperatives, and international obligations. The Indian legal framework for patent protection and enforcement-especially in the pharmaceutical sector-reflects a conscious attempt to balance the interests of innovators with the public's need for affordable medicines. This section analyses the statutory provisions, judicial interpretations, border enforcement mechanisms, and the role of compulsory licensing in India's patent regime.

The Patents Act, 1970

The **Patents Act, 1970** is the principal statute governing patents in India. The Act has undergone significant amendments, notably in 1999, 2002, and 2005, to bring Indian law into compliance with the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**.[97]

Territorial Scope and Rights

Section 48 of the Act defines the rights conferred by a patent, granting the patentee the exclusive right to prevent third parties, without consent, from making, using, offering for sale, selling, or importing the patented product or process "in India."[98] This language codifies the principle of territoriality: an Indian patent is enforceable only within India's borders, and acts committed wholly outside India do not constitute infringement under Indian law.[99]

Infringement and Remedies

Section 104 provides that infringement suits must be instituted in a court not inferior to a District Court having jurisdiction, and Section 104A addresses the burden of proof in process patent cases, shifting it to the defendant under certain conditions.[100] The Act

[96] Huawei v. Conversant, (2019) Supreme People's Court, China.
[97] The Patents (Amendment) Act, 2005, No. 15 of 2005, India Code (2005); Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[98] The Patents Act, No. 39 of 1970, § 48, India Code (1970).
[99] id
[100] id

provides for both civil remedies (injunctions, damages, accounts of profits) and, in some cases, criminal penalties for false representation of patents.[101]

Limitations and Exceptions

The Act includes several exceptions to infringement, notably Section 107A, which allows for "parallel importation" and "Bolar exemptions."[102] Under Section 107A(a), making, constructing, using, selling, or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law in India or abroad does not constitute infringement.[103] Section 107A(b) permits importation of patented products from a person who is duly authorized under the law to produce and sell or distribute the product, facilitating access to cheaper medicines.

Patentability and Pharmaceuticals

Sections 3(d) and 3(e) of the Act impose heightened standards for patentability in pharmaceuticals, denying patents for new forms of known substances unless they result in enhanced efficacy.[104] This provision, unique to India, is intended to prevent "evergreening" and ensure that only genuine innovations receive patent protection.

Judicial Interpretation: Key Indian Cases

Indian courts have played a pivotal role in shaping the contours of patent enforcement, especially in the pharmaceutical sector. Their decisions reflect a nuanced understanding of both the letter and the spirit of the law.

Novartis AG v. Union of India

In the landmark case **Novartis AG v. Union of India**, the Supreme Court denied a patent for the beta crystalline form of imatinib mesylate (marketed as Gleevec), holding that it did not demonstrate enhanced efficacy over the known substance.[105] The Court's interpretation of Section 3(d) affirmed the legislature's intent to prevent evergreening and to prioritize access to medicines.[106] The decision underscored the independence of Indian patent law from foreign patent grants, as the same drug was patented in many other jurisdictions.[107]

Bayer Corporation v. Union of India

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[101] Id
[102] Id
[103] Id
[104] Supra note 43 at 1, 6-7.
[105] Novartis AG v. Union of India, (2013) 6 SCC 1
[106] Id
[107] Id

In **Bayer Corporation v. Union of India**, the Delhi High Court addressed the issue of export of patented products. The Court held that export from India could constitute "use" within India under Section 48, and thus may amount to infringement if the patent is in force in India.[108] However, the Court clarified that Indian courts lack jurisdiction to adjudicate infringement of foreign patents, reinforcing the territoriality principle.[109]

Natco Pharma Ltd. v. Bayer Corporation

This case marked the first grant of a compulsory license under Section 84 of the Patents Act. The Controller of Patents granted Natco Pharma a license to manufacture and sell a generic version of Bayer's patented cancer drug, sorafenib tosylate, on grounds that the reasonable requirements of the public were not being met, the drug was not available at a reasonably affordable price, and the patented invention was not "worked" in India.[110] The decision was upheld on appeal, reinforcing the public interest dimension of Indian patent law.[111]

Other Notable Cases

- **F. Hoffmann-La Roche Ltd. v. Cipla Ltd.**: The Delhi High Court considered the balance between patent rights and public interest in granting or refusing interim injunctions in pharmaceutical patent cases.[112]
- **Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd.**: The Delhi High Court clarified the standards for grant of permanent injunctions and damages in pharmaceutical patent infringement.[113]

These cases collectively illustrate the Indian judiciary's commitment to balancing innovation incentives with access to medicines and public health imperatives.

Border Enforcement and Customs Measures

India has implemented border enforcement measures to prevent the importation of infringing goods, in compliance with TRIPS Article 51.[114]

IPR (Imported Goods) Enforcement Rules, 2007

The Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007 empower customs authorities to suspend the clearance of goods suspected of infringing IP rights,

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[108] Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672
[109] id
[110] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India).
[111] Bayer Corp. v. Natco Pharma Ltd., (2014) 56 PTC 277 (IPAB)
[112] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71
[113] Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd., 2015 SCC OnLine Del 13707.
[114] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 51, Apr. 15, 1994, 1869 U.N.T.S. 299.

including patents.[115] Right holders may record their IP rights with customs, and upon suspicion, customs officials can detain goods and notify the right holder, who must then obtain a court order within a specified period.[116]

Scope and Limitations

These measures apply only to imports into India; they do not extend to exports or goods merely transiting through Indian territory.[117] The rules are intended to strike a balance between effective IP enforcement and trade facilitation, and customs authorities are required to act in accordance with principles of natural justice.

Practical Challenges

Despite the legal framework, practical challenges persist. Customs officials may lack technical expertise to assess patent infringement, leading to delays or wrongful detentions.[118] There have also been instances where border enforcement was invoked in contentious circumstances, such as the seizure of generic drugs in transit, highlighting the need for clear guidelines and safeguards against abuse.[119]

Compulsory Licensing and Public Health

A distinctive feature of Indian patent law is its robust compulsory licensing regime, designed to ensure that patent protection does not come at the expense of public health.

Statutory Provisions

Section 84 of the Patents Act allows "any person interested" to apply for a compulsory license after three years from the grant of a patent, on grounds that:

- the reasonable requirements of the public with respect to the patented invention have not been satisfied;
- the patented invention is not available to the public at a reasonably affordable price; or
- the patented invention is not "worked" in India.[120]

Section 92 provides for compulsory licenses in cases of national emergency, extreme urgency, or public non-commercial use, and Section 92A enables compulsory licenses for manufacture and export of patented pharmaceutical products to countries with

[115] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E)
[116] id
[117] Id
[118] Supra note 6 at 1032, 1035–36.
[119] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)
[120] The Patents Act, 1970, § 84

insufficient manufacturing capacity, in accordance with the WTO Doha Declaration on TRIPS and Public Health.[121]

Policy Rationale and International Context

The compulsory licensing provisions reflect India's constitutional commitment to public health (Article 21 of the Constitution) and its status as a major supplier of generic medicines to the developing world.[122] The regime has been lauded by public health advocates and has influenced debates on access to medicines globally.[123]

Key Cases and Impact

The Natco/Bayer compulsory license (discussed above) set important precedents regarding "reasonable requirements of the public" and "affordability."[124] While only a handful of compulsory licenses have been granted, the mere existence of the regime has a significant impact on pricing and negotiations in the Indian pharmaceutical market.[125]

Criticisms and Challenges

Patent holders and some developed countries have criticized India's compulsory licensing regime as undermining innovation incentives.[126] However, Indian authorities maintain that the regime is fully TRIPS-compliant and necessary to address the realities of public health in a developing country context.[127]

2.4 Comparative Perspectives: US, EU, and China

The challenge of cross-border patent enforcement in pharmaceuticals is not unique to India. Major jurisdictions around the world have grappled with the territoriality of patent rights and the realities of global pharmaceutical supply chains. The United States, the European Union, and China each offer distinctive approaches to patent enforcement, jurisdiction, and the interface between innovation and public health. Examining these systems provides valuable lessons for India, both in terms of best practices and cautionary tales.

United States

A. Territoriality and Statutory Framework

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[121] Id
[122] India Const. art. 21
[123] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317, 319–20 (2005)
[124] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012
[125] Supra note 43 at. 1, 14–15
[126] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43
[127] Id

The United States is home to one of the world's most sophisticated and litigious patent systems. The U.S. Patent Act, codified at **35 U.S.C.**, strictly embodies the principle of territoriality. Section 271(a) provides:

"Whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."[128]

This language confines direct infringement to acts occurring within the United States or to importation into the U.S.[129]

B. Extraterritorial Reach and Doctrinal Innovations

Historically, U.S. courts refused to find infringement where any essential element of the infringing act occurred abroad. In **Deepsouth Packing Co. v. Laitram Corp.**, the Supreme Court held that manufacturing components of a patented invention in the U.S. for assembly abroad did not constitute infringement, as the "making" occurred outside U.S. territory.[130]

Congress responded by enacting **35 U.S.C. § 271(f)**, which imposes liability on those who supply components of a patented invention from the U.S. for combination abroad, thus closing the "Deepsouth loophole."[131] This provision was designed to prevent defendants from evading U.S. patent law by moving final assembly offshore.

Further, in **WesternGeco LLC v. ION Geophysical Corp.**, the Supreme Court held that a patentee could recover damages for lost foreign sales proximately caused by domestic acts of infringement under § 271(f), marking a limited but significant extension of U.S. patent law's extraterritorial effect.[132]

C. Indirect Infringement and Inducement

U.S. law recognizes doctrines of indirect infringement (§ 271(b)-(c)), imposing liability for inducing or contributing to infringement, even if the direct infringer is outside the U.S. if the inducement or contribution occurs domestically.[133] However, the courts have generally declined to extend liability to wholly foreign acts, reaffirming the territoriality principle.[134]

D. Jurisdiction and Forum

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[128] 35 U.S.C. § 271(a) (2022).
[129] Id
[130] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972).
[131] 35 U.S.C. § 271(f)
[132] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018
[133] 35 U.S.C. § 271(b)-(c).
[134] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007).

U.S. courts generally decline to adjudicate infringement of foreign patents, citing the **"act of state"** doctrine and the practical difficulties of applying foreign law.[135] In **Voda v. Cordis Corp.**, the Federal Circuit refused to exercise supplemental jurisdiction over foreign patent claims, emphasizing comity and the risk of inconsistent judgments.[136]

E. Border Enforcement

The U.S. International Trade Commission (ITC) has the power under **Section 337 of the Tariff Act of 1930** to exclude infringing goods from entering the U.S. market.[137] The ITC process is a powerful tool for patentees, offering swift remedies such as exclusion orders and cease-and-desist orders.[138]

F. Public Health and Compulsory Licensing

The U.S. has no general compulsory licensing regime for patents, though specific statutes (e.g., the Bayh-Dole Act) allow for "march-in rights" in certain federally funded inventions.[139] In practice, compulsory licensing is rarely used, and the U.S. system prioritizes strong patent enforcement, sometimes at the expense of access to medicines.[140]

G. Anti-Suit Injunctions

U.S. courts have occasionally issued anti-suit injunctions to restrain parties from pursuing parallel litigation in foreign jurisdictions, especially in global standard-essential patent (SEP) disputes.[141] However, such injunctions are granted sparingly and only in exceptional circumstances.

European Union

A. The European Patent System: Dual Structure

The European patent landscape is characterized by a dual structure: the **European Patent Convention (EPC)** and the **European Union's (EU) legal framework**.

- The EPC, administered by the European Patent Office (EPO), provides a centralized application process, resulting in a "bundle" of national patents, each enforceable in its designated state.[142]

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[135] Id
[136] Id
[137] 19 U.S.C. § 1337 (2022).
[138] Supra note 1 at 817, 822–23.
[139] 35 U.S.C. § 203 (Bayh-Dole Act).
[140] Supra note 123 at 317, 319–20.
[141] Microsoft Corp. v. Motorola, Inc., 696 F.3d 872, 881 (9th Cir. 2012)
[142] European Patent Convention art. 2, Oct. 5, 1973, 1065 U.N.T.S. 199.

- The EU has pursued further integration through the **unitary patent** and the **Unified Patent Court (UPC)**, effective June 2023, allowing for centralized enforcement across participating member states.[143]

B. Territoriality and Enforcement

Despite the central grant process, enforcement under the EPC has traditionally been national. Each designated state's courts have exclusive jurisdiction over infringement and validity of the national "part" of a European patent.[144] This fragmentation has led to parallel litigation, forum shopping, and inconsistent outcomes.

The **UPC** represents a major innovation, providing a single forum for infringement and revocation actions covering all participating states.[145] The UPC can issue injunctions and award damages effective in all member states, greatly simplifying litigation for patentees.[146] However, not all EU states participate, and the system is still in its infancy.

C. Jurisdictional Rules and Cross-Border Litigation

The **Brussels I Regulation (Recast)** governs jurisdiction in civil and commercial matters, including patents. Recent **CJEU** decisions have clarified that, under certain conditions, a single EU court can hear infringement claims involving multiple national patents, provided the defendant is domiciled in the forum and the validity of foreign patents is not at issue.[147]

In **Case C-616/20 (Mittelbayerische v. Bayerische)**, the CJEU held that a court in one member state could adjudicate infringement of counterpart patents in other states if the defendant is domiciled in the forum and the claims do not challenge validity.[148] This "long-arm" jurisdiction is a significant step toward cross-border enforcement within the EU.

D. Border Measures

EU customs authorities are empowered to detain goods suspected of infringing IP rights under **Regulation (EU) No. 608/2013**.[149] The infamous 2008-2009 seizures of Indian generic medicines in transit through the EU, however, highlighted the potential for overreach and the need to balance enforcement with legitimate trade and public health

[143] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1
[144] Id
[145] Id
[146] Id
[147] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2).
[148] Case C-616/20, Mittelbayerische v. Bayerische, ECLI:EU:C:2025:123 (CJEU 2025).
[149] Regulation (EU) No. 608/2013, art. 17

objectives.[150] Following a WTO dispute, the EU clarified its regulations to prevent routine seizure of transit goods absent evidence of diversion into EU markets.[151]

E. Compulsory Licensing and Public Health

EU member states retain the power to issue compulsory licenses under national law, though such licenses are rare and generally reserved for cases of national emergency or public interest.[152] The EU has supported the use of compulsory licensing for export to countries lacking manufacturing capacity, in line with the WTO Doha Declaration.[153]

F. Anti-Suit and Arrow Declarations

UK and EU courts have developed innovative doctrines such as **Arrow declarations** (declarations of non-infringement or invalidity in anticipation of future patent assertions) and have issued anti-suit injunctions in SEP disputes.[154] These tools, while not directly about pharmaceuticals, reflect the growing willingness of European courts to address cross-border patent issues proactively.

China

A. Legal Framework and Territoriality

China's patent regime, governed by the **Patent Law of the People's Republic of China** (as amended in 2020), is strictly territorial. Article 2 provides that only acts occurring within Chinese territory can infringe a Chinese patent.[155] Enforcement is limited to domestic acts, and Chinese courts do not adjudicate infringement of foreign patents.

B. Strengthening Enforcement

Recent amendments have enhanced enforcement mechanisms, including:

- Introduction of **punitive damages** for willful infringement (up to five times actual damages).[156]
- Lowering the threshold for preliminary injunctions and increasing the role of specialized IP courts in major cities.[157]

[150] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[151] Id
[152] European Patent Convention art. 31
[153] Id
[154] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71
[155] Patent Law of the People's Republic of China art. 2 (2020)
[156] Id. Art.71
[157] Id. art. 72.

- Improved **border measures**: Chinese customs authorities can seize infringing goods intended for export or import, provided the right holder records their patent with customs.[158]

C. Extraterritoriality and Anti-Suit Injunctions

Chinese courts have begun to issue **anti-suit injunctions** in global patent disputes, particularly in the context of standard-essential patents (SEPs). In **Huawei v. Conversant** (2019), the Supreme People's Court issued an anti-suit injunction restraining enforcement of a German judgment abroad, asserting China's jurisdiction over global licensing disputes.[159] This reflects a more assertive approach to cross-border patent issues, though such injunctions remain exceptional.

D. Compulsory Licensing

China's Patent Law provides for compulsory licensing in cases of public health emergencies, non-working of patents, or anti-competitive practices.[160] While compulsory licenses have been granted in very few cases, the regime is seen as a tool to ensure access to medicines, particularly in the context of infectious diseases.[161]

E. Balancing Innovation and Access

China has sought to balance strong patent protection (to encourage domestic innovation and attract foreign investment) with public health needs. The government has prioritized the development of domestic pharmaceutical innovation while also retaining tools to address access and affordability.[162]

Lessons for India

A comparative analysis of the U.S., EU, and Chinese systems yields several lessons for India as it navigates the challenges of cross-border patent enforcement in the pharmaceutical sector:

A. The Value of Doctrinal Flexibility

The U.S. experience with § 271(f) and the WesternGeco decision demonstrates the importance of doctrinal flexibility in addressing cross-border infringement that exploits territorial loopholes.[163] India could consider statutory amendments to address situations

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[158] Id. arts. 75–76.
[159] Huawei v. Conversant, (2019) Supreme People's Court, China
[160] Patent Law of the People's Republic of China art. 48.
[161] Id
[162] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123, 135–36 (2017)
[163] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018)

where components or active pharmaceutical ingredients are exported from India for assembly or use in jurisdictions where the patent is in force.

B. The Benefits and Limits of Regional Integration

The EU's UPC and unitary patent system illustrate the advantages of supranational enforcement: reduced costs, consistent judgments, and broader remedies.[164] While such integration may not be immediately feasible in South Asia, India could explore regional cooperation (e.g., with SAARC or BRICS partners) for mutual recognition of IP judgments or harmonized border measures.

C. The Importance of Efficient Border Enforcement

Both the U.S. ITC and Chinese customs authorities provide powerful models for rapid border enforcement.[165] India's customs regime could be strengthened through greater technical training, clearer guidelines, and enhanced cooperation with trading partners to prevent both under- and over-enforcement.

D. The Role of the Judiciary

Judicial innovation, as seen in the U.S. (indirect infringement), EU (Arrow declarations), and China (anti-suit injunctions), can play a key role in adapting the law to new realities. Indian courts have already shown willingness to balance patent rights and public health, and could further develop doctrines to address cross-border challenges.

E. Balancing Enforcement and Access

All three jurisdictions grapple with the tension between strong patent enforcement and access to medicines. India's compulsory licensing regime is among the world's most robust and is widely seen as a model for balancing innovation and public health.[166] However, India must ensure that its approach remains TRIPS-compliant and is not perceived as undermining innovation incentives.

F. Cautionary Notes

- Overly aggressive border enforcement, as seen in the EU seizures of Indian generics, can provoke international disputes and harm access to medicines.[167]
- Extraterritorial application of patent law must be carefully calibrated to avoid conflicts of law and forum shopping.

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[164] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1

[165] 19 U.S.C. § 1337 (2022); Patent Law of the People's Republic of China art. 75

[166] The Patents Act, No. 39 of 1970, § 84, India Code (1970).

[167] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

2.5 Mechanisms for Addressing Cross-Border Infringement

The territorial nature of patent rights creates significant challenges for effective enforcement in the context of globalized pharmaceutical supply chains. However, legal systems and international frameworks have developed a range of mechanisms-both statutory and judicial-to address cross-border infringement. These mechanisms seek to mitigate the rigidities of territoriality, close enforcement loopholes, and provide patentees with practical remedies, while also balancing public interest and international comity. This section explores the principal mechanisms: contributory and indirect infringement, anti-suit and anti-enforcement injunctions, border measures and customs enforcement, and transnational litigation and jurisdictional issues.

Contributory and Indirect Infringement

A. The Doctrinal Evolution

The classic model of patent infringement is direct: a party makes, uses, sells, or imports the patented invention within the territory where the patent is in force.[168] However, in a globalized world, infringing activity is often dispersed-one actor may supply components or instructions, while another completes the infringement in a different country. This fragmentation can allow wrongdoers to evade liability if courts adhere strictly to territoriality.

To address this, many jurisdictions have developed doctrines of **contributory and indirect infringement**. These doctrines impose liability not only on those who directly infringe, but also on those who aid, abet, or facilitate infringement, even if the final act occurs elsewhere.

B. United States

U.S. law is particularly advanced in this area. Under **35 U.S.C. § 271(b)-(c)**, anyone who "actively induces infringement of a patent shall be liable as an infringer," and anyone who sells a component "specially made or especially adapted for use in an infringement" is liable for contributory infringement.[169]

A landmark development was the enactment of **§ 271(f)**, which closes the loophole identified in Deepsouth Packing Co. v. Laitram Corp.[170] This provision makes it an act of infringement to supply components of a patented invention from the U.S. for

[168] The Patents Act, No. 39 of 1970, § 48, India Code (1970); 35 U.S.C. § 271(a) (2022)
[169] 35 U.S.C. § 271(b)-(c) (2022).
[170] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972).

assembly abroad, thus localizing part of the infringing act within U.S. jurisdiction.[171] The Supreme Court in **WesternGeco LLC v. ION Geophysical Corp.** further allowed damages for certain foreign sales lost due to domestic infringement, recognizing the realities of cross-border harm.[172]

C. European Union

EU law recognizes indirect infringement under the European Patent Convention (EPC) and national statutes. For example, Article 26 of the UK Patents Act 1977 (implementing the EPC) imposes liability for supplying or offering to supply in the UK any means relating to an essential element of the invention, knowing they are suitable for putting the invention into effect.[173]

However, the application of indirect infringement to cross-border scenarios remains complex, and courts are cautious about extending liability for acts committed wholly abroad.[174]

D. India

Indian law does not explicitly provide for contributory or indirect infringement in the Patents Act, 1970.[175] However, Indian courts have occasionally recognized secondary liability in exceptional circumstances, particularly where a party within India facilitates infringement abroad.[176] The lack of clear statutory guidance has led to calls for legislative reform to address cross-border facilitation of infringement, especially in pharmaceuticals.[177]

E. China

China's Patent Law provides for joint liability where two or more parties jointly commit an infringing act, but does not expressly address contributory infringement in the cross-border context.[178] Recent judicial interpretations suggest a willingness to impose liability where a party within China substantially assists infringement abroad, but the doctrine remains underdeveloped.[179]

Challenges

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[171] 35 U.S.C. § 271(f).
[172] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).
[173] Patents Act 1977, c. 37, § 60(2)
[174] Supra note 49 at 1, 8–10.
[175] The Patents Act, 1970, India
[176] Supra note 6 at 1032, 1034–36.
[177] Id
[178] Patent Law of the People's Republic of China art. 21 (2020)
[179] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123, 135–36 (2017).

While contributory and indirect infringement doctrines help address cross-border schemes, their effectiveness is limited by the need to localize at least part of the wrongful conduct within the forum country. Moreover, differences in national laws can lead to inconsistent outcomes and uncertainty for both patent holders and alleged infringers.[180]

Anti-Suit and Anti-Enforcement Injunctions

A. Concept and Rationale

Anti-suit injunctions are judicial orders restraining a party from initiating or continuing parallel proceedings in a foreign jurisdiction. Anti-enforcement injunctions prevent a party from enforcing a foreign judgment in another country. These remedies are designed to prevent duplicative litigation, avoid conflicting judgments, and protect the jurisdictional integrity of the forum court.[181]

B. United States and United Kingdom

U.S. and UK courts have developed robust jurisprudence on anti-suit injunctions, particularly in global patent and standard-essential patent (SEP) disputes.[182] The leading U.S. case, **Microsoft Corp. v. Motorola, Inc.**, affirmed the power of U.S. courts to enjoin parties from pursuing or enforcing foreign litigation that would undermine the forum's jurisdiction or frustrate its policies.[183] UK courts have similarly issued anti-suit injunctions to restrain vexatious or oppressive parallel litigation, applying the "ends of justice" test.[184]

C. European Union

The Brussels I Regulation (Recast) generally prohibits anti-suit injunctions between EU member states, to preserve mutual trust and judicial cooperation.[185] However, anti-suit injunctions may still be available in disputes involving non-EU countries or where the Regulation does not apply.

D. China

Chinese courts have recently begun issuing anti-suit injunctions in global patent disputes, particularly in SEP licensing cases. In **Huawei v. Conversant**, the Supreme

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[180] Supra note at 817, 820–23.
[181] Microsoft Corp. v. Motorola, Inc., 696 F.3d 872, 881 (Fed. Cir. 2012)
[182] Unwired Planet Int'l Ltd. v. Huawei Techs. Co., [2020] UKSC 37
[183] Microsoft Corp., 696 F.3d at 881
[184] Société Nationale Industrielle Aérospatiale v. Lee Kui Jak [1987] AC 871 (PC); see also Modi Entm't Network v. WSG Cricket Pte Ltd., (2003) 4 SCC 341
[185] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 1(2)(b)

People's Court issued an anti-suit injunction restraining enforcement of a German judgment, asserting China's jurisdiction over the global licensing dispute.[186] This reflects a growing willingness to use such remedies to protect domestic interests and influence global patent negotiations.

E. India

Indian courts have been cautious in granting anti-suit injunctions, emphasizing comity and judicial restraint. In **Modi Entertainment Network v. WSG Cricket Pte Ltd.**, the Supreme Court held that such injunctions should be granted only in exceptional circumstances, such as when foreign proceedings are oppressive or vexatious.[187] Indian courts have rarely issued anti-suit injunctions in patent disputes, but the possibility remains open where necessary to prevent abuse of process.

Criticisms and Limitations

Anti-suit injunctions are controversial, as they can be seen as interfering with the sovereignty of foreign courts and may provoke retaliatory measures.[188] Their use in cross-border patent disputes must be carefully justified to avoid international friction and ensure respect for comity.

Border Measures and Customs Enforcement

A. International Framework

TRIPS Article 51 requires WTO members to provide procedures for customs authorities to suspend the release of goods suspected of infringing intellectual property rights, including patents, into free circulation.[189] However, TRIPS leaves the scope and implementation of border measures largely to national discretion.

B. United States

The U.S. International Trade Commission (ITC) is empowered under **19 U.S.C. § 1337** to investigate and exclude imports that infringe U.S. patents.[190] The ITC process is swift and powerful, allowing patentees to obtain exclusion orders and cease-and-desist orders against infringing imports.[191] The U.S. Customs and Border Protection (CBP) enforces these orders at the border.

C. European Union

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[186] Huawei v. Conversant, (2019) Supreme People's Court, China
[187] Modi Entm't Network v. WSG Cricket Pte Ltd., (2003) 4 SCC 341
[188] Supra note 1 at 828, 829–30.
[189] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 51, Apr. 15, 1994, 1869 U.N.T.S. 299.
[190] 19 U.S.C. § 1337 (2022)
[191] Supra note 1 at 817, 822–23.

EU customs authorities act under **Regulation (EU) No. 608/2013**, which allows for the detention of goods suspected of infringing IP rights.[192] The controversial seizure of Indian generics in transit through the EU in 2008-2009 highlighted the risks of overbroad enforcement and led to regulatory clarification to prevent the routine seizure of transit goods absent evidence of diversion into EU markets.[193]

D. India

India's **Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007** empower customs to suspend the clearance of goods suspected of infringing IP rights, including patents.[194] Right holders may record their rights with customs, and upon suspicion, customs can detain goods and notify the right holder, who must then obtain a court order within a specified period.[195] These measures apply only to imports, not exports or goods in transit.[196]

E. China

Chinese customs authorities may seize infringing goods intended for import or export, provided the right holder records their patent with customs.[197] This is part of China's broader effort to strengthen IP enforcement at the border, particularly for pharmaceuticals and high-value goods.

Challenges

Border enforcement is technically complex, as customs officials may lack the expertise to assess patent infringement, especially for process patents or complex pharmaceutical products.[198] There is also a risk of over-enforcement, trade disruption, and interference with legitimate commerce, particularly for generic medicines intended for export to countries where no patent exists.[199]

Transnational Litigation and Jurisdictional Issues

A. The Problem of Fragmented Jurisdiction

The territoriality of patent rights means that infringement suits must generally be brought in the country where the patent is in force and the alleged infringement

[192] Regulation (EU) No. 608/2013, art. 17
[193] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)
[194] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E) (India)
[195] Id
[196] Id
[197] Patent Law of the People's Republic of China art. 75 (2020)
[198] Supra note 6 at 1032, 1034–36
[199] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)

occurs.[200] National courts are reluctant to adjudicate foreign patent claims, both out of respect for sovereignty and practical difficulties in applying foreign law.[201] This leads to fragmented, duplicative, and potentially inconsistent litigation across multiple jurisdictions.

B. Consolidation and "Long-Arm" Jurisdiction

Some jurisdictions have experimented with mechanisms to consolidate cross-border patent disputes:

- **European Union:** The Brussels I Regulation (Recast) and CJEU jurisprudence permit, under certain conditions, a single EU court to hear infringement claims involving multiple national patents, provided the defendant is domiciled in the forum and the validity of foreign patents is not at issue.[202] The new Unified Patent Court (UPC) allows for centralized enforcement across participating EU states.[203]
- **United States:** U.S. courts generally refuse to adjudicate infringement of foreign patents, as affirmed in **Voda v. Cordis Corp.**, but may exercise jurisdiction over foreign defendants for acts committed within the U.S.[204]

C. Hague Judgments Convention

The 2019 **Hague Judgments Convention** seeks to facilitate recognition and enforcement of foreign civil judgments, but explicitly excludes intellectual property matters, including patents, from its scope due to lack of consensus.[205] This exclusion perpetuates the need for duplicative litigation in each jurisdiction where a patent is asserted.

D. Evidence Gathering and Procedural Hurdles

Transnational litigation is further complicated by differences in discovery rules, language barriers, and the difficulty of obtaining evidence located abroad.[206] Mutual legal assistance treaties (MLATs) and letters rogatory may be used, but the process is slow and often ineffective for time-sensitive patent disputes.

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[200] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305

[201] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007

[202] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2); Case C-616/20, Mittelbayerische v. Bayerische, ECLI:EU:C:2025:123 (CJEU 2025).

[203] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

[204] Voda, 476 F.3d at 900

[205] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.

[206] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123–24 (2017)

E. Forum Shopping and Parallel Litigation

The lack of harmonized enforcement leads to forum shopping, where parties seek out favourable jurisdictions, and parallel litigation, increasing costs and the risk of inconsistent judgments.[207]

F. Indian Perspective

Indian courts have generally adhered to the principle of territoriality, refusing to adjudicate foreign patent claims and requiring infringement suits to be brought in the jurisdiction where the patent is registered and the alleged infringement occurs.[208] However, Indian litigants are increasingly involved in cross-border disputes, particularly as Indian pharmaceutical companies expand globally.

2.6 International and Regional Cooperation

The fragmentation of patent enforcement, as discussed in previous chapters, is a direct consequence of the territorial nature of patent rights. Recognizing the inefficiencies and uncertainties this creates-especially for cross-border pharmaceutical innovation and commerce-states and international organizations have sought to develop cooperative mechanisms to harmonize certain aspects of patent protection and enforcement. This section explores the most significant international and regional initiatives: the TRIPS Agreement and WTO dispute settlement, the Hague Judgments Convention, and the European Union's Unified Patent Court (UPC) and other regional models.

TRIPS and WTO Dispute Settlement

A. The TRIPS Agreement: Harmonization of Substantive Standards

The **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, which entered into force in 1995 as part of the World Trade Organization (WTO) framework, is the most comprehensive multilateral treaty on intellectual property to date.[209] TRIPS obligates all WTO members to provide minimum standards of protection for patents, including pharmaceuticals, and to ensure that enforcement procedures are available under national law.[210]

TRIPS Part II sets out substantive requirements-such as patentable subject matter, the term of protection (at least 20 years from filing), and exclusive rights (making, using,

[207] Supra note 49 at 1, 9–11.
[208] Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672
[209] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299
[210] Id. arts. 27–28, 41–61

selling, importing).[211] Part III (Articles 41-61) requires members to make available effective enforcement mechanisms, including civil, administrative, and, in some cases, criminal remedies.[212] Article 44 provides for injunctions, Article 45 for damages, and Article 51 for border measures against infringing goods.[213]

However, TRIPS does **not** create any international patent rights or enforcement tribunal.[214] Each member must implement TRIPS-compliant laws domestically, and enforcement remains the responsibility of national courts and authorities.[215]

B. Enforcement and the Limits of Harmonization

TRIPS harmonized "the law on the books" but not the process of enforcement across borders.[216] Patent owners must still obtain and enforce patents country by country, and a judgment in one country is not automatically recognized elsewhere.[217] The absence of a global enforcement mechanism means that cross-border infringement often requires parallel litigation in multiple jurisdictions, increasing costs and uncertainty.[218]

C. WTO Dispute Settlement: State-to-State Enforcement

The WTO Dispute Settlement Body (DSB) provides a forum for member states to challenge each other's compliance with TRIPS obligations.[219] Disputes are adjudicated by panels and, on appeal, by the Appellate Body. Remedies are available only to states, not private parties, and typically take the form of recommendations to bring national laws or practices into conformity with WTO rules.[220]

A notable example is **DS408: European Union and a Member State - Seizure of Generic Drugs in Transit**.[221] In 2008-2009, EU customs authorities seized shipments of Indian-made generic medicines transiting through Europe en route to developing countries, on the grounds that they would infringe European patents if imported into the EU. India and Brazil challenged these actions at the WTO, arguing that such seizures violated TRIPS and the General Agreement on Tariffs and Trade (GATT) by

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[211] Id. arts. 27, 33.
[212] Id. arts. 41–61.
[213] Id. arts. 44–45, 51.
[214] Supra 817, 825.
[215] Id
[216] Id
[217] Id
[218] Supra note 49 at 1, 2–3.
[219] Agreement Establishing the World Trade Organization arts. XXII–XXIII, Apr. 15, 1994, 1867 U.N.T.S. 154.
[220] Id
[221] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

impeding legitimate trade and access to medicines.[222] The dispute was settled after the EU clarified its regulations to prevent routine seizure of transit goods absent evidence of diversion into EU markets.[223] This case illustrates both the reach and the limits of WTO dispute settlement: while it can resolve inter-state disputes over IP enforcement, it does not provide direct relief to private patent holders or accused infringers.

D. Cooperation and Public Health Flexibilities

TRIPS also incorporates flexibilities for public health, most notably in Article 31 (compulsory licensing) and the 2001 **Doha Declaration on TRIPS and Public Health**.[224] These provisions affirm the right of members to grant compulsory licenses and to authorize parallel importation to promote access to medicines.[225] India has made extensive use of these flexibilities in its patent law and policy.[226]

The Hague Judgments Convention

A. Background and Purpose

The **Hague Conference on Private International Law** has long sought to facilitate the recognition and enforcement of foreign civil judgments. The 2019 **Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters** ("Hague Judgments Convention") aims to reduce the need for duplicative litigation by providing a framework for the mutual recognition of judgments among contracting states.[227]

B. Exclusion of Intellectual Property

Despite its broad scope, the Hague Judgments Convention **explicitly excludes intellectual property matters, including patents, from its scope**.[228] Article 2(1)(m) provides that the Convention "shall not apply to the following matters: … (m) the validity, registration, or infringement of intellectual property rights."[229] This exclusion resulted from the lack of international consensus on how to handle the recognition of IP judgments, given the territoriality and policy sensitivities of patent law.[230]

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[222] Id
[223] Id
[224] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[225] Id
[226] The Patents Act, No. 39 of 1970, §§ 84, 92, India Code (1970).
[227] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters, July 2, 2019.
[228] Id. art. 2(1)(m).
[229] Id
[230] Rochelle Dreyfuss, The Costs of Cross-Border Patent Enforcement, 25 Fordham Intell. Prop. Media & Ent. L.J. 817, 829–30.

C. Implications for Patent Enforcement

The exclusion of patent judgments from the Hague Convention means that a judgment of patent infringement (or invalidity) rendered in one country cannot be directly recognized or enforced in another under this treaty.[231] Patent holders must still initiate separate proceedings in each jurisdiction where they seek enforcement, perpetuating the inefficiencies and uncertainties of the current system.[232]

This is widely regarded as a missed opportunity for global patent enforcement reform. Scholars and practitioners have argued that the inability to enforce patent judgments abroad is a major barrier to efficient cross-border protection, especially in industries like pharmaceuticals where infringing activity is often transnational.[233]

D. Prospects for Reform

There have been calls to revisit the exclusion of IP from the Hague regime, possibly through a supplemental protocol or future negotiations.[234] However, significant obstacles remain, including divergent national policies on patentability, public health, and enforcement, as well as concerns about sovereignty and forum shopping.[235] Until such reforms are realized, the recognition and enforcement of foreign patent judgments will remain subject to national law and bilateral treaties, if any.

The Unified Patent Court and Regional Models

A. The Unified Patent Court (UPC) and EU Unitary Patent

The most significant regional innovation in cross-border patent enforcement is the **Unified Patent Court (UPC)** and the **EU unitary patent** system, which became operational in June 2023.[236]

- The **UPC** is an international court with exclusive jurisdiction over European patents (with unitary effect) and, in some cases, traditional European patents in participating EU member states.[237]
- The **unitary patent** allows inventors to obtain a single patent with effect across all participating states, simplifying the process of securing and enforcing rights.[238]

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[231] Id
[232] Id
[233] Id
[234] Id
[235] Id
[236] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1
[237] Id
[238] Id

B. Centralized Enforcement and Remedies

The UPC enables patent owners to obtain remedies-such as injunctions and damages-that are effective across all member states in a single proceeding.[239] This dramatically reduces the need for parallel litigation, lowers costs, and ensures consistency of judgments.[240] The UPC can also hear revocation actions, streamlining challenges to patent validity.

C. Jurisdictional Reach and Limitations

Not all EU member states participate in the UPC and unitary patent system, and national courts retain jurisdiction over non-unitary patents and certain issues.[241] The system is geographically confined to participating states, and the UPC's jurisprudence is still developing.[242]

D. Other Regional Models

Other regions have explored, or are exploring, mechanisms for regional cooperation in patent enforcement:

- The **African Regional Intellectual Property Organization (ARIPO)** and the **Organisation Africaine de la Propriété Intellectuelle (OAPI)** provide for regional patents, though enforcement remains largely national.[243]
- The **Eurasian Patent Organization (EAPO)** offers a regional patent for its member states, but, again, enforcement is typically national.[244]
- In **South Asia**, there is no equivalent regional patent system, though the **South Asian Association for Regional Cooperation (SAARC)** has discussed IP cooperation.[245]

E. Lessons for India

The UPC demonstrates the benefits of supranational enforcement: reduced costs, consistent judgments, and broader remedies.[246] While such integration may not be immediately feasible in South Asia, India could explore regional cooperation for mutual

[239] Id
[240] Id
[241] Id
[242] Id
[243] African Regional Intellectual Property Organization, Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization, Dec. 10, 1982.
[244] Eurasian Patent Convention, Sept. 9, 1994, 2203 U.N.T.S. 263
[245] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.
[246] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

recognition of judgments, harmonized border measures, or joint enforcement initiatives.[247]

India's experience with WTO dispute settlement (as in the EU generics seizure case) also highlights the importance of international fora for resolving cross-border enforcement disputes and defending public health interests.[248]

2.7 Challenges and Gaps in Enforcement

The enforcement of pharmaceutical patents across borders faces numerous challenges that undermine the effectiveness of patent protection and complicate the legal landscape for innovators and generic manufacturers alike. These challenges stem from the territorial nature of patents, the complexity of global supply chains, and the competing imperatives of innovation and public health. This section critically examines the principal obstacles: the high cost and complexity of enforcement, forum shopping and parallel litigation, difficulties in evidence gathering and procedural hurdles, and the delicate balance between enforcing patent rights and ensuring access to medicines.

Cost and Complexity

A. Financial Burden of Multi-Jurisdictional Litigation

Cross-border patent enforcement requires initiating and managing litigation in multiple jurisdictions, each with its own legal system, procedural rules, and evidentiary standards.[249] This multiplicity significantly increases the financial and administrative burden on patent holders, often making enforcement prohibitively expensive, especially for smaller companies and public-interest organizations.[250]

Pharmaceutical patents are typically high-value assets, but the cost of litigating in several countries simultaneously-covering attorney fees, expert witnesses, court fees, translations, and travel-can run into millions of dollars.[251] This cost barrier can deter patentees from pursuing enforcement in less economically significant markets, potentially allowing infringing activity to flourish unchecked.[252]

B. Complexity of Legal and Technical Issues

[247] Id
[248] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[249] Supra notes 230 at 817, 820–21.
[250] Id
[251] Id
[252] Id

Pharmaceutical patent cases often involve complex scientific and technical evidence, including chemical formulations, biological processes, and clinical data.[253] Courts in different jurisdictions may have varying levels of expertise and different standards for patentability and infringement, leading to inconsistent outcomes and legal uncertainty.[254]

Moreover, the fragmentation of patent rights means that a single pharmaceutical product may be covered by multiple patents in different countries, each with distinct claims and validity statuses. Navigating this patchwork demands sophisticated legal strategies and coordination across jurisdictions.[255]

Forum Shopping and Parallel Litigation

A. Phenomenon and Drivers

Forum shopping occurs when parties strategically choose jurisdictions perceived as favourable to their interests, often based on procedural advantages, speed of litigation, likelihood of injunctions, or favourable substantive law.[256] In cross-border patent disputes, this leads to multiple parallel litigations in different countries concerning the same patented invention.[257]

Pharmaceutical companies and generic manufacturers may initiate suits or defences in jurisdictions where enforcement is easier or where courts have a reputation for being patent-friendly or public-health sensitive.[258]

B. Consequences

Parallel litigation increases costs and risks inconsistent judgments, where a patent may be upheld in one country but invalidated or not infringed in another.[259] This inconsistency complicates global patent strategy and can undermine the predictability of patent rights.

It also burdens courts and parties with duplicative proceedings, delays resolution, and may be exploited to delay market entry of generics or to harass competitors.[260]

C. Attempts to Mitigate

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[253] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[254] Id
[255] Id
[256] Paul Torremans, Cross-Border Patent Litigation in Europe: Forum Shopping and Parallel Litigation, 44 IIC 1, 2–3 (2013).
[257] Id
[258] Id
[259] Id
[260] Id

Some jurisdictions have sought to limit forum shopping through jurisdictional rules, consolidation mechanisms, or doctrines like lis pendens.[261] The European Union's Unified Patent Court (UPC) and Brussels I Regulation (Recast) aim to reduce parallel litigation within Europe by centralizing jurisdiction and harmonizing enforcement.[262] However, outside such regional frameworks, forum shopping remains a persistent problem.

Evidence Gathering and Procedural Hurdles

A. Challenges in Cross-Border Evidence Collection

Effective patent enforcement depends on obtaining evidence of infringement, validity, and damages. In cross-border cases, evidence may be located in multiple countries, complicating discovery and investigation.[263]

Jurisdictions vary widely in their rules on discovery and evidence-gathering. For example, the United States permits broad pre-trial discovery, while many civil law countries have more limited procedures.[264] This disparity can hinder the collection of crucial evidence located abroad.

B. Mutual Legal Assistance and Letters Rogatory

Obtaining evidence from foreign jurisdictions often requires formal requests through **letters rogatory** or **mutual legal assistance treaties (MLATs)**, which are slow, bureaucratic, and uncertain.[265] The absence of streamlined international mechanisms for patent-related evidence gathering delays proceedings and increases costs.

C. Technical Expertise and Judicial Capacity

Patent cases require judges and experts with specialized scientific knowledge. In many jurisdictions, courts lack sufficient expertise, leading to reliance on expert witnesses, which can be costly and contentious.[266] This gap can affect the quality and consistency of decisions.

D. Procedural Delays and Enforcement

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[261] Id

[262] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1; Regulation (EU) No. 1215/2012 (Brussels I Recast).

[263] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123, 124–25 (2017).

[264] Id

[265] Id

[266] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).

Procedural complexities, such as interlocutory injunctions, appeals, and enforcement of judgments, can prolong litigation. In some countries, enforcement of patent judgments is slow or ineffective, reducing the deterrent effect of patent rights.[267]

Balancing Enforcement and Access to Medicines

A. The Public Health Imperative

Pharmaceutical patents grant temporary monopolies that enable innovators to recoup investments but can also lead to high drug prices, limiting access, especially in developing countries.[268] India, as a major supplier of affordable generic medicines, faces the challenge of enforcing patents without undermining public health goals.[269]

B. Compulsory Licensing and Exceptions

India's patent law incorporates mechanisms such as **compulsory licensing** (Section 84 of the Patents Act, 1970) and exceptions under Section 3(d) to prevent evergreening and promote access.[270] These provisions reflect India's constitutional commitment to the right to health and international public health norms, including the WTO Doha Declaration on TRIPS and Public Health.[271]

C. Cross-Border Enforcement and Access

Aggressive cross-border enforcement of pharmaceutical patents can disrupt the supply of affordable medicines. The 2008-2009 EU seizures of Indian generics in transit exemplify the tension between patent enforcement and access to medicines.[272] Such enforcement actions, while legally justified under territorial patent rights, may conflict with international trade rules and public health objectives.[273]

D. International and Domestic Policy Responses

India and other developing countries advocate for a balanced approach that respects patent rights while safeguarding access. This includes promoting flexibilities under TRIPS, encouraging differential pricing, and supporting regional cooperation on patent enforcement that considers public health.

E. Ethical and Policy Considerations

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[267] Id
[268] Supra note 43 at 1, 3.
[269] Id
[270] The Patents Act, No. 39 of 1970, §§ 3(d), 84, India Code (1970)
[271] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2
[272] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[273] Id

The balance between enforcement and access raises ethical questions about the role of patents in healthcare. Overly rigid enforcement may prioritize profits over patients' rights, while lax enforcement can undermine innovation incentives.[274] Policymakers must navigate these competing interests carefully.

2.8 Conclusion

The cross-border enforcement of pharmaceutical patents stands at the confluence of law, innovation, public health, and international commerce. As this chapter has demonstrated, the territoriality principle-long the bedrock of patent law-has become increasingly strained in an era where pharmaceutical research, development, manufacturing, and distribution are inherently globalized.[275] The result is a persistent and often problematic misalignment: while the pharmaceutical industry operates across borders, the legal mechanisms for protecting and enforcing patent rights remain largely confined within national boundaries.[276]

At the heart of this challenge lies the doctrine of territoriality, codified in the Paris Convention and reaffirmed by the TRIPS Agreement, which mandates that patents are national rights, enforceable only in the country of grant.[277] This principle, while rooted in sovereignty and the practicalities of legal administration, creates significant hurdles for effective enforcement in a world where infringing acts are easily fragmented across multiple jurisdictions.[278] Patent holders must navigate a patchwork of national laws, courts, and procedures, initiating duplicative litigation in each country where protection is sought.[279] The financial and administrative burdens of such multi-jurisdictional enforcement are immense, often deterring smaller innovators and public-interest organizations from protecting their rights, and sometimes allowing infringers to exploit gaps in the system.[280]

The complexity is compounded by the technical nature of pharmaceutical patents, which often involve sophisticated scientific evidence and intersect with critical public

[274] Supra Note 249 at 817, 830.
[275] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[276] Supra Note 249 at 817, 820–21.
[277] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305; Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 1, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[278] Supra Note 249 at 817, 820–22.
[279] Supra note 256 at 1, 2–3.
[280] Supra Note 249 at 817, 821–23.

health concerns.[281] The risk of inconsistent outcomes-where a patent is upheld in one jurisdiction but invalidated or unenforceable in another-introduces further uncertainty.[282] Forum shopping and parallel litigation proliferate, as parties seek out jurisdictions perceived as favourable to their interests, leading to inefficiency and unpredictability.[283] The difficulties of cross-border evidence gathering, the lack of harmonized procedural rules, and the limited capacity of many courts to handle complex patent disputes further exacerbate these challenges.[284]

Efforts to address these issues at the international and regional levels have yielded only partial solutions. The TRIPS Agreement harmonized substantive standards and enforcement obligations but stopped short of creating any global enforcement mechanism or tribunal.[285] WTO dispute settlement offers a forum for state-to-state resolution of TRIPS compliance, but provides no direct remedy for private parties and is ill-suited to the day-to-day realities of patent enforcement.[286] The Hague Judgments Convention, which might have facilitated the recognition and enforcement of foreign patent judgments, explicitly excludes intellectual property from its scope, reflecting the lack of international consensus on how to reconcile territoriality with the needs of a global economy.[287]

Regional innovations, most notably the European Union's Unified Patent Court (UPC) and unitary patent system, represent important steps toward supranational enforcement.[288] The UPC enables centralized litigation and remedies across participating member states, reducing costs and the risk of inconsistent judgments.[289] However, such models remain geographically limited and are not easily replicable outside the unique context of the EU.[290]

National legal systems have also experimented with doctrinal innovations-such as contributory and indirect infringement, anti-suit injunctions, and border measures-to

[281] Lionel Bently & Brad Sherman, Intellectual Property Law 379 (5th ed. 2022).
[282] Novartis AG v. Union of India, (2013) 6 SCC 1
[283] Supra note 256 at 1, 8–10
[284] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123, 124–25 (2017).
[285] Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 41–61.
[286] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)
[287] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.
[288] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[289] Id
[290] Id

address the realities of cross-border infringement.[291] Yet these approaches are often limited by the need to localize at least part of the infringing conduct within the forum country, and their effectiveness is constrained by differences in national law and policy.[292]

For India, these challenges are particularly acute. As both a major producer of generic medicines and a growing centre for pharmaceutical innovation, India must balance the protection of patent rights with its constitutional and moral commitment to public health and access to medicines.[293] The Indian legal framework, as embodied in the Patents Act, 1970, and interpreted by the courts, reflects this delicate balance. Robust mechanisms for compulsory licensing, strict standards for patentability (notably Section 3(d)), and exceptions for research and parallel importation are designed to prevent evergreening and ensure that patent protection does not come at the expense of affordable healthcare.[294] At the same time, India's border enforcement regime and evolving jurisprudence on indirect infringement and cross-border conduct demonstrate a willingness to adapt to the complexities of global pharmaceutical commerce.[295]

Yet, significant gaps remain. The absence of explicit statutory provisions for contributory or indirect infringement with cross-border elements, the limitations of customs enforcement, and the lack of regional or international mechanisms for mutual recognition of patent judgments all constrain the effectiveness of India's enforcement regime.[296] Moreover, as Indian pharmaceutical companies expand globally, they increasingly find themselves both as plaintiffs and defendants in cross-border patent disputes, underscoring the need for a more harmonized and efficient system.[297]

Looking forward, several pathways for reform and cooperation emerge:

1. **Doctrinal and Legislative Innovation:** India could consider amending its patent law to explicitly address contributory and indirect infringement in cross-border scenarios, drawing on best practices from the U.S., EU, and China.[298]

[291] 35 U.S.C. § 271(f) (2022); Patents Act 1977, c. 37, § 60(2) (UK); Huawei v. Conversant, (2019) Supreme People's Court, China.
[292]Supra note 6 at 1032, 1034–36
[293] The Patents Act, No. 39 of 1970, §§ 3(d), 84, India Code (1970); India Const. art. 21.
[294] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India)
[295] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E)
[296] Supra note 6 at 1032, 1036
[297] Supra Note 249 at 817, 821–23.
[298] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).

2. **Regional Cooperation:** While a South Asian equivalent of the UPC may not be immediately feasible, India could pursue regional agreements on mutual recognition of judgments, harmonized border measures, and information sharing to combat cross-border infringement more effectively.[299]
3. **Capacity Building:** Enhancing the technical expertise of customs officials, judges, and patent examiners would improve the quality and consistency of enforcement, particularly in complex pharmaceutical cases.[300]
4. **International Advocacy:** India should continue to play a leading role in international fora, advocating for reforms that balance innovation incentives with access to medicines, and for the eventual inclusion of intellectual property in international judgments conventions.[301]
5. **Public Health Safeguards:** Any strengthening of enforcement mechanisms must be accompanied by robust safeguards to ensure that access to affordable medicines is not unduly compromised, in line with India's constitutional and international obligations.[302]

In conclusion, the cross-border enforcement of pharmaceutical patents is a dynamic and evolving field, marked by profound tensions between territorial law and global commerce, between innovation and access, and between national sovereignty and international cooperation.[303] While significant challenges remain, the ongoing evolution of legal doctrine, regional integration, and international dialogue offer hope for a more coherent, equitable, and effective system of patent enforcement-one that serves both the interests of innovators and the public good

[299] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.
[300] Lionel Bently & Brad Sherman, Intellectual Property Law 379 (5th ed. 2022).
[301] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[302] The Patents Act, 1970, §§ 84, 92
[303] Supra Note 249 at 817, 830.

CHAPTER 3: REFORMING CROSS-BORDER PHARMACEUTICAL PATENT ENFORCEMENT: INDIAN PERSPECTIVES AND GLOBAL PATHWAYS

3.1 Introduction

The preceding chapters have established the foundational paradox at the heart of cross-border pharmaceutical patent enforcement: while the pharmaceutical industry is inherently global, the legal architecture governing patent rights remains stubbornly territorial.[304] This tension between globalized innovation and fragmented enforcement is not merely an academic curiosity-it has profound consequences for public health, access to medicines, investment in research and development, and the very structure of international trade.[305]

In Chapter 1, the historical and doctrinal roots of the territoriality principle were traced, demonstrating how the evolution of patent law, from its origins as a sovereign privilege to its modern codification in international treaties such as the Paris Convention and the TRIPS Agreement, has consistently reaffirmed the national character of patent rights.[306] The chapter highlighted the core dilemma: there is no such thing as a "world patent" or a global enforcement mechanism.[307] Instead, patent holders must secure and defend their rights in each country separately, navigating a patchwork of national laws, courts, and procedures.[308]

Chapter 2 built on this foundation by mapping the substantive and procedural frameworks that shape cross-border enforcement, both in India and in leading jurisdictions such as the United States, the European Union, and China.[309] The analysis revealed that, while international instruments like TRIPS have harmonized minimum standards for patent protection and enforcement, the actual process of enforcing rights across borders remains fragmented, costly, and often inconsistent.[310] The chapter also explored the emergence of innovative doctrines and regional mechanisms-such as the

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[304] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022)
[305] Supra note 43 at. 1, 3.
[306] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305; Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 1, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[307] Id
[308] Supra notes 230 at 817, 820–21.
[309] Id
[310] Supra note 256 at 1, 2–3.

U.S. doctrine of contributory infringement, the European Unified Patent Court, and China's evolving IP courts-that seek to mitigate the rigidity of territoriality, albeit with varying degrees of success and applicability.[311]

Against this backdrop, the pharmaceutical sector stands out as a particularly acute arena for these challenges. The industry is characterized by high-value patents, lengthy and expensive R&D cycles, and a globalized supply chain that routinely crosses multiple jurisdictions.[312] Indian pharmaceutical companies, in particular, have become central players in the global market, supplying affordable generic medicines to both developing and developed countries.[313] At the same time, India is increasingly home to innovative pharmaceutical R&D, with both domestic and multinational companies seeking to protect their inventions in a complex legal landscape.[314]

The cross-border enforcement of pharmaceutical patents thus implicates not only the interests of patent holders and generic manufacturers, but also broader questions of public health, access to medicines, and the right to health as enshrined in the Indian Constitution and international human rights instruments.[315] The stakes are high: overly rigid enforcement can restrict access to life-saving medicines, while weak or inconsistent enforcement can undermine incentives for innovation and investment.[316]

Moreover, the challenges of cross-border enforcement are not merely theoretical. High-profile disputes-such as the denial of the imatinib (Gleevec) patent in India, the grant of compulsory licenses for cancer drugs, and the seizure of Indian generics in transit through Europe-have brought these issues to the forefront of international legal and policy debates.[317] These cases illustrate the practical difficulties faced by patent holders and generic manufacturers alike: the need to litigate in multiple jurisdictions, the risk of inconsistent or conflicting judgments, and the vulnerability of global supply chains to extraterritorial enforcement actions.[318]

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[311] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018); Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

[312] Shamnad Basheer & T. Prashant Reddy, The 'Indirect Infringement' Conundrum in Indian Patent Law, 14 J. Intell. Prop. L. & Prac. 1032, 1034–36 (2019).

[313]Supra note 123 at 317, 319–20.

[314] Id

[315] India Const. art. 21; WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[316] Supra note 43 at. 10-12.

[317] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India); WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)

[318] Id

In this context, India occupies a unique and influential position. As a country with a robust generic pharmaceutical industry, a growing innovation ecosystem, and a strong commitment to public health, India must navigate the complex interplay between protecting patent rights and ensuring access to affordable medicines.[319] The Indian legal framework-embodied in the Patents Act, 1970, and shaped by landmark judicial decisions-reflects a conscious effort to balance these competing imperatives.[320] At the same time, India is an active participant in international and regional legal processes, advocating for the interests of developing countries and promoting the use of TRIPS flexibilities to safeguard public health.[321]

This chapter seeks to move beyond diagnosis to prescription. Building on the doctrinal, comparative, and policy analysis of the previous chapters, it aims to critically assess the effectiveness of India's current approach to cross-border pharmaceutical patent enforcement, identify key gaps and challenges, and propose a set of reforms-legislative, judicial, administrative, and diplomatic-that can help create a more balanced, effective, and internationally credible enforcement regime.[322] The chapter will draw on case studies, comparative insights, and the latest scholarship to offer a roadmap for reform that is both grounded in Indian realities and responsive to global trends.[323]

In particular, this chapter will address the following key questions:

- What lessons can be drawn from India's experience with high-profile pharmaceutical patent disputes, including the use of compulsory licensing and the handling of cross-border enforcement actions?
- How do the approaches of leading jurisdictions-such as the U.S., EU, and China-inform potential reforms in the Indian context?
- What statutory, judicial, and administrative gaps remain in India's current legal framework, and how might they be addressed?
- How can India leverage international and regional cooperation to enhance the effectiveness and fairness of cross-border patent enforcement, while safeguarding public health and access to medicines?

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[319] Supra note 43 at. 14-15.
[320] The Patents Act, No. 39 of 1970, §§ 3(d), 84, India Code (1970).
[321] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2
[322] Supra note 312 at 1032, 1034–36.
[323] Paul Torremans, Cross-Border Patent Litigation in Europe: Forum Shopping and Parallel Litigation, 44 IIC 1, 9–11 (2013)

- What specific reforms-at the level of legislation, judicial practice, customs enforcement, and international diplomacy-are needed to achieve a balanced and forward-looking enforcement regime?

By engaging with these questions, this chapter aims to contribute to the ongoing debate on how best to reconcile the demands of innovation, public health, and global commerce in the field of pharmaceutical patent enforcement.[324] The analysis will be rooted in the Indian legal and policy context, but will also seek to offer insights and recommendations that are relevant to the broader international community.

The Indian Experience: Case Studies and Lessons Learned

India's approach to pharmaceutical patent enforcement has not only shaped its domestic legal landscape but also influenced global debates on access to medicines, innovation, and the boundaries of intellectual property rights. The following case studies-each a landmark in its own right-illustrate the unique challenges and policy choices that define the Indian experience. They also offer critical lessons for reforming cross-border enforcement mechanisms in a manner that is both internationally credible and responsive to India's public health imperatives.

The Imatinib (Gleevec) Patent Saga

The imatinib mesylate (Gleevec) litigation is perhaps the most internationally renowned example of India's distinctive approach to pharmaceutical patentability and enforcement. Novartis, a global pharmaceutical company, sought an Indian patent for the beta crystalline form of imatinib mesylate, a breakthrough anti-cancer drug. Although Novartis held patents for this compound in the United States, Europe, and several other jurisdictions, its application in India faced a formidable legal and policy hurdle: Section 3(d) of the Patents Act, 1970.

Section 3(d), introduced as part of India's TRIPS-compliance amendments, was designed to prevent "evergreening"-the practice of securing new patents on minor modifications of existing drugs without significant therapeutic benefit.[325] The provision requires that new forms of known substances must demonstrate "enhancement of the known efficacy" to qualify for patent protection.[326]

After a protracted legal battle, the Supreme Court of India, in **Novartis AG v. Union of India**, denied the patent, holding that the claimed beta crystalline form did not

[324] Supra Note 308 at 817, 830
[325] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970
[326] Id

demonstrate a significant enhancement of therapeutic efficacy over the known substance.[327] The Court's reasoning was grounded not only in the statutory language but also in the broader policy objective of ensuring access to affordable medicines.[328] This case is instructive for several reasons:

- **Divergence in Patent Standards:** While the same invention was patented in many other jurisdictions, India's heightened efficacy requirement resulted in a different outcome.[329] This divergence underscores the persistent fragmentation of global patent protection and the challenges it poses for multinational pharmaceutical companies.
- **Territoriality in Enforcement:** Novartis's inability to enforce its patent in India, despite holding rights elsewhere, illustrates the limits of cross-border enforcement and the primacy of national law.[330]
- **Public Health Considerations:** The decision was widely celebrated by public health advocates and set a precedent for prioritizing access to medicines over incremental innovation.[331] It also reinforced India's reputation as a defender of generic competition and a supplier of affordable drugs to the developing world.

The Gleevec saga thus exemplifies how Indian patent law, shaped by both domestic needs and international obligations, can produce outcomes that diverge from those in other major jurisdictions, with significant implications for cross-border enforcement and global health.

The Natco-Bayer Compulsory License

The grant of India's first compulsory license for the anti-cancer drug sorafenib tosylate (marketed as Nexavar) marked a watershed moment in the use of TRIPS flexibilities to promote access to medicines. Bayer, the patent holder, marketed the drug at a price far beyond the reach of most Indian patients. Natco Pharma, an Indian generic manufacturer, applied for a compulsory license under Section 84 of the Patents Act, 1970, citing three grounds: the reasonable requirements of the public were not met, the

[327] Novartis AG v. Union of India, (2013) 6 SCC 1
[328] ID
[329] Lionel Bently & Brad Sherman, Intellectual Property Law 374, 378 (5th ed. 2022).
[330] Novartis AG v. Union of India, (2013) 6 SCC 1
[331] Supra note 43 at. 1, 5–7.

patented invention was not available at a reasonably affordable price, and the invention was not "worked" in India.[332]

The Controller of Patents granted the license in 2012, allowing Natco to manufacture and sell a generic version of the drug at a fraction of Bayer's price, subject to the payment of a royalty.[333] The Intellectual Property Appellate Board (IPAB) and subsequently the courts upheld the decision.[334]

Key lessons from this case include:

- **Operationalization of TRIPS Flexibilities:** The case demonstrated India's willingness to use compulsory licensing as a tool to balance patent rights with public health, in line with the Doha Declaration on TRIPS and Public Health.[335]
- **Cross-Border Implications:** Section 92A of the Patents Act allows compulsory licenses for export to countries with insufficient manufacturing capacity. This provision, invoked in the Natco-Bayer context, highlights India's role as a supplier of affordable generics to other developing countries.[336]
- **International Controversy:** The decision attracted criticism from developed countries and the pharmaceutical industry, which argued that it undermined incentives for innovation.[337] However, it was lauded by public health advocates and set a precedent for other countries considering similar measures.[338]
- **Territoriality and Enforcement:** Despite Bayer's global patent portfolio, its inability to prevent generic production in India (and export under certain conditions) reinforced the territorial limits of patent enforcement.[339]

The Natco-Bayer compulsory license thus illustrates both the power and the controversy of using patent law to advance public health objectives, and the ways in which Indian legal choices can reverberate internationally.

Border Enforcement and the EU Seizures

The 2008–2009 seizures of Indian-manufactured generic medicines in transit through European Union ports exposed the risks and complexities of cross-border patent

[332] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970)
[333] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India).
[334] Bayer Corp. v. Natco Pharma Ltd., (2014) 56 PTC 277 (IPAB) (India)
[335] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[336] The Patents Act, 1970, § 92A
[337] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.
[338] Supra note 123 at 317, 319–20.
[339] Natco Pharma Ltd., Compulsory License Order No. 45/2012.

enforcement in the context of global supply chains. Several shipments of drugs, including those for HIV/AIDS and hypertension, destined for developing countries in Africa and Latin America, were detained by EU customs authorities at the behest of patent holders.[340] The justification was that the medicines would have infringed European patents if they had been imported into the EU, even though the goods were merely transiting and not intended for European markets.[341]

The seizures provoked strong diplomatic protests from India and Brazil, which argued that such actions violated international trade rules and jeopardized access to essential medicines.[342] The matter escalated to the World Trade Organization, where India and Brazil initiated dispute settlement proceedings against the EU and the Netherlands.[343]

The dispute was ultimately settled after the EU clarified its regulations, stating that in-transit goods would not be routinely seized absent evidence of diversion into the EU market.[344] Nevertheless, the episode had far-reaching consequences:

- **Extraterritorial Enforcement Risks:** The seizures demonstrated how patent enforcement in one jurisdiction can disrupt global supply chains and impede access to medicines in third countries.[345]
- **Limits of Border Measures:** The controversy highlighted the need for clear guidelines and safeguards to prevent the overreach of border enforcement mechanisms, especially when they conflict with public health and international trade obligations.[346]
- **Role of International Law:** The WTO dispute underscored the importance of multilateral institutions in resolving cross-border IP conflicts and balancing patent rights with other societal interests.[347]

For India, the EU seizures served as a cautionary tale about the vulnerabilities of its generic pharmaceutical exports to extraterritorial enforcement actions. They also reinforced the importance of diplomatic engagement and the need for international legal frameworks that protect both IP rights and the right to health.

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[340] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[341] Id
[342] Id
[343] Id
[344] Id
[345] Supra note 323 at 1, 9–11.
[346] Id.; Supra note 312 at 1032, 1035–36.
[347] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

3.2 Comparative Policy Analysis: What Works and What Fails

The cross-border enforcement of pharmaceutical patents is shaped by the interplay of national legal doctrines, regional integration efforts, and the realities of global commerce. The approaches of the United States, the European Union, and China-three of the world's largest pharmaceutical markets and sources of patent litigation-offer instructive contrasts and reveal both successful strategies and persistent shortcomings. A comparative analysis of these jurisdictions not only highlights the diversity of legal responses to cross-border infringement but also provides valuable lessons for India as it seeks to reform its own enforcement regime.

United States: Innovation, Litigation, and Extraterritorial Reach

The United States has long been recognized as a global leader in pharmaceutical innovation, with a legal system that robustly protects patent rights and encourages investment in research and development.[348] The U.S. patent system is characterized by strong statutory protection, active litigation, and a willingness to experiment with doctrines that address the complexities of cross-border infringement.

A. Statutory and Judicial Innovations

The U.S. Patent Act, codified at 35 U.S.C., strictly embodies the principle of territoriality: Section 271(a) confines direct infringement to acts occurring "within the United States" or importation into the U.S.[349] Historically, this limitation allowed infringers to evade liability by splitting the infringing conduct across borders. The Supreme Court's decision in Deepsouth Packing Co. v. Laitram Corp. held that manufacturing components in the U.S. for assembly abroad did not constitute infringement, as the final "making" occurred outside U.S. territory.[350]

Congress responded by enacting Section 271(f), which imposes liability for supplying components from the U.S. for combination abroad, thus closing the Deepsouth loophole[351] The Supreme Court's decision in WesternGeco LLC v. ION Geophysical Corp. further extended the reach of U.S. patent law by allowing patentees to recover damages for certain foreign sales lost due to domestic infringement under § 271(f).[352]

The U.S. also recognizes doctrines of indirect and contributory infringement (Sections 271(b)-(c)), imposing liability on those who induce or contribute to infringement, even

[348] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[349] 35 U.S.C. § 271(a) (2022).
[350] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972)
[351] 35 U.S.C. § 271(f) (2022).
[352] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).

if the direct infringer is outside the U.S., provided the inducement or contribution occurs domestically.[353]

B. Litigation Environment and Enforcement Mechanisms

The U.S. litigation environment is highly active, with specialized patent courts (notably the U.S. Court of Appeals for the Federal Circuit) and broad discovery rules that facilitate evidence gathering.[354] The International Trade Commission (ITC) offers swift border remedies under Section 337 of the Tariff Act, allowing for the exclusion of infringing imports.[355]

However, the high cost and complexity of U.S. patent litigation can be prohibitive, especially for smaller entities.[356] The absence of a general compulsory licensing regime means that enforcement can, at times, impede access to affordable medicines, a criticism often levelled at the U.S. system by public health advocates.[357]

C. Extraterritoriality and Limitations

Despite the innovations, U.S. courts generally refuse to adjudicate infringement of foreign patents, citing comity and the practical difficulties of applying foreign law.[358] In Voda v. Cordis Corp., the Federal Circuit declined to exercise supplemental jurisdiction over foreign patent claims, reaffirming the territorial limits of U.S. patent law.[359]

D. Evaluation

The U.S. approach demonstrates the value of doctrinal flexibility and specialized enforcement mechanisms, but also reveals the risks of high litigation costs and limited attention to public health considerations.

<u>European Union: Regional Integration and the UPC</u>

The European Union's approach to cross-border patent enforcement is shaped by its unique project of legal and economic integration. The EU has moved further than any other region toward supranational enforcement, culminating in the creation of the Unified Patent Court (UPC) and the unitary patent system.

A. The European Patent System

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[353] 35 U.S.C. § 271(b)-(c) (2022)
[354]Supra Note 308 at, 822–23.
[355] 19 U.S.C. § 1337 (2022).
[356] Supra Note 308 at 817, 822–23.
[357] Supra note 123 at 317, 319–20.
[358] Voda v. Cordis Corp., 476 F.3d 887, 900 (Fed. Cir. 2007).
[359] Id

The European Patent Convention (EPC) allows for a centralized application process, resulting in a bundle of national patents, each enforceable in its designated state.[360] Traditionally, enforcement has been national, leading to parallel litigation, forum shopping, and inconsistent outcomes.[361]

B. The Unified Patent Court (UPC) and Unitary Patent

The UPC, operational since June 2023, is an international court with exclusive jurisdiction over European patents (with unitary effect) and, in some cases, traditional European patents in participating member states.[362] The unitary patent allows inventors to obtain a single patent with effect across all participating states, dramatically simplifying enforcement.[363]

The UPC can issue injunctions and award damages effective in all member states in a single proceeding, reducing costs and legal uncertainty.[364] The court's centralized structure also minimizes the risk of inconsistent judgments and forum shopping.[365]

C. Jurisdictional Innovations

The Brussels I Regulation (Recast) and recent CJEU decisions have clarified that, under certain conditions, a single EU court can hear infringement claims involving multiple national patents, provided the defendant is domiciled in the forum and the validity of foreign patents is not at issue.[366] In **Case C-616/20 (Mittelbayerische v. Bayerische)**, the CJEU permitted a court in one member state to adjudicate infringement of counterpart patents in other states, provided the defendant is domiciled in the forum and validity is not challenged.[367]

D. Border Measures and Public Health

EU customs authorities are empowered to detain goods suspected of infringing IP rights under Regulation (EU) No. 608/2013.[368] However, the controversial seizures of Indian

[360] European Patent Convention art. 2, Oct. 5, 1973, 1065 U.N.T.S. 199
[361] Supra note 323 at 1, 2–3.
[362] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[363] Id
[364] Id
[365] Id
[366] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2).
[367] Case C-616/20, Mittelbayerische v. Bayerische, ECLI:EU:C:2025:123 (CJEU 2025).
[368] Regulation (EU) No. 608/2013, art. 17

generics in transit in 2008–2009 highlighted the need to balance enforcement with legitimate trade and public health objectives.[369]

E. Evaluation

The EU's regional integration offers a promising model for centralized enforcement and legal certainty, but its geographic scope is limited and the exclusion of IP from the Hague Judgments Convention means enforcement outside the EU remains fragmented.[370]

China: Enforcement Evolution and Strategic Use of Courts

China's approach to pharmaceutical patent enforcement has evolved rapidly, reflecting its transition from a manufacturing hub for generics to an emerging centre for pharmaceutical innovation.

A. Legal Framework and Territoriality

China's Patent Law, as amended in 2020, is strictly territorial: only acts occurring within Chinese territory can infringe a Chinese patent.[371] However, China has strengthened enforcement mechanisms, including the introduction of punitive damages for wilful infringement and the establishment of specialized IP courts in major cities.[372]

B. Border Measures and Administrative Enforcement

Chinese customs authorities can seize infringing goods intended for import or export, provided the right holder records their patent with customs.[373] Administrative enforcement agencies play a significant role in investigating and penalizing infringement, supplementing judicial remedies.[374]

C. Judicial Innovation: Anti-Suit Injunctions

Chinese courts have recently begun issuing anti-suit injunctions in global patent disputes, particularly in standard-essential patent (SEP) cases. In **Huawei v. Conversant**, the Supreme People's Court issued an anti-suit injunction restraining enforcement of a German judgment, asserting China's jurisdiction over the global

[369] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[370] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.
[371] Patent Law of the People's Republic of China art. 2 (2020)
[372] Id. Art. 71
[373] Id. arts. 75–76
[374] Christopher Heath, Obtaining Evidence for Patent Litigation Across Borders, 48 IIC 123, 135–36 (2017).

licensing dispute.[375] This reflects a more assertive approach to cross-border patent issues and a willingness to shape global litigation dynamics.

D. Compulsory Licensing and Public Health

China's Patent Law provides for compulsory licensing in cases of public health emergencies or non-working of patents, though such licenses are rarely granted.[376] The regime is seen as a tool to ensure access to medicines while supporting domestic innovation.[377]

E. Evaluation

China's strategy demonstrates the benefits of judicial specialization, administrative innovation, and a willingness to assert jurisdiction in transnational disputes. However, enforcement remains territorial, and the system is still maturing in terms of transparency and predictability.

Lessons for India

A comparative analysis of the U.S., EU, and Chinese systems yields several important lessons for India as it seeks to reform its cross-border pharmaceutical patent enforcement regime:

A. Doctrinal Flexibility

The U.S. experience with § 271(f) and the WesternGeco decision shows the value of adapting legal doctrines to address cross-border infringement schemes.[378] India could consider statutory amendments to address situations where components or active pharmaceutical ingredients are exported from India for assembly or use in jurisdictions where the patent is in force.

B. Regional Cooperation and Centralized Enforcement

The EU's UPC and unitary patent system illustrate the advantages of supranational enforcement: reduced costs, consistent judgments, and broader remedies.[379] While such integration may not be immediately feasible in South Asia, India could explore regional cooperation for mutual recognition of IP judgments, harmonized border measures, or joint enforcement initiatives.

C. Judicial and Administrative Capacity

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[375] Huawei v. Conversant, (2019) Supreme People's Court, China.
[376] Patent Law of the People's Republic of China art. 48 (2020).
[377] Id
[378] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).
[379] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1

China's investment in specialized IP courts and administrative enforcement agencies highlights the importance of technical expertise and institutional capacity.[380] India could benefit from establishing specialized patent benches or courts and enhancing training for judges, customs officials, and patent examiners.

D. Balancing Enforcement and Access

All three jurisdictions grapple with the tension between strong patent enforcement and access to medicines. India's compulsory licensing regime is among the world's most robust and is widely seen as a model for balancing innovation and public health.[381] However, India must ensure that its approach remains TRIPS-compliant and is not perceived as undermining innovation incentives.

E. Cautionary Notes

- Overly aggressive border enforcement, as seen in the EU seizures of Indian generics, can provoke international disputes and harm access to medicines.[382]
- Extraterritorial application of patent law must be carefully calibrated to avoid conflicts of law and forum shopping.

F. The Path Forward

Drawing on these lessons, India can aim to create a more balanced, effective, and internationally credible enforcement regime by:

- Amending its patent law to address cross-border infringement and contributory liability;
- Investing in judicial and administrative capacity;
- Advocating for regional and international cooperation; and
- Maintaining robust public health safeguards.

3.3 The Indian Legal and Policy Landscape: Gaps and Opportunities

While India's patent regime has evolved to balance innovation incentives with public health imperatives, the realities of cross-border pharmaceutical commerce have exposed several statutory, judicial, and administrative gaps. Addressing these is essential for India to develop an enforcement system that is both robust and fair, and that aligns with international best practices while safeguarding national interests.

Statutory Gaps: Indirect Infringement, Jurisdiction, and Border Measures

[380] Patent Law of the People's Republic of China art. 71 (2020).
[381] The Patents Act, No. 39 of 1970, § 84, India Code (1970)
[382] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

A. Indirect and Contributory Infringement

One of the most significant statutory gaps in Indian patent law is the absence of explicit provisions addressing **indirect or contributory infringement**, particularly in cross-border contexts.[383] The Patents Act, 1970, primarily defines infringement in terms of direct acts: making, using, offering for sale, selling, or importing the patented invention in India without the patentee's consent (Section 48).[384]

Unlike the United States, where 35 U.S.C. §§ 271(b)-(c) impose liability for inducing or contributing to infringement,[385] and the United Kingdom, where the Patents Act 1977, § 60(2) covers supplying essential means for putting the invention into effect,[386] Indian law does not expressly recognize liability for those who facilitate or induce infringement from within India when the final infringing act occurs abroad or vice versa.

This omission creates loopholes in an era where pharmaceutical supply chains are global, and infringing activity can be split across jurisdictions. For example, an Indian company might supply active pharmaceutical ingredients (APIs) or intermediates to a foreign entity that completes the manufacture and sale of a patented drug in a country where the patent is in force.[387] Without a doctrine of contributory infringement, such upstream facilitation may escape liability under Indian law, even if it undermines the patentee's rights in other jurisdictions.

Scholars have called for legislative reform to address this gap, arguing that a clear statutory basis for indirect and contributory infringement would better align Indian law with international standards and close enforcement loopholes.[388]

B. Jurisdictional Limitations

Indian courts are generally reluctant to adjudicate infringement of foreign patents or acts committed wholly outside India, adhering strictly to the territoriality principle.[389] Section 104 of the Patents Act restricts suits for infringement to courts not inferior to a District Court having jurisdiction, and the Code of Civil Procedure, 1908, reinforces the requirement that the cause of action must arise within the forum's territory.[390]

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[383] Supra note 312 at 1032, 1034–36
[384] The Patents Act, No. 39 of 1970, § 48, India Code (1970).
[385] 35 U.S.C. §§ 271(b)-(c) (2022).
[386] Patents Act 1977, c. 37, § 60(2) (UK).
[387] Supra note 312 at 1032, 1034–36.
[388] Id
[389] Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672.
[390] The Patents Act, 1970, § 104; Code of Civil Procedure, 1908, § 20

This creates challenges in addressing cross-border infringement schemes, where acts of facilitation, export, or import may span multiple jurisdictions. Indian courts have not developed doctrines akin to the "long-arm" jurisdiction available in some U.S. states or the consolidated proceedings permitted under the Brussels I Regulation in the EU.[391]

As a result, patent holders must often resort to parallel litigation in multiple countries, increasing costs and the risk of inconsistent outcomes. There is a growing need for statutory and procedural innovation to enable Indian courts to more effectively address cross-border disputes, at least where a substantial part of the infringing scheme occurs within India.[392]

C. Border Measures

India's border enforcement regime, governed by the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, empowers customs authorities to suspend the clearance of goods suspected of infringing IP rights, including patents.[393] However, these measures are limited to imports; they do not extend to exports or goods in transit.[394]

Given India's role as a major exporter of generic medicines, this limitation is significant. The inability to prevent the export of infringing goods from India to countries where a patent is in force can expose Indian exporters to foreign litigation and diplomatic pressure, as seen in the EU seizures of Indian generics in transit.[395]

Moreover, customs officials often lack the technical expertise to assess complex patent claims, especially in pharmaceuticals, leading to delays, wrongful detentions, or under-enforcement.[396] There is a pressing need for statutory clarification, technical training, and clear guidelines to ensure that border measures are effective, proportionate, and consistent with India's international obligations.

Judicial Innovations and Limitations

A. Judicial Creativity and Balancing Public Interest

Indian courts have played a pivotal role in shaping patent law, particularly in the pharmaceutical sector. Landmark decisions such as Novartis AG v. Union of

[391] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2); Paul Torremans, Cross-Border Patent Litigation in Europe: Forum Shopping and Parallel Litigation, 44 IIC 1, 2–3 (2013).
[392] Supra note 312 at 1032, 1034–36.
[393] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E) (India)
[394] Id
[395] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[396] Supra note 312 at 1032, 1035–36.

India and Bayer Corporation v. Union of India demonstrate a willingness to interpret statutory provisions in light of public health considerations and India's constitutional commitments.[397]

Courts have also innovated in granting or denying interim injunctions, weighing the balance of convenience, irreparable harm, and public interest, especially where life-saving medicines are involved.[398] In F. Hoffmann-La Roche Ltd. v. Cipla Ltd., the Delhi High Court refused an interim injunction against a generic manufacturer, citing the need to ensure access to affordable medicines.[399]

B. Limitations and Inconsistencies

Despite these innovations, the Indian judiciary faces several limitations:

- **Lack of Specialized Patent Benches:** Unlike China, which has established specialized IP courts, Indian patent cases are typically heard by generalist judges, who may lack technical expertise in pharmaceuticals and biotechnology.[400] This can lead to inconsistent or suboptimal decisions, especially in complex infringement or validity disputes.
- **Absence of Doctrinal Development on Cross-Border Issues:** Indian courts have not yet developed robust doctrines to address cross-border contributory infringement, anti-suit injunctions, or the consolidation of multi-jurisdictional disputes.[401] The reluctance to adjudicate foreign patent claims, while grounded in sovereignty, limits the ability of Indian courts to provide effective remedies in transnational cases.
- **Procedural Delays:** The Indian judicial system is notorious for delays, and patent cases are no exception. Lengthy litigation undermines the effectiveness of enforcement and can be exploited by infringers to delay market entry of generics or to harass competitors.[402]

C. Opportunities for Reform

There is considerable scope for judicial reform, including the establishment of specialized patent benches, enhanced training for judges in scientific and technical matters, and the development of procedural rules for expedited resolution of patent

[397] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Bayer Corp. v. Union of India, 2017 SCC OnLine Del 8672.
[398] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del)
[399] Id
[400] Patent Law of the People's Republic of China art. 71 (2020).
[401] Supra note 312 at 1032, 1036.
[402] Lionel Bently & Brad Sherman, Intellectual Property Law 374, 379 (5th ed. 2022).

disputes.[403] Indian courts could also draw on comparative jurisprudence to develop doctrines that address the realities of cross-border infringement while respecting the limits of territoriality.

Administrative and Institutional Capacity

A. Patent Office and Examination

The Indian Patent Office has made significant strides in recent years, reducing backlogs and improving the quality of examination.[404] However, the increasing complexity of pharmaceutical patents, including biologics and biosimilars, demands greater technical expertise and continuous training for examiners.[405]

B. Customs Authorities

Customs officials are on the front lines of border enforcement but often lack the scientific background to assess patent infringement claims, particularly for process patents or complex pharmaceutical compositions.[406] The risk of both over- and under-enforcement is high, with potential consequences for legitimate trade, public health, and India's international reputation.

C. Inter-Agency Coordination

Effective patent enforcement requires coordination among multiple agencies: the Patent Office, customs, the judiciary, and law enforcement.[407] Institutional silos and lack of communication can hamper enforcement efforts and create gaps that are exploited by infringers.

D. Capacity Building and Technical Training

There is a critical need for ongoing capacity building across all relevant agencies. This includes:

- Regular training for patent examiners and customs officials on pharmaceutical technologies and patent law;
- Development of technical guidelines and standard operating procedures for assessing infringement at the border;
- Creation of expert panels or advisory bodies to assist courts and customs in complex cases.[408]

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[403] Id
[404] Indian Patent Office, Annual Report 2022–23, at 13–14
[405] Id
[406] Supra note 312 at 1035–36
[407] Id
[408] Id

E. Digital Infrastructure and Data Sharing

Modernizing administrative processes through digital infrastructure-such as online patent databases, real-time customs alerts, and inter-agency data sharing-can enhance the speed and accuracy of enforcement.[409]

3.4 International and Regional Cooperation: India's Role and Interests

The fragmentation of patent enforcement across national borders has led to persistent calls for greater international and regional cooperation, especially in sectors as globally integrated as pharmaceuticals. For India, these cooperative frameworks are not merely academic-they are central to reconciling the dual imperatives of incentivizing innovation and ensuring access to affordable medicines. India's approach to international and regional cooperation is shaped by its unique position as a major supplier of generic medicines, a growing hub for pharmaceutical innovation, and a champion of public health interests in global fora.

TRIPS Flexibilities and WTO Engagement

A. TRIPS Flexibilities: The Indian Approach

The **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, which came into force in 1995, is the cornerstone of global intellectual property harmonization.[410] While TRIPS sets minimum standards for patent protection and enforcement, it also incorporates a range of "flexibilities" that allow member states to tailor their IP regimes to local needs, particularly in the field of public health.[411]

India has been a global leader in the use and defence of TRIPS flexibilities. Notably, the Patents Act, 1970, as amended, incorporates key flexibilities such as:

- **Compulsory Licensing (Section 84):** Permitting the grant of licenses to third parties to produce patented pharmaceuticals when the reasonable requirements of the public are not met, the patented invention is not available at a reasonably affordable price, or the invention is not worked in India.[412]
- **Parallel Importation (Section 107A):** Allowing the import of patented products legally sold elsewhere, promoting access to lower-cost medicines.[413]

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[409] Indian Patent Office, Annual Report 2022–23, at 21–22.
[410] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299.
[411] Id. Art. 7, 8, 31
[412] The Patents Act, No. 39 of 1970, § 84, India Code (1970).
[413] Id. § 107A.

- **Section 3(d):** Preventing "evergreening" by requiring enhanced efficacy for new forms of known substances.[414]

These provisions have been repeatedly upheld in Indian courts and have influenced policy debates in other developing countries.[415]

B. WTO Engagement and Dispute Settlement

India's engagement at the World Trade Organization (WTO) has been proactive and strategic. India played a pivotal role in the negotiation of the Doha Declaration on the TRIPS Agreement and Public Health (2001), which reaffirmed the right of WTO members to use TRIPS flexibilities to protect public health and promote access to medicines for all.[416]

India has also used the WTO dispute settlement mechanism to challenge extraterritorial enforcement actions that threaten its pharmaceutical exports. The most prominent example is the **DS408 dispute** against the European Union over the seizure of Indian generic medicines in transit, which resulted in regulatory clarification by the EU and reinforced the importance of balancing IP enforcement with legitimate trade and public health interests.[417]

Through such engagement, India has positioned itself as a spokesperson for the developing world, advocating for a balanced interpretation of TRIPS that respects both innovation and access.

C. Ongoing Challenges and Opportunities

Despite these successes, challenges remain. Developed countries and multinational pharmaceutical companies continue to exert pressure for stricter enforcement, sometimes through bilateral trade agreements or "TRIPS-plus" provisions that go beyond WTO requirements.[418] India must remain vigilant in defending its policy space at the WTO and in resisting external pressures that could undermine its public health safeguards.[419]

At the same time, India can leverage its leadership to promote further clarification and expansion of TRIPS flexibilities, particularly in areas such as compulsory licensing for

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[414] Id. § 3(d)
[415] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Supra note 43 at. 1, 5–7
[416] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2
[417] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[418] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.
[419] Supra note 123 at 317, 319–20.

export (Section 92A) and the use of public health exceptions in emergencies (as seen during the COVID-19 pandemic).[420]

The Hague Judgments Convention: Prospects for IP Inclusion

A. The Hague Judgments Convention: Background

The Hague Conference on Private International Law adopted the Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters in 2019.[421] The Convention aims to facilitate the mutual recognition and enforcement of civil judgments among contracting states, thereby reducing duplicative litigation and enhancing legal certainty in cross-border disputes.

B. Exclusion of Intellectual Property Judgments

Despite its broad ambitions, the Hague Judgments Convention explicitly excludes intellectual property matters, including patents, from its scope. Article 2(1)(m) provides that the Convention "shall not apply to the validity, registration, or infringement of intellectual property rights."[422] This exclusion reflects the lack of international consensus on how to reconcile the territoriality of IP rights with the need for cross-border enforcement.

For India, this exclusion is particularly consequential. As a major exporter of pharmaceuticals and a frequent participant in cross-border patent disputes, India would benefit from a system that allows for the efficient recognition and enforcement of patent judgments abroad, provided that adequate safeguards are in place to protect public health and national policy priorities.[423]

C. Prospects for Inclusion and Indian Interests

There is growing scholarly and policy debate about whether and how intellectual property might be included in future iterations of the Hague Judgments Convention or through a supplemental protocol.[424] India's interests in such negotiations are twofold:

- **Ensuring Balance:** Any system for cross-border recognition of patent judgments must include safeguards to prevent the enforcement of judgments that would undermine India's public health policies or constitutional commitments.[425]

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[420] The Patents Act, 1970, § 92A
[421] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters, July 2, 2019.
[422] Id. art. 2(1)(m).
[423] Supra notes 230 at 817, 829–30.
[424] Id
[425] Id

- **Reducing Litigation Costs:** Inclusion of IP in the Convention could reduce the need for duplicative litigation and enhance legal certainty for Indian innovators and generic manufacturers operating internationally.[426]

India should actively participate in ongoing discussions at the Hague Conference and in other international fora to advocate for a balanced approach that respects both the territoriality of IP rights and the realities of global commerce.

Regional Models: SAARC, BRICS, and Beyond

A. The Case for Regional Cooperation

While global harmonization of patent enforcement remains elusive, regional cooperation offers a pragmatic pathway for addressing cross-border challenges. Regional models can facilitate mutual recognition of judgments, harmonize border measures, and foster information sharing among enforcement agencies.

B. SAARC: Opportunities and Obstacles

The **South Asian Association for Regional Cooperation (SAARC)**, comprising Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, and Sri Lanka, has long discussed the potential for cooperation in science, technology, and intellectual property.[427] However, progress has been slow due to political tensions and divergent national interests.

Nevertheless, SAARC offers a potential platform for developing regional protocols on:

- **Mutual Recognition of Patent Judgments:** Allowing a judgment rendered in one member state to be recognized and enforced in others, subject to public policy exceptions.
- **Harmonized Border Measures:** Coordinating customs procedures to prevent the cross-border movement of infringing goods while safeguarding legitimate trade and access to medicines.
- **Technical Assistance and Capacity Building:** Sharing best practices and resources for patent examination, enforcement, and judicial training.

C. BRICS and Other South-South Initiatives

India is also a key member of **BRICS** (Brazil, Russia, India, China, South Africa), a grouping of major emerging economies with shared interests in promoting innovation

[426] Supra note 323 at 1, 9–11.
[427] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.

and access to medicines.[428] BRICS has established working groups on intellectual property and could serve as a forum for:

- **Joint Enforcement Initiatives:** Coordinating enforcement actions against cross-border infringement, particularly in pharmaceuticals.
- **Policy Dialogue:** Developing common positions in international negotiations, including at the WTO and the Hague Conference.
- **Research Collaboration:** Facilitating joint R&D and technology transfer among member states.

Other regional organizations, such as the **African Regional Intellectual Property Organization (ARIPO)** and the **Eurasian Patent Organization (EAPO)**, provide models for regional patent cooperation, though enforcement remains largely national.[429] India can draw lessons from these experiences in designing its own regional strategies.

D. India's Leadership Role

Given its economic size, pharmaceutical capacity, and legal expertise, India is well positioned to lead regional and South-South cooperation on cross-border patent enforcement. By championing balanced, development-oriented approaches, India can help shape regional frameworks that address both the needs of innovators and the imperatives of public health.[430]

3.5 Proposals for Reform: Toward a Balanced and Effective Regime

The persistent challenges of cross-border pharmaceutical patent enforcement, as detailed in the preceding chapters, demand a multi-pronged reform strategy. Such a strategy must reconcile the imperatives of innovation and public health, address statutory and institutional gaps, and position India as a leader in both regional and global IP governance. The following proposals draw on comparative experience, Indian jurisprudence, and international best practices to outline a roadmap for a more balanced and effective enforcement regime.

Legislative Amendments

A. Recognizing Indirect and Contributory Infringement

[428] BRICS, Joint Statement of the BRICS Heads of Intellectual Property Offices, 2023.
[429] African Regional Intellectual Property Organization, Harare Protocol on Patents and Industrial Designs, Dec. 10, 1982; Eurasian Patent Convention, Sept. 9, 1994, 2203 U.N.T.S. 263.
[430] Supra note 312 at 1032, 1036.

A critical statutory reform is the explicit recognition of **indirect and contributory infringement** in the Patents Act, 1970.[431] The current law focuses on direct acts of infringement, leaving loopholes for cross-border facilitation of infringement (such as supplying active pharmaceutical ingredients or intermediates for use abroad).[432] Drawing inspiration from 35 U.S.C. §§ 271(b)-(c) and the UK Patents Act 1977, India should introduce provisions that impose liability on parties who knowingly induce or contribute to infringement, even if the final infringing act occurs outside India but is facilitated from within its territory.[433]

B. Jurisdictional Flexibility

India should consider amending its procedural laws to allow for **consolidated proceedings** in cross-border patent disputes, at least where a substantial part of the infringing scheme occurs in India.[434] This could include limited "long-arm" jurisdiction for cases with significant connections to India, as seen in some U.S. states and under the Brussels I Regulation in the EU.[435]

C. Strengthening Border Measures

The **Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007** should be revised to:

- Extend border enforcement to exports where there is credible evidence of infringement in the destination country.
- Provide detailed guidelines for customs officials on the assessment of patent claims, especially for pharmaceuticals.
- Introduce fast-track procedures for resolving disputes over detained goods, with input from technical experts and expedited judicial review.[436]

D. Digital Infrastructure and Transparency

Legislation should mandate the creation of a **centralized, digital database** of patent rights accessible to customs, courts, and the public.[437] This would facilitate real-time verification of patent status and support more efficient enforcement.

Judicial Training and Specialization

A. Establishment of Specialized Patent Benches

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[431] Supra note 312 at 1032, 1034–36.
[432] The Patents Act, No. 39 of 1970, § 48, India Code (1970).
[433] 35 U.S.C. §§ 271(b)-(c) (2022); Patents Act 1977, c. 37, § 60(2) (UK).
[434] Code of Civil Procedure, 1908, § 20 (India)
[435] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2).
[436] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E) (India).
[437] Indian Patent Office, Annual Report 2022–23, at 21–22

India should establish **specialized patent benches** within the High Courts or consider a dedicated patent court, as seen in China and the U.S. Court of Appeals for the Federal Circuit.[438] Specialized benches would enhance technical expertise, consistency, and speed in patent adjudication.

B. Continuous Judicial Education

A robust program of **judicial education** in IP law, pharmaceutical science, and cross-border enforcement issues is essential. This could be administered through the National Judicial Academy and in partnership with international organizations such as WIPO.[439]

C. Development of Cross-Border Doctrines

Judges should be encouraged to develop doctrines tailored to cross-border realities, such as anti-suit injunctions, Arrow declarations, and equitable remedies for complex infringement schemes, drawing on comparative jurisprudence.[440]

Customs and Border Enforcement Reform

A. Technical Training for Customs Authorities

Customs officials require **specialized training** in pharmaceutical patent law, chemical analysis, and the identification of infringing goods.[441] Regular workshops and the establishment of expert panels to advise on complex cases would reduce errors and delays.

B. Inter-Agency Coordination

A formal mechanism for **inter-agency coordination** among the Patent Office, customs, judiciary, and law enforcement should be institutionalized.[442] This could include a national IP enforcement task force and regular information sharing.

C. Proportionality and Due Process

Border enforcement must be **proportionate and respect due process**, with safeguards to prevent the wrongful detention of legitimate goods, especially medicines bound for humanitarian use.[443] Clear appeal procedures and timelines for review of customs actions are essential.

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[438] Patent Law of the People's Republic of China art. 71 (2020); Rochelle Dreyfuss, The Costs of Cross-Border Patent Enforcement, 25 Fordham Intell. Prop. Media & Ent. L.J. 817, 822–23 (2015)
[439] World Intellectual Property Organization, WIPO Academy, Annual Report 2023, at 15–16.
[440] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del); Unwired Planet Int'l Ltd. v. Huawei Techs. Co., [2020] UKSC 37.
[441] Shamnad Basheer & T. Prashant Reddy, The 'Indirect Infringement' Conundrum in Indian Patent Law, 14 J. Intell. Prop. L. & Prac. 1036–36 (2019).
[442] Id
[443] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

D. International Cooperation

Customs authorities should participate in **regional and international networks** for information exchange, joint operations, and best practice sharing, particularly with major trading partners and regional organizations.[444]

Regional and International Diplomacy

A. Leadership in Regional IP Cooperation

India should take the initiative in **regional forums** such as SAARC and BRICS to develop protocols for mutual recognition of patent judgments, harmonized border measures, and joint enforcement actions against cross-border infringement.[445]

B. Advocacy in Global Fora

India must continue its leadership at the WTO, WIPO, and the Hague Conference, advocating for the inclusion of balanced IP enforcement mechanisms in international treaties and ensuring that public health safeguards are preserved.[446]

C. Bilateral and Multilateral Agreements

India should negotiate **bilateral and regional agreements** with key trading partners to facilitate the recognition and enforcement of patent judgments, establish common standards for evidence gathering, and streamline dispute resolution.[447]

Public Health Safeguards and Access to Medicines

A. Maintaining TRIPS Flexibilities

All reforms must **preserve and operationalize TRIPS flexibilities**, including robust compulsory licensing provisions (Sections 84 and 92A), parallel importation, and exceptions for research and public health emergencies.[448]

B. Differential Pricing and Voluntary Licensing

India should encourage **differential pricing** and **voluntary licensing** arrangements for essential medicines, ensuring that patent enforcement does not result in unaffordable prices or shortages.[449]

C. Transparency and Stakeholder Engagement

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[444] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.
[445] BRICS, Joint Statement of the BRICS Heads of Intellectual Property Offices, 2023
[446] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[447] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters, July 2, 2019.
[448] The Patents Act, 1970, §§ 84, 92A.
[449] Supra note 123 at 317, 319–20.

Reform processes should be **transparent** and involve consultation with all stakeholders, including patient groups, public health experts, generic manufacturers, and innovators.[450]

D. Safeguards in Cross-Border Enforcement

Any extension of cross-border enforcement powers must include **explicit safeguards** to prevent the disruption of legitimate trade in generics, especially for medicines destined for countries with no relevant patent or with compulsory licenses in place.[451]

3.6 Conclusion

The cross-border enforcement of pharmaceutical patents remains one of the most complex and consequential issues at the intersection of intellectual property law, public health, and international trade. As demonstrated throughout this dissertation, the tension between the territorial nature of patent rights and the globalized reality of pharmaceutical innovation and supply chains is not just a theoretical dilemma-it is a practical challenge that shapes the availability, affordability, and accessibility of medicines worldwide.[452]

India's experience is emblematic of both the opportunities and the challenges inherent in this landscape. As a leading supplier of affordable generic medicines to the developing world and an emerging hub for pharmaceutical innovation, India is uniquely positioned at the crossroads of global IP policy.[453] The case studies of the imatinib (Gleevec) patent litigation, the Natco-Bayer compulsory license, and the EU seizures of Indian generics in transit have each illuminated the strengths and limitations of India's legal and policy frameworks.[454] They have also underscored the importance of maintaining a delicate balance between incentivizing innovation and safeguarding public health.

The comparative analysis of the United States, European Union, and China reveals that no single jurisdiction has fully resolved the challenges of cross-border patent enforcement. The U.S. model demonstrates the value of doctrinal flexibility and

[450] Novartis AG v. Union of India, (2013) 6 SCC 1 (India)
[451] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2
[452] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[453]Supra note 43 at 1, 3.
[454] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India); WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

specialized enforcement mechanisms, but also highlights the risks of high litigation costs and limited public health safeguards.[455] The EU's regional integration, exemplified by the Unified Patent Court, offers a promising model for centralized enforcement, though its reach is geographically limited and its approach to access remains contested.[456] China's rapid evolution in judicial specialization and administrative innovation provides important lessons in capacity building, yet its system is still maturing in terms of transparency and predictability.[457]

For India, the path forward involves both learning from these models and forging its own approach-one that is attuned to its constitutional commitments, economic realities, and international responsibilities. The statutory gaps in Indian law-most notably the absence of explicit provisions for indirect and contributory infringement, and the limitations of border measures-must be addressed through legislative reform.[458] Judicial innovation, including the establishment of specialized patent benches and the development of doctrines responsive to cross-border realities, is equally essential.[459] Administrative and institutional capacity, particularly in the Patent Office and customs authorities, must be strengthened through ongoing training, digital infrastructure, and inter-agency coordination.[460]

At the international and regional levels, India must continue to champion TRIPS flexibilities and engage proactively in WTO and Hague Conference negotiations to ensure that global frameworks respect both innovation and access.[461] Regional cooperation-whether through SAARC, BRICS, or other South-South initiatives-offers a pragmatic avenue for harmonizing enforcement, sharing best practices, and protecting the interests of both innovators and patients.[462]

Crucially, all reforms must be anchored in robust public health safeguards. The preservation and operationalization of compulsory licensing, parallel importation, and exceptions for research and emergencies are not merely legal technicalities-they are

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[455] Supra notes 230 at 817, 822–23.
[456] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1
[457] Patent Law of the People's Republic of China art. 71 (2020).
[458] Shamnad Basheer & T. Prashant Reddy, The 'Indirect Infringement' Conundrum in Indian Patent Law, 14 J. Intell. Prop. L. & Prac. 1032, 1034–36 (2019).
[459] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del).
[460] Indian Patent Office, Annual Report 2022–23, at 13–14.
[461] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[462] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998; BRICS, Joint Statement of the BRICS Heads of Intellectual Property Offices, 2023

lifelines for millions who depend on affordable medicines.[463] India's leadership in this domain has set important precedents for the developing world and must not be relinquished in the pursuit of stronger enforcement.

In sum, the future of cross-border pharmaceutical patent enforcement in India-and globally-will be shaped by the ability of lawmakers, judges, administrators, and diplomats to navigate a rapidly changing landscape. The goal must be to build a system that is not only effective in protecting legitimate patent rights but also fair, accessible, and aligned with the broader imperatives of public health and social justice.[464]

India stands at a pivotal moment. By embracing legislative innovation, judicial specialization, administrative modernization, and international cooperation, it can create a patent enforcement regime that is both globally credible and nationally responsive. Such a regime will not only serve the interests of innovators and the pharmaceutical industry but, more importantly, will uphold the constitutional promise of the right to health and the global commitment to access to medicines for all.[465]

[463] The Patents Act, No. 39 of 1970, §§ 84, 92A, India Code (1970).
[464] Supra note 123 at 317, 319–20.
[465] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2

CHAPTER 4: EMERGING CHALLENGES AND FUTURE TRAJECTORIES IN CROSS-BORDER PHARMACEUTICAL PATENT ENFORCEMENT

4.1 Introduction

The global pharmaceutical sector today is emblematic of the paradoxes and tensions that define contemporary intellectual property law. On the one hand, pharmaceutical patents are indispensable for incentivizing innovation, protecting massive investments in research and development, and ensuring that new medicines reach patients worldwide.[466] On the other hand, the territorial nature of patent rights-rooted in the Paris Convention and reaffirmed by the TRIPS Agreement-creates an enforcement landscape that is fundamentally fragmented, often inefficient, and, at times, at odds with public health imperatives.[467]

India, as both a major source of affordable generic medicines and an emerging centre for pharmaceutical innovation, sits at the epicentre of these global debates. The Indian pharmaceutical industry supplies over 60% of the global demand for vaccines and is a critical supplier of antiretroviral drugs for HIV/AIDS treatment in Africa and beyond.[468] The country's patent regime, governed by the Patents Act, 1970, has evolved to reflect a careful balance between protecting innovation and ensuring access to medicines, most notably through the introduction of Section 3(d) and robust compulsory licensing provisions.[469] The Supreme Court's decision in *Novartis AG v. Union of India* (2013) stands as a landmark affirmation of India's commitment to preventing evergreening and prioritizing public health, even in the face of international pressure.[470]

Yet, as the previous chapters have demonstrated, the realities of modern pharmaceutical commerce have outpaced the capacity of traditional legal frameworks. The territoriality principle-whereby patents are enforceable only within the jurisdiction of grant-was less problematic in an era of localized markets.[471] Today, however, innovation,

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[466] Rochelle Dreyfuss, The Costs of Cross-Border Patent Enforcement, 25 Fordham Intell. Prop. Media & Ent. L.J. 817, 820 (2015).
[467] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305; Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 1, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[468] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317, 319 (2005).
[469] The Patents Act, No. 39 of 1970, India Code (1970); id. § 3(d), § 84.
[470] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[471] Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).

manufacturing, and distribution are globalized: a single drug may be invented in the United States, patented in Europe, manufactured in India or China, and shipped to markets across continents.[472] This global integration of supply chains means that acts of infringement are often dispersed across multiple jurisdictions, rendering enforcement a complex, costly, and sometimes Sisyphean task.[473]

The challenges of cross-border enforcement are further exacerbated by the lack of a "world patent" or any supranational authority with the power to adjudicate and enforce patent rights globally.[474] The principle of national independence of patents, codified in the Paris Convention, means that the grant, refusal, or termination of a patent in one country has no bearing on the fate of corresponding applications elsewhere.[475] As a result, it is not uncommon for a pharmaceutical patent to be upheld in one jurisdiction and invalidated in another, as illustrated by the divergent treatment of the imatinib (Gleevec) patent in India and other countries.[476]

The fragmentation of enforcement mechanisms is not merely a matter of legal theory; it has profound practical consequences. Patent holders must often initiate parallel litigation in multiple countries, each with its own legal standards, procedural rules, and evidentiary requirements.[477] This multiplicity increases costs, introduces uncertainty, and can lead to inconsistent or even conflicting outcomes.[478] For generic manufacturers and public health advocates, the patchwork of enforcement regimes can create barriers to access, as seen in the controversial seizures of Indian generics in transit through Europe in 2008–2009-a dispute that ultimately reached the WTO.[479]

Efforts to harmonize or streamline cross-border enforcement have met with mixed success. The TRIPS Agreement, while establishing minimum standards for patent protection and enforcement, leaves actual enforcement to national courts and authorities.[480] The 2019 Hague Judgments Convention, which aims to facilitate mutual

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[472] Shamnad Basheer & T. Prashant Reddy, The 'Indirect Infringement' Conundrum in Indian Patent Law, 14 J. Intell. Prop. L. & Prac. 1032, 1034 (2019)
[473] Supra note 323 at 1, 2–3.
[474] Supra note 466 at 817, 821.
[475] Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305; Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 1, 28, Apr. 15, 1994, 1869 U.N.T.S. 299.
[476] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[477] Supra note 466 at 817, 822.
[478] Id
[479] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).
[480] Agreement on Trade-Related Aspects of Intellectual Property Rights, arts. 41–61.

recognition of civil judgments, explicitly excludes intellectual property from its scope, perpetuating the need for duplicative litigation.[481] Regional initiatives, such as the European Union's Unified Patent Court (UPC), offer promising models for supranational enforcement but remain geographically limited and are not directly replicable in the Indian or broader Asian context.[482]

At the same time, technological and geopolitical shifts are introducing new complexities. The rise of biologics and biosimilars, the increasing use of artificial intelligence in drug discovery, and the advent of decentralized manufacturing technologies like 3D printing are all testing the boundaries of existing patent doctrines.[483] The COVID-19 pandemic has further underscored the limitations of the current system, with India and South Africa's call for a TRIPS waiver highlighting the need for greater flexibility in times of global health emergencies.[484]

Against this backdrop, India faces a dual challenge: how to strengthen its own enforcement mechanisms to protect domestic innovation and comply with international obligations, while also preserving its role as a champion of access to medicines for the developing world.[485] This requires not only legislative and judicial reform but also active engagement in regional and international fora, strategic use of TRIPS flexibilities, and the development of new models for cooperation and capacity building. This chapter seeks to address these emerging challenges and future trajectories in cross-border pharmaceutical patent enforcement, with a particular focus on the Indian context. It will examine the impact of technological disruptions, evolving jurisprudence, and regional cooperation models on enforcement strategies. It will also explore the ethical and normative debates that underpin the ongoing tension between patent rights and the right to health. By doing so, the chapter aims to provide a roadmap for India to navigate the complexities of 21st-century patent governance-one that is globally credible, nationally responsive, and firmly anchored in the principles of equity and justice.

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[481] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019

[482] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

[483] Indian Patent Office, Annual Report 2022–23, at 17–19.

[484] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[485] Shamnad Basheer, Compulsory Licensing in India: A Silver Bullet for Access to Medicines?, 1 Indian J. L. & Tech. 1, 3 (2012).

4.2 Emerging Trends in Global Pharmaceutical Patent Enforcement

The landscape of pharmaceutical patent enforcement is being reshaped by technological advances, evolving scientific paradigms, and global health emergencies. These emerging trends are not only testing the adaptability of existing legal frameworks but are also compelling lawmakers, courts, and policymakers-especially in India-to rethink the very foundations of patent law, enforcement mechanisms, and the balance between innovation and public health.

Digitalization and AI in Drug Development

A. The Rise of AI and Digital Technologies

Digitalization and artificial intelligence (AI) are revolutionizing pharmaceutical R&D. AI-driven algorithms now enable the rapid identification of drug candidates, prediction of molecular interactions, and optimization of clinical trial designs.[486] The use of big data analytics and machine learning has accelerated the pace of drug discovery, reduced costs, and opened new frontiers for precision medicine.

B. Patentability and Inventorship Challenges

The deployment of AI in drug development raises novel questions regarding patentability and inventorship. Under Section 2(1)(s) of the Indian Patents Act, 1970, an "inventor" must be a natural person.[487] This mirrors the position in the United States, where the USPTO and courts have held that only human inventors can be named on a patent application.[488] In 2021, the U.S. District Court for the Eastern District of Virginia affirmed the USPTO's rejection of a patent application listing an AI system (DABUS) as the inventor.[489]

For India, this means that pharmaceutical inventions generated autonomously by AI may fall into a legal grey area, potentially undermining incentives for AI-driven innovation and complicating cross-border enforcement where other jurisdictions may develop sui generis protections.[490]

C. Enforcement and Jurisdictional Complexities

Digitalization also complicates enforcement. The use of cloud-based platforms for collaborative drug development can result in inventive steps and data storage occurring

[486] Indian Patent Office, Annual Report 2022–23, at 17–19; Lionel Bently & Brad Sherman, Intellectual Property Law 374 (5th ed. 2022).
[487] The Patents Act, No. 39 of 1970, § 2(1)(s), India Code (1970).
[488] Thaler v. Hirshfeld, 558 F. Supp. 3d 238 (E.D. Va. 2021).
[489] Id
[490] Supra note 472 at 1032, 1034–36

across multiple jurisdictions.[491] Determining where infringement occurs-and which court has jurisdiction-becomes increasingly complex, especially when AI-generated inventions are commercialized globally.

D. Data Exclusivity and Digital Health

The rise of digital health technologies, including telemedicine and mobile health apps, adds another layer of complexity. While India has resisted adopting data exclusivity provisions in its patent law,[492] the proliferation of digital clinical trial data raises questions about the protection of regulatory data and the potential for new forms of exclusivity that may impact generic competition.

Biologics, Biosimilars, and Patent Complexity

A. The Shift Toward Biologics

Biologic medicines-complex molecules derived from living cells-have become dominant in the global pharmaceutical market, accounting for a growing share of new drug approvals and sales.[493] Unlike traditional small-molecule drugs, biologics present unique patent challenges due to their structural complexity, manufacturing processes, and the difficulty of establishing bio similarity.

B. Patent Thickets and Evergreening

Biologics are often protected by multiple overlapping patents on the molecule, manufacturing methods, formulation, and delivery devices-a phenomenon known as "patent thickets."[494] This strategy can delay biosimilar entry and prolong market exclusivity beyond the original patent term. In India, Section 3(d) of the Patents Act has been used to challenge evergreening attempts, but the sheer number and complexity of biologics patents make enforcement and invalidation proceedings more resource-intensive.[495]

C. Regulatory Exclusivity and Biosimilar Approval

Unlike the United States (which offers 12 years of data exclusivity for biologics under the Biologics Price Competition and Innovation Act) and the European Union (which provides 8+2+1 years of exclusivity), India does not grant regulatory data exclusivity

[491] Supra note 466 at 817, 820–21.
[492] The Patents Act, 1970, § 135; Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[493] Supra note 486 at 317, 319.
[494] Paul Torremans, Cross-Border Patent Litigation in Europe: Forum Shopping and Parallel Litigation, 44 IIC 1, 2–3 (2013).
[495] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

for biologics.[496] This policy supports early biosimilar entry but can create friction in trade negotiations and complicate cross-border enforcement when Indian biosimilars are exported to jurisdictions with longer exclusivity periods.[497]

D. Recent Indian Jurisprudence

The Delhi High Court's decision in *Roche Products (India) Pvt. Ltd. v. Drugs Controller General of India* (2021) exemplifies the challenges of biosimilar patent enforcement. The court allowed Biocon and Mylan to market a biosimilar of Roche's trastuzumab (Herceptin) despite ongoing patent disputes, emphasizing the need for patient access and affordable medicines.[498] This reflects India's policy of prioritizing public health but also highlights the legal uncertainties facing innovators and biosimilar manufacturers alike.

E. Cross-Border Enforcement Issues

The global nature of biologics manufacturing-where cell lines, processes, and know-how may be transferred across borders-complicates enforcement. Indian companies exporting biosimilars to the U.S. or EU may face patent infringement suits or regulatory barriers, while foreign biologics patent holders may struggle to enforce their rights in India due to the high bar for patentability and the absence of data exclusivity.[499]

Pandemic-Driven Shifts: Compulsory Licensing and TRIPS Waivers

A. The COVID-19 Pandemic and Patent Flexibilities

The COVID-19 pandemic triggered a seismic shift in the global discourse on pharmaceutical patents. The urgent need for vaccines, diagnostics, and therapeutics highlighted the limitations of the existing IP regime in responding to global health emergencies.[500] India, in partnership with South Africa, spearheaded a proposal at the WTO for a temporary waiver of certain TRIPS obligations for COVID-19-related products.[501]

B. Compulsory Licensing in Practice

Section 92 and Section 92A of the Indian Patents Act, 1970, provide for compulsory licensing in cases of national emergency, extreme urgency, or public non-commercial

[496] Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262 (2018); Directive 2001/83/EC, 2001 O.J. (L 311) 67 (EU).
[497] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.
[498] Roche Products (India) Pvt. Ltd. v. Drugs Controller General of India, 2021 SCC OnLine Del 5432.
[499] Indian Patent Office, Annual Report 2022–23, at 26–27.
[500] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[501] WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020).

use, as well as for export to countries with insufficient manufacturing capacity.[502] While India did not issue a compulsory license for COVID-19 vaccines during the pandemic, the legal framework was invoked as a bargaining tool and a demonstration of India's commitment to public health.[503]

Globally, only a handful of compulsory licenses were issued for COVID-19 treatments, reflecting both the procedural hurdles and the political pressures that surround their use.[504] The pandemic exposed the need for more streamlined and coordinated mechanisms to ensure timely access to essential medicines during crises.

C. The TRIPS Waiver Debate

The India-South Africa TRIPS waiver proposal sought to suspend certain IP protections for COVID-19 vaccines, treatments, and diagnostics for the duration of the pandemic.[505] While the WTO adopted a limited waiver in June 2022 (focusing only on vaccines), the outcome was criticized as insufficient by many developing countries and public health advocates.[506] The debate underscored the limitations of existing TRIPS flexibilities and the need for greater international solidarity in times of global emergencies.

D. Implications for Cross-Border Enforcement

The pandemic-driven debates over compulsory licensing and TRIPS waivers have lasting implications for cross-border patent enforcement. They highlight the tension between national sovereignty, global public health, and the interests of multinational pharmaceutical companies.[507] For India, these developments reinforce the importance of maintaining robust legal tools for compulsory licensing and advocating for more flexible international norms that prioritize access to medicines in emergencies.

4.3 Technological Disruptions and Enforcement Challenges

The rapid evolution of technology is fundamentally reshaping the pharmaceutical sector-not only in how drugs are discovered and manufactured, but also in how intellectual property rights are enforced and circumvented. As digital and decentralized technologies proliferate, traditional enforcement paradigms face new and complex

[502] The Patents Act, 1970, §§ 92, 92A.
[503] Supra note 485 at 1, 3.
[504] Id
[505] WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020).
[506] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).
[507] Supra note 486 at 324-25.

challenges, particularly in the context of cross-border pharmaceutical patent protection. This section examines three of the most significant technological disruptions: 3D printing and decentralized manufacturing, blockchain-based supply chain tracking, and the tension between data exclusivity and open-source drug discovery.

3D Printing and Decentralized Manufacturing

A. The Rise of 3D Printing in Pharmaceuticals

Three-dimensional (3D) printing, or additive manufacturing, is revolutionizing the production of pharmaceuticals by enabling the precise fabrication of complex drug formulations, personalized medicines, and even medical devices at the point of care[508] The U.S. Food and Drug Administration (FDA) approved the first 3D-printed drug, Spritam (levetiracetam), in 2015, signalling the potential for this technology to disrupt conventional manufacturing and distribution models[509]

B. Legal and Enforcement Challenges

3D printing introduces profound enforcement challenges for patent holders:

- **Decentralized Production:** With 3D printers, drugs can be manufactured locally-by hospitals, pharmacies, or even individuals-using digital blueprints.[510] This decentralization makes it difficult to monitor and control infringement, as the locus of manufacturing shifts away from large, regulated facilities to dispersed, often unregulated, sites.
- **Digital Blueprints and Secondary Liability:** Patent infringement may occur not only through the unauthorized manufacture of a patented drug but also through the distribution of digital files containing the design or formulation.[511] The current Indian Patents Act, 1970, does not explicitly address the liability of those who create, share, or host such files, creating a statutory gap similar to the early days of peer-to-peer file sharing in copyright law.
- **Jurisdictional Ambiguity:** If a digital file is uploaded in one country, downloaded in another, and the drug is printed in a third, it becomes exceedingly difficult to determine where infringement occurs and which court has jurisdiction.[512]

C. Regulatory and Policy Implications

[508] Indian Patent Office, Annual Report 2022–23, at 17–19.
[509] U.S. Food and Drug Administration, FDA Approves First 3D Printed Drug Product, 2015.
[510] Supra note 472 at 1032, 1034–36.
[511] Id
[512] Supra notes 466 at 817, 820–21.

India's regulatory framework, governed by the Drugs and Cosmetics Act, 1940, does not yet contemplate 3D-printed medicines, leaving a legal vacuum concerning quality control, safety, and intellectual property enforcement.[513] Policymakers must consider whether to regulate digital blueprints as controlled items, require registration of 3D printers for pharmaceutical use, or impose liability on intermediaries who facilitate infringement.

D. International Dimensions

Given the ease with which digital files cross borders, international cooperation is essential. Harmonizing standards for digital file regulation, evidence collection, and enforcement will be crucial to prevent the proliferation of infringing activity and to protect public health.[514]

Blockchain in Supply Chain Tracking

A. Blockchain and Pharmaceutical Supply Chains

Blockchain technology, a form of distributed ledger, offers a promising solution to the perennial problem of counterfeit and substandard medicines in global supply chains. By enabling transparent, tamper-evident tracking of pharmaceuticals from manufacturer to end-user, blockchain can enhance both regulatory compliance and patent enforcement.[515]

B. Enforcement Benefits

- **Traceability and Authentication:** Blockchain enables real-time verification of product provenance, making it easier to detect and intercept counterfeit or infringing goods at the border or in the marketplace.[516]
- **Evidence for Litigation:** Immutable blockchain records can serve as reliable evidence in infringement proceedings, supporting claims of unauthorized manufacturing, diversion, or parallel importation.[517]

C. Implementation Challenges

- **Interoperability and Standardization:** For blockchain-based tracking to be effective across borders, countries must agree on technical standards and protocols.[518] India's Track-and-Trace initiative for pharmaceutical exports is a

[513] Drugs and Cosmetics Act, No. 23 of 1940, India Code (1940)
[514] Supra note 494 at 1, 2–3.
[515] Supra note 486 at 317, 319.
[516] Indian Patent Office, Annual Report 2022–23, at 21–22.
[517] Id
[518] Id

step in this direction, but participation remains voluntary and integration with global systems is limited.

- **Privacy and Data Protection:** The use of blockchain raises concerns about the protection of sensitive commercial and patient data, especially under India's evolving data protection regime.[519]

D. Policy Recommendations

India should accelerate the adoption of blockchain in pharmaceutical supply chains, mandate participation for high-risk products, and collaborate with major trading partners to harmonize standards.[520] This will not only improve enforcement but also bolster India's reputation as a reliable exporter of safe, high-quality medicines.

Data Exclusivity vs. Open-Source Drug Discovery

A. Data Exclusivity: The Global Debate

Data exclusivity refers to the period during which generic manufacturers are prohibited from relying on the originator's clinical trial data to obtain regulatory approval for a generic version of a drug.[521] The United States and European Union provide significant periods of data exclusivity (five years for new chemical entities in the U.S.; eight years plus two years of market exclusivity in the EU), which can extend effective market monopoly beyond the patent term.[522]

India, by contrast, has resisted incorporating data exclusivity into its patent and regulatory regimes, arguing that it is not required under Article 39(3) of TRIPS and would undermine access to affordable medicines.[523] Indian courts have consistently upheld this position, most notably in *Novartis AG v. Union of India* (2013), where the Supreme Court rejected arguments for data exclusivity as contrary to public health interests.[524]

B. Open-Source Drug Discovery

The open-source movement in pharmaceuticals, exemplified by initiatives such as the Medicines Patent Pool and the Open COVID Pledge, seeks to accelerate innovation by sharing data, research tools, and even patent rights.[525] Open-source drug discovery

[519] Personal Data Protection Bill, 2019, Bill No. 373 of 2019 (India).
[520] Indian Patent Office, Annual Report 2022–23, at 23.
[521] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39(3), Apr. 15, 1994, 1869 U.N.T.S. 299.
[522] Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262 (2018); Directive 2001/83/EC, 2001 O.J. (L 311) 67 (EU).
[523] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[524] Id
[525] Medicines Patent Pool, Annual Report 2023, at 5–7.

platforms leverage collaborative networks to lower barriers to entry, reduce duplication of effort, and promote the rapid development of treatments for neglected diseases.

C. Enforcement and Policy Tensions

- **Balancing Incentives and Access:** Data exclusivity is justified as a reward for costly clinical trials, but it can delay generic entry even after patent expiry. Open-source models, while promoting access, may struggle to attract private investment without some form of exclusivity or reward.[526]
- **Cross-Border Challenges:** Indian generic manufacturers seeking to export to jurisdictions with strong data exclusivity laws may face delays or litigation, even if their products are lawful in India. Conversely, open-source drugs developed in India may be blocked from certain markets due to regulatory or exclusivity barriers.[527]

D. India's Strategic Position

India's refusal to adopt data exclusivity has been a cornerstone of its pro-access policy, but it faces ongoing pressure in free trade negotiations, particularly with the EU and U.S.[528] Policymakers must weigh the benefits of open-source innovation and access against the realities of global regulatory environments and the risk of retaliatory trade measures.

4.4 India's Legal and Policy Evolution

India's legal and policy landscape on pharmaceutical patent enforcement has undergone significant transformation in the past decade. This evolution is shaped by landmark judicial decisions, legislative amendments, and India's assertive stance in international forums. The country's approach reflects a conscious effort to balance the imperatives of innovation, trade, and public health, while responding to emerging global challenges such as pandemics and technological disruption.

Post-2013 Jurisprudence: Strengthening Public Health Protections

The Supreme Court's decision in *Novartis AG v. Union of India* (2013) marked a watershed moment in Indian patent jurisprudence, particularly for pharmaceuticals.[529] By denying patent protection for the beta crystalline form of imatinib mesylate (Gleevec), the Court upheld the strict requirements of Section 3(d) of the Patents Act,

[526]Supra note 485 at 1, 3.
[527] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.
[528] Id
[529] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

1970, which mandates that new forms of known substances must demonstrate "enhanced efficacy" to qualify for patent protection.[530]

This ruling not only prevented "evergreening" but also set a precedent for subsequent cases involving incremental pharmaceutical innovations. The judiciary has since consistently interpreted Section 3(d) and other provisions in a manner that prioritizes access to medicines and public health over the extension of monopoly rights.[531]

For example, in *Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd.* (2015), the Delhi High Court addressed the balance between patent rights and public interest by granting an injunction against an infringing generic, but only after considering the availability and affordability of the drug for Indian patients.[532] Similarly, in *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* (2008), the Delhi High Court refused an interim injunction, emphasizing the need to ensure public access to affordable cancer medication.[533]

These decisions collectively reinforce a judicial philosophy that views patents not as absolute rights, but as privileges subject to reasonable restrictions in the interest of public welfare.[534] The Indian judiciary's willingness to scrutinize patent claims rigorously and to weigh public health considerations has made India a global reference point for balancing innovation and access.

Recent Amendments to the Patents Act, 1970

In response to evolving technological and public health challenges, India has periodically amended its patent legislation. The most significant changes since 2013 include:

A. Expedited Examination and Public Health

The Patents (Amendment) Rules, 2016 and subsequent amendments introduced provisions for expedited examination of patent applications relating to sectors of public interest, including pharmaceuticals and vaccines.[535] This reform aims to reduce delays in granting patents for critical health technologies, while maintaining rigorous scrutiny of patentability criteria.

B. Stricter Penalties for Wilful Infringement

[530] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970).
[531] Supra note 485 at 1, 6–8.
[532] Merck Sharp & Dohme Corp. v. Glenmark Pharmaceuticals Ltd., 2015 SCC OnLine Del 13707.
[533] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del)
[534] Novartis AG, (2013) 6 SCC 1, at ¶ 191–99.
[535] Patents (Amendment) Rules, 2016, G.S.R. 359(E) (India).

Recent proposals, such as the Patents (Amendment) Bill, 2022, seek to introduce stricter penalties for wilful infringement and to clarify the remedies available to patentees, including enhanced damages and the possibility of criminal sanctions in egregious cases.[536] These measures are intended to deter deliberate infringement, especially by entities engaged in large-scale counterfeiting or unauthorized exports.

C. Addressing Cross-Border and Contributory Infringement

Despite these advances, Indian law still lacks explicit provisions addressing cross-border contributory infringement. The absence of statutory language on indirect infringement creates enforcement gaps, particularly in cases where Indian entities supply intermediates or APIs for patented drugs manufactured and sold abroad.[537] The need for legislative reform in this area is increasingly recognized, especially as India's pharmaceutical industry becomes more integrated into global supply chains.

D. Data Exclusivity and Biosimilars

India has consistently resisted pressure to introduce data exclusivity provisions, arguing that such measures are not required under TRIPS Article 39(3) and would undermine access to generics.[538] The regulatory pathway for biosimilars has been clarified through guidelines issued by the Central Drugs Standard Control Organization (CDSCO), but the lack of data exclusivity continues to be a contentious issue in trade negotiations with the EU and U.S.[539]

India's Position on TRIPS Waivers and Global Vaccine Equity

The COVID-19 pandemic brought the issue of global access to medicines and vaccines into sharp relief. India, in partnership with South Africa, led the call for a temporary waiver of certain TRIPS obligations for COVID-19-related products, arguing that existing flexibilities were insufficient to address the scale and urgency of the crisis.[540]

A. The TRIPS Waiver Proposal

The India-South Africa proposal at the WTO sought to suspend patent, copyright, industrial design, and trade secret protections for COVID-19 vaccines, treatments, and diagnostics for the duration of the pandemic.[541] This initiative was supported by over

[536] Patents (Amendment) Bill, 2022 (India).
[537] Supra note 472 at 1032, 1034–36.
[538] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[539] Central Drugs Standard Control Organization, Guidelines on Similar Biologics, 2016.
[540] WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020).
[541] Id

100 countries and a broad coalition of civil society organizations, but faced strong opposition from several developed countries and the pharmaceutical industry.

Despite intense negotiations, the WTO Ministerial Conference in June 2022 adopted only a limited waiver focused on vaccines, with procedural hurdles that many critics argue render it largely symbolic.[542] Nonetheless, India's leadership in this debate reaffirmed its commitment to global health equity and its willingness to challenge the status quo in international IP governance.

B. Compulsory Licensing and Export

India's legal framework for compulsory licensing, particularly Section 92A of the Patents Act, 1970, allows for the manufacture and export of patented pharmaceuticals to countries with insufficient manufacturing capacity.[543] While India did not issue a compulsory license for COVID-19 vaccines during the pandemic, the existence of this legal tool served as leverage in negotiations with multinational companies and as a model for other developing countries.

C. Advocacy for Technology Transfer and Local Production

India has also advocated for technology transfer and local production of vaccines and essential medicines as part of its broader strategy for global health security. In forums such as the Quad Vaccine Partnership, COVAX, and the G20, India has emphasized the need for equitable access, voluntary licensing, and the sharing of know-how to ensure timely and affordable supply.[544]

D. Ongoing Challenges

Despite these efforts, significant challenges remain. The limited scope of the TRIPS waiver, the slow pace of technology transfer, and persistent barriers to local production in many countries have highlighted the need for more robust international mechanisms to ensure vaccine equity in future pandemics.[545] India's continued advocacy for reforming global IP rules and strengthening South-South cooperation will be critical in addressing these gaps

[542] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022)
[543] The Patents Act, 1970, § 92A.
[544] BRICS, Joint Statement of the BRICS Heads of Intellectual Property Offices, 2023; G20 Health Working Group, 2022.
[545] WTO, TRIPS Council, IP/C/M/102 (Mar. 2022).

4.5 Regional and Bilateral Cooperation Models

The limitations of territorial patent enforcement underscore the growing importance of regional and bilateral cooperation in addressing cross-border pharmaceutical patent challenges. For India, regional frameworks such as SAARC and BRICS, as well as bilateral negotiations with major trading partners like the European Union, offer both opportunities and obstacles. These cooperative models are crucial not only for harmonizing enforcement standards but also for safeguarding India's public health priorities and maintaining its leadership role as a supplier of affordable medicines.

SAARC: Potential for Harmonized IP Frameworks

A. The Promise of Regional Integration

The South Asian Association for Regional Cooperation (SAARC) brings together Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, and Sri Lanka-countries with shared economic, social, and public health challenges.[546] Regional harmonization of intellectual property (IP) frameworks within SAARC could significantly reduce transaction costs, enhance legal certainty, and facilitate the movement of pharmaceuticals across borders.

B. Current Status and Challenges

Despite the potential, SAARC's progress on IP harmonization has been slow. The SAARC Agreement on Trade in Services (SATIS) and discussions on a SAARC Intellectual Property Rights Organization (SIPRO) have not yet yielded a binding regional IP regime.[547] Political tensions, divergent levels of economic development, and varying national priorities have hindered substantive cooperation.

C. Opportunities for Patent Enforcement Cooperation

Nevertheless, SAARC remains a promising platform for:

- **Mutual Recognition of Judgments:** Establishing protocols for the recognition and enforcement of patent judgments across member states, subject to public policy exceptions.
- **Regional Exhaustion Regimes:** Adopting a regional exhaustion principle would allow parallel imports of patented pharmaceuticals within SAARC, increasing access and reducing prices.[548]

[546] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.
[547] Supra note 485 at 1, 15–17.
[548] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2

- **Capacity Building:** Joint training programs for patent examiners, customs officials, and judges to foster best practices and technical expertise.
- **Shared Databases:** Creating a regional patent database to improve transparency and reduce duplication in examination and enforcement.

D. India's Leadership Role

India, as the largest economy and pharmaceutical producer in SAARC, is well placed to drive these initiatives. By championing harmonized standards and mutual recognition mechanisms, India can help create a more predictable and equitable patent enforcement landscape in South Asia-one that balances innovation incentives with access to medicines.

BRICS and South-South Collaboration

A. BRICS IPR Cooperation Mechanism

BRICS (Brazil, Russia, India, China, South Africa) is an influential bloc of emerging economies with a shared interest in promoting innovation, technology transfer, and access to medicines. In recent years, BRICS has established working groups on intellectual property, aiming to harmonize patent examination procedures, combat counterfeit drug trafficking, and facilitate technology transfer among member states.[549]

B. Joint Enforcement and Information Sharing

BRICS cooperation offers several advantages:

- **Patent Examination Harmonization:** Sharing search and examination reports can reduce duplication and improve patent quality.
- **Compulsory Licensing Database:** A joint database of compulsory licenses issued by BRICS countries could enhance transparency, reduce duplication in generic production, and support coordinated responses to public health emergencies.
- **Cross-Border Enforcement:** Joint enforcement actions against transnational counterfeiting and infringement networks can be more effective than isolated national efforts.

C. South-South Solidarity and Access to Medicines

BRICS and other South-South partnerships offer a counterweight to TRIPS-plus demands from developed countries. By developing common negotiating positions and

[549] BRICS Framework Agreement on Intellectual Property Cooperation, 2022.

sharing best practices, these alliances can resist external pressures to adopt stricter IP standards that may undermine access to medicines.[550]

D. Challenges and Limitations

Despite these opportunities, differences in national IP laws, economic interests, and patent office capacities persist among BRICS members. Sustained political will and institutional investment are required to translate cooperation into concrete outcomes.

India-EU FTA Negotiations: Patent Enforcement Clauses

A. The Strategic Importance of the India-EU Relationship

The European Union is one of India's largest trading partners and a key market for Indian pharmaceuticals. Negotiations for an India-EU Free Trade Agreement (FTA) have been ongoing for over a decade, with IP protection and enforcement as central points of contention.[551]

B. EU's Demands and India's Red Lines

The EU has consistently pushed for TRIPS-plus provisions in the FTA, including:

- **Data Exclusivity:** Demanding that India provide regulatory data exclusivity for pharmaceuticals, which would delay generic entry even after patent expiry.
- **Patent Term Extensions:** Seeking extensions to compensate for regulatory delays in patent grant or drug approval.
- **Border Enforcement:** Proposing stronger border measures, including the power to detain goods suspected of patent infringement in transit, similar to the controversial EU seizures of Indian generics in 2008–2009.
- **Accession to the Unified Patent Court (UPC):** Pressuring India to recognize the UPC system or adopt similar supranational enforcement mechanisms.[552]

India has resisted these demands, arguing that they would undermine access to affordable medicines, violate constitutional commitments to public health, and exceed TRIPS obligations.[553] India's counterproposals have included:

- **Public Health Carve-Outs:** Explicit exceptions for compulsory licensing, parallel importation, and other TRIPS flexibilities.

[550] Supra note 486 at 317, 324–25.
[551] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.
[552] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[553] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

- **Safeguards Against Over-Enforcement:** Mechanisms to prevent wrongful detention of legitimate generics in transit and to protect exports to countries with no relevant patent.
- **Recognition of Indian Patent Standards:** Insisting that Indian courts retain jurisdiction over patent disputes involving Indian exports and that Section 3(d) and other safeguards remain non-negotiable.

C. Implications for Cross-Border Patent Enforcement

The outcome of the India-EU FTA negotiations will have far-reaching consequences for cross-border pharmaceutical patent enforcement:

- **If TRIPS-plus standards are adopted, Indian generic manufacturers could face new barriers to exporting to the EU and other markets with similar FTAs.**
- **Conversely, strong public health carve-outs would reinforce India's leadership in balancing innovation and access, and could serve as a model for other developing countries.**

D. The Path Forward

India's negotiating strategy must continue to prioritize access to medicines, resist undue expansion of enforcement measures, and leverage its market power to secure a balanced agreement. At the same time, India should remain open to cooperation on anti-counterfeiting, patent quality, and regulatory harmonization-areas where mutual interests align.

4.6 Ethical and Normative Debates

The enforcement of pharmaceutical patents is not merely a technical or economic issue; it is deeply intertwined with fundamental ethical questions and normative frameworks. The debates around human rights, environmental sustainability, and equitable access have become increasingly prominent in the global discourse, especially as India asserts its role as both a pharmaceutical innovator and a champion of public health. This section explores three major ethical and normative debates shaping the future of cross-border pharmaceutical patent enforcement.

Human Rights vs. Patent Monopolies

A. The Right to Health and Access to Medicines

The right to health is enshrined in international human rights instruments, including Article 12 of the International Covenant on Economic, Social and Cultural Rights

(ICESCR), and is recognized as a fundamental right under Article 21 of the Indian Constitution.[554] This right encompasses access to essential medicines, as affirmed by the United Nations Committee on Economic, Social and Cultural Rights and the World Health Organization.[555]

Patent monopolies, by granting exclusive rights to inventors, can lead to high prices and restricted access to life-saving medicines, particularly in low- and middle-income countries.[556] The ethical tension arises when the pursuit of innovation and profit by pharmaceutical companies conflicts with the imperative to ensure affordable access for all. The landmark *Novartis AG v. Union of India* (2013) decision exemplifies India's commitment to prioritizing public health over patent monopolies, with the Supreme Court explicitly invoking the right to life and health in its reasoning.[557]

B. International Norms and TRIPS Flexibilities

The Doha Declaration on the TRIPS Agreement and Public Health (2001) reaffirmed the primacy of public health over intellectual property in international law, stating that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health."[558] India has consistently invoked TRIPS flexibilities, such as compulsory licensing and parallel importation, to fulfil its human rights obligations and resist external pressures to adopt TRIPS-plus standards that could undermine access.

C. Ongoing Ethical Dilemmas

Despite these safeguards, ethical dilemmas persist. Patent holders argue that without robust protection, there is little incentive to invest in costly and risky pharmaceutical R&D.[559] Public health advocates counter that the social value of medicines should override private monopolies, especially during health emergencies. The COVID-19 pandemic reignited these debates, with calls for a TRIPS waiver to ensure global vaccine equity facing resistance from countries and companies prioritizing IP rights.

Climate Change and Access to Green Pharmaceuticals

A. The Intersection of Health, Environment, and IP

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[554] India Const. art. 21; International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

[555] U.N. Committee on Economic, Social and Cultural Rights, General Comment No. 14, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000); World Health Organization, Access to Medicines and the Right to Health, 2016.

[556] Supra note 485 at 1, 3.

[557] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).

[558] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[559] Supra note 466 at 817, 820–21.

Climate change is increasingly recognized as a public health crisis, with rising temperatures and environmental degradation contributing to the spread of infectious diseases, malnutrition, and other health challenges.[560] The development of "green pharmaceuticals"-drugs and vaccines designed to address climate-related diseases or produced through environmentally sustainable processes-has become a new frontier in both innovation and ethics.

B. Patent Thickets and Barriers to Green Technology

Patent thickets on green technologies, including climate-sensitive pharmaceuticals such as mRNA-based vaccines for vector-borne diseases, can hinder technology transfer and limit access in developing countries.[561] The concentration of patents in the hands of a few multinational corporations risks replicating the access barriers seen in traditional pharmaceuticals.

India's National Green Tribunal and environmental policy frameworks have begun to address the intersection of IP and environmental sustainability, but there is a need for clearer legal mechanisms-such as compulsory licensing for green technologies-to ensure that patent rights do not impede the diffusion of climate-adaptive health solutions.[562]

C. Ethical Imperatives for Global Cooperation

The ethical imperative to address climate change and its health impacts requires a rethinking of IP norms to facilitate the rapid dissemination of green pharmaceuticals. International agreements, such as the Paris Agreement, encourage technology transfer, but stronger legal and policy tools are needed to operationalize these commitments in the context of pharmaceutical patents.[563]

Ethical Licensing and Equitable Access Frameworks

A. The Rise of Ethical Licensing

Ethical licensing refers to the incorporation of access-oriented conditions in patent and technology licensing agreements. This may include provisions that waive or reduce royalties for low-income countries, require licensees to supply affordable generics, or mandate technology transfer to local manufacturers.[564] Initiatives like the Medicines

[560] Intergovernmental Panel on Climate Change, Climate Change 2022: Impacts, Adaptation and Vulnerability, Summary for Policymakers (2022)
[561] Supra note 486 at 317, 324–25.
[562] National Green Tribunal Act, No. 19 of 2010, India Code (2010).
[563] Paris Agreement, Dec. 12, 2015, T.I.A.S. No. 16-1104
[564] Medicines Patent Pool, Annual Report 2023, at 5–7.

Patent Pool and the Open COVID Pledge have popularized ethical licensing as a tool for balancing innovation incentives with public health needs.[565]

B. India's Policy Initiatives

India's Department of Pharmaceuticals has explored the development of a model ethical licensing framework for public-private partnerships, particularly in the context of pandemic preparedness and neglected diseases.[566] By encouraging or requiring publicly funded research to be licensed on terms that promote access in low- and middle-income countries, India can set a precedent for responsible IP stewardship.

C. Equitable Access and Global Health Governance

The World Health Organization and United Nations have called for the adoption of equitable access frameworks in global health governance, emphasizing the need for transparency, accountability, and fairness in the allocation of medical innovations.[567] India's advocacy for equitable access in international forums, including the WTO and G20, reflects its commitment to these principles.

D. Challenges and the Way Forward

Implementing ethical licensing on a wide scale faces challenges, including resistance from patent holders, the complexity of negotiating multi-jurisdictional agreements, and the need for robust monitoring and enforcement mechanisms.[568] Nonetheless, the growing acceptance of ethical licensing and equitable access frameworks signals a shift toward a more socially responsible approach to pharmaceutical patent enforcement.

4.7 Strategic Pathways for India

India's unique position as a global supplier of affordable medicines and an emerging pharmaceutical innovator demands a strategic approach to cross-border patent enforcement. To address the challenges of territoriality, technological disruption, and public health imperatives, India must adopt a three-pronged strategy: legislative reform, institutional capacity building, and leadership in global intellectual property (IP) governance. These pathways will enable India to balance innovation incentives with equitable access while safeguarding its constitutional commitment to public health.

Legislative Reforms for Cross-Border Infringement

[565] Open COVID Pledge, Model License, 2021.
[566] Department of Pharmaceuticals, Government of India, National Pharmaceutical Policy 2023, at 18–19.
[567] World Health Organization, Equitable Access to COVID-19 Tools, 2022; United Nations, Political Declaration of the High-level Meeting on Universal Health Coverage, 2019
[568] Supra note 494 at 1, 9–11.

A. Statutory Recognition of Indirect and Contributory Infringement

India's Patents Act, 1970, lacks explicit provisions for indirect infringement, such as supplying components for patented inventions or facilitating infringement across borders.[569] To close this gap, India should amend Section 107A to include liability for:

- **Cross-Border Contributory Infringement:** Imposing liability on entities that knowingly supply APIs, intermediates, or manufacturing tools from India for use in infringing activities abroad.[570]
- **Digital Infringement:** Addressing the distribution of 3D-printable drug blueprints or AI-generated formulations that circumvent territorial patents.

B. Jurisdictional Expansion

Amend the Code of Civil Procedure, 1908, to allow Indian courts to adjudicate cross-border disputes where:

- A substantial part of the infringing activity occurs in India (e.g., API production for export to patent-protected markets)[571]
- The defendant is domiciled in India, and the infringement impacts global supply chains.[572]

C. Border Measures Reform

Revise the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, to:

- Empower customs authorities to detain exports infringing foreign patents, provided the destination country has a valid patent.[573]
- Establish expert committees to assess technical patent claims and prevent wrongful seizures of legitimate generics.[574]

D. Public Health Safeguards

Codify TRIPS flexibilities into domestic law by:

- Expanding Section 92A to streamline compulsory licensing for export during health emergencies.

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[569] The Patents Act, No. 39 of 1970, § 107A, India Code (1970)
[570] 35 U.S.C. § 271(f) (2022).
[571] Code of Civil Procedure, 1908, § 20 (India); *Bayer Corp. v. Union of India*, 2017 SCC OnLine Del 8672.
[572] Regulation (EU) No. 1215/2012 (Brussels I Recast), art. 7(2)
[573] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E) (India)
[574] WTO Dispute DS408: *European Union and a Member State – Seizure of Generic Drugs in Transit* (2012)

- Introducing a public interest defence to infringement for drugs addressing neglected tropical diseases or climate-sensitive ailments.[575]

Building Institutional Capacity

A. Specialized Patent Benches

Establish **dedicated IP divisions** in High Courts, modelled after the Delhi High Court's Intellectual Property Appellate Board (IPAB), to handle complex cross-border cases.[576] These benches should:

- Include judges with technical expertise in pharmaceuticals and biotechnology.
- Adopt fast-track procedures for public health-related disputes.

B. Training and Technical Expertise

- **Judicial Training:** Partner with organizations like WIPO and the National Judicial Academy to conduct workshops on global patent trends, AI in drug development, and biologics.[577]
- **Customs Modernization:** Train officials to identify infringing goods using blockchain-tracked supply chain data and AI-powered authentication tools.[578]

C. Digital Infrastructure

Launch a **National Patent Enforcement Portal** to:

- Centralize patent registrations, litigation statuses, and compulsory licenses.
- Integrate with international databases (e.g., WIPO's PATENTSCOPE) to reduce duplication in patent examinations.[579]

D. Inter-Agency Coordination

Create a Pharmaceutical IP Task Force under the Department of Pharmaceuticals to coordinate between:

- The Indian Patent Office, Customs, and Drug Controller General of India (DCGI).
- International agencies like INTERPOL to combat counterfeit drug networks.[580]

Leadership in Global IP Governance

A. Advocating TRIPS Flexibilities

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[575] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[576] Delhi High Court Intellectual Property Division Rules, 2021.
[577] World Intellectual Property Organization, *WIPO Academy Annual Report 2023*, at 15–16.
[578] Indian Patent Office, *Annual Report 2022–23*, at 21–22
[579] Id. at 23.
[580] INTERPOL, *Operation Pangea XVI* (2023).

- **WTO Engagement:** Lead a coalition of developing nations to expand the 2022 TRIPS waiver to cover therapeutics and diagnostics, ensuring equitable access in future pandemics.[581]
- **Model Legislation:** Share India's compulsory licensing framework (Section 84) as a blueprint for low-income countries through the World Health Assembly.[582]

B. Regional Cooperation

- **SAARC Harmonization:** Propose a SAARC Patent Protocol for mutual recognition of judgments and regional exhaustion of patent rights.[583]
- **BRICS Initiatives:** Establish a BRICS Patent Pool for climate-sensitive pharmaceuticals, enabling shared R&D and equitable licensing.[584]

C. Ethical Licensing Frameworks

- **Global Vaccine Equity:** Partner with the Medicines Patent Pool to negotiate ethical licenses for Indian-manufactured generics, waiving royalties for Least Developed Countries (LDCs).[585]
- **Open-Source Collaboration:** Launch an Open Pharma Initiative to crowdsource drug discovery for neglected diseases, with IP rights vested in public trusts.[586]

D. Countering TRIPS-Plus Pressures

- **FTA Negotiations:** Resist data exclusivity and patent term extensions in trade deals with the EU and U.S., leveraging India's market size to secure public health carve-outs.[587]
- **Diplomatic Advocacy:** Mobilize the G77 coalition at WIPO to oppose stringent enforcement measures that undermine access to medicines.[588]

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[581] WTO, *Ministerial Decision on the TRIPS Agreement*, WT/MIN(22)/30 (June 17, 2022).
[582] World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21 (2008).
[583] South Asian Association for Regional Cooperation, *SAARC Framework Agreement on Cooperation in Science and Technology*, 1998.
[584] BRICS, *Joint Statement on Climate-Sensitive Pharmaceuticals*, 2023.
[585] Medicines Patent Pool, *Annual Report 2023*, at 5–7.
[586] Open COVID Pledge, *Model License*, 2021.
[587] U.S. Trade Representative, *2024 Special 301 Report* (Apr. 2024), at 42–43.
[588] WIPO, *Proposal by the Group of 77 and China for a Development Agenda*, WO/GA/49/12 (2023).

4.8 Conclusion

India's strategic pathways-legislative reform, institutional strengthening, and global leadership-are interdependent. By closing statutory gaps, investing in technical expertise, and championing equitable IP norms, India can transform its dual role as a generic supplier and innovator into a global model for balanced patent enforcement. These reforms will not only enhance India's domestic enforcement regime but also solidify its position as a moral authority in the global quest for health equity.

CHAPTER 5: CONCLUSION SYNTHESIZING THE CROSS-BORDER PATENT ENFORCEMENT DILEMMA: AN INDIAN PERSPECTIVE ON GLOBAL CHALLENGES AND PATHWAYS FORWARD

5.1 Revisiting the Hypothesis: Territoriality vs. Globalization

The dissertation's central hypothesis posited that the territorial patent system-a relic of 19th-century sovereignty principles-is fundamentally incompatible with the realities of a globalized pharmaceutical industry. This hypothesis has been resoundingly validated through empirical analysis, comparative case studies, and policy critiques across Chapters 2–5. The territorial framework, which confines patent rights to the jurisdiction of grant, has proven inadequate in addressing the transnational nature of pharmaceutical innovation, manufacturing, and distribution. However, the system's resilience, manifested through regional adaptations and strategic national policies, offers partial remedies to its inherent inefficiencies.

A. Fragmented Enforcement: Divergent Jurisdictional Outcomes

The territorial system's most glaring flaw lies in its fragmentation, which forces patent holders to navigate disparate legal regimes with conflicting priorities. This fragmentation is exemplified by the imatinib (Gleevec) saga, where Novartis secured patents in the U.S. and EU but faced rejection in India under Section 3(d) of the Patents Act, 1970.[589] The Indian Supreme Court's refusal to grant a patent for the beta crystalline form of imatinib mesylate-a decision grounded in public health considerations-highlighted how national priorities can disrupt global enforcement coherence.[590] While the U.S. and EU prioritized incremental innovation, India's interpretation of "enhanced efficacy" under Section 3(d) prioritized access to affordable generics, creating a legal schism that undermines the predictability of patent enforcement.[591]

This jurisdictional divergence extends beyond patentability criteria. For instance, the U.S. employs doctrines like §271(f) of the Patent Act to penalize the supply of components for overseas infringement,[592] whereas India's lack of analogous provisions

[589] Novartis AG v. Union of India, (2013) 6 SCC 1 (India).
[590] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970).
[591] Supra note 485 at 1, 6–8.
[592] 35 U.S.C. § 271(f) (2022).

allows generic manufacturers to export APIs to jurisdictions where patents are in force without domestic liability.[593] Such inconsistencies force multinational companies to engage in costly, multi-jurisdictional litigation, while generic producers exploit regulatory arbitrage to supply global markets.

B. Inconsistent Remedies: The EU Seizures and Access Barriers

The 2008–2009 EU seizures of Indian generic medicines in transit underscored the ethical and practical contradictions of territorial enforcement. EU customs authorities, acting on patent holders' requests, detained shipments of legally produced generics (e.g., losartan for hypertension and abacavir for HIV) bound for Latin America and Africa, citing potential infringement of European patents.[594] These actions, though legally permissible under EU Regulation 1383/2003,[595] violated the spirit of the Doha Declaration on TRIPS and Public Health, which safeguards access to medicines in developing countries.[596]

The WTO dispute initiated by India and Brazil (DS408) challenged the EU's interpretation of "counterfeit" goods and the extraterritorial reach of its patent laws.[597] The eventual settlement, which limited seizures to cases of proven diversion into EU markets,[598] exposed the tension between aggressive territorial enforcement and global public health imperatives. This episode illustrates how rigid adherence to territoriality can weaponize patent rights to disrupt legitimate trade, disproportionately affecting low-income nations reliant on affordable generics.

C. Resilience Through Regional Adaptations

Despite systemic inefficiencies, the territorial system has demonstrated resilience through regional and national innovations:

1. The EU's Unified Patent Court (UPC)

The UPC, operational since 2023, represents the most ambitious effort to mitigate fragmentation. By enabling pan-European patent enforcement through a single court, the UPC reduces litigation costs and minimizes forum shopping.[599] A UPC injunction

[593]Supra note 472 at. 1032, 1035.
[594] WTO Dispute DS408: *European Union and a Member State – Seizure of Generic Drugs in Transit* (2012).
[595] Council Regulation (EC) No. 1383/2003, 2003 O.J. (L 196) 7.
[596] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.
[597] WTO Dispute DS408: *European Union and a Member State – Seizure of Generic Drugs in Transit* (2012).
[598] Id
[599] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

against a generic manufacturer, for instance, applies across all participating EU states, streamlining enforcement. However, the UPC's geographic limitations (excluding non-EU states like Switzerland and the UK) and its exclusion from the Hague Judgments Convention perpetuate enforcement gaps beyond Europe.[600]

2. India's Compulsory Licensing Regime

India's strategic use of compulsory licensing under Section 84 of the Patents Act exemplifies how national policies can counterbalance territorial rigidity. The grant of a compulsory license to Natco Pharma for Bayer's sorafenib (Nexavar) in 2012 prioritized public health over patent monopolies, enabling domestic production and export to countries lacking manufacturing capacity.[601] This approach, while controversial, has inspired similar measures in Brazil and South Africa, fostering a Global South alliance advocating for TRIPS flexibilities.[602]

3. Anti-Suit Injunctions in China

China's courts have issued anti-suit injunctions to restrain global patent disputes, asserting jurisdiction over multinational licensing terms. In *Huawei v. Conversant*, the Supreme People's Court barred enforcement of a German injunction, signalling a shift toward strategic territorial assertiveness.[603] While such measures risk jurisdictional conflicts, they reflect adaptive strategies to counteract fragmentation.

D. The Limits of Resilience

Regional and national adaptations, though innovative, are stopgap solutions. The UPC's success hinges on EU political cohesion, while India's compulsory licensing faces backlash in trade negotiations.[604] Moreover, these measures do not address the root cause of fragmentation: the absence of a global enforcement mechanism. The Hague Judgments Convention's exclusion of IP rights and TRIPS's silence on cross-border remedies perpetuate a system where "islands" of regional coherence exist within a sea of jurisdictional chaos.[605]

E. Hypothesis Confirmed, but With Nuance

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[600] Hague Conference on Private International Law, *Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters* art. 2(1)(m), July 2, 2019

[601] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India).

[602] Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317, 324–25 (2005)

[603] Huawei v. Conversant, (2019) Supreme People's Court, China.

[604] U.S. Trade Representative, *2024 Special 301 Report* (Apr. 2024), at 42–43.

[605] Supra note 466 at 817, 829–30.

The hypothesis that territoriality is misaligned with globalization is overwhelmingly confirmed. However, the system's resilience through regional cooperation and strategic national policies suggests that reform is possible within the existing framework. India's jurisprudence and the UPC's regional integration demonstrate that sovereignty and globalization need not be mutually exclusive. Yet, without systemic overhauls-such as including IP in the Hague Judgments Convention or expanding TRIPS waivers-the tensions between territorial enforcement and global health equity will persist.

5.2 Key Findings: Bridging Innovation and Access

A. Case Studies as Microcosms of Global Tensions

The case studies examined in this dissertation serve as vivid illustrations of the systemic tensions and policy dilemmas that define cross-border pharmaceutical patent enforcement. Each case not only reflects the legal and ethical complexities of territoriality but also highlights the broader stakes for innovation, access, and global equity.

Imatinib (Gleevec) Saga

India's rejection of Novartis' patent application for the beta crystalline form of imatinib mesylate under Section 3(d) of the Patents Act, 1970,[606] was more than a technical decision on patentability. It was a watershed moment that crystallized the ethical imperative to prioritize public health and access to medicines over incremental pharmaceutical innovation. The Supreme Court's ruling in *Novartis AG v. Union of India* (2013[607] established a high threshold for patenting new forms of known substances, thereby curbing "evergreening" and setting a global precedent for other developing nations. This case demonstrated India's willingness to assert its sovereign right to tailor patent law in accordance with constitutional values and public health needs, even at the risk of diplomatic friction and industry criticism.[608]

The Gleevec saga also exposed the broader consequences of territoriality: while Novartis enjoyed patent protection in the U.S. and EU, Indian generic manufacturers were able to supply affordable versions to the developing world, breaking the monopoly and saving countless lives. This divergence in outcomes across jurisdictions

[606] The Patents Act, No. 39 of 1970, § 3(d), India Code (1970)
[607] Novartis AG v. Union of India, (2013) 6 SCC 1 (India)
[608] Supra note 485 at 1, 6–8.

underscored the fragmented nature of global patent enforcement and the potential for national law to serve as a tool of health justice.

Natco-Bayer Compulsory License

The grant of India's first compulsory license to Natco Pharma for Bayer's patented cancer drug sorafenib tosylate (Nexavar) in 2012[609] reinforced the operationalization of TRIPS flexibilities in domestic law. Invoking Section 84 of the Patents Act, the Controller General of Patents found that Bayer had failed to make the drug available at a reasonably affordable price and had not sufficiently "worked" the patent in India.[610] The compulsory license enabled Natco to produce and sell the drug at a fraction of the original price, dramatically increasing access for Indian patients.

However, this landmark use of compulsory licensing also exposed the political economy of enforcement. Developed countries and multinational pharmaceutical companies criticized the decision, warning that it could deter foreign investment and R&D.[611] The episode highlighted the diplomatic tensions that can arise when a country exercises its sovereign rights under TRIPS, and the need for careful calibration between public health objectives and international commercial relations.

EU Seizures

The 2008–2009 seizures of Indian generic medicines in transit through European ports, at the instigation of patent holders, brought into sharp relief the collision between territorial enforcement and global trade norms.[612] Although the generics were lawfully manufactured in India and destined for countries where no relevant patent existed, EU customs authorities detained the shipments on the grounds of potential infringement under European patent law.

This led to a WTO dispute (DS408), with India and Brazil challenging the EU's actions as violations of international trade law and public health commitments.[613] The controversy prompted regulatory reforms in the EU, limiting the seizure of in-transit goods absent evidence of diversion into EU markets.[614] The case illustrated how

[609] Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India)
[610] The Patents Act, 1970, § 84.
[611] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43
[612] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012)
[613] Id
[614] Id

aggressive territorial enforcement can disrupt legitimate trade, impede access to medicines in the Global South, and provoke international legal and diplomatic conflict.

B. Comparative Jurisdictional Strategies

A nuanced comparative analysis reveals that different jurisdictions have adopted distinct strategies to address the cross-border challenges of pharmaceutical patent enforcement, each reflecting underlying policy priorities and legal cultures.

United States

The U.S. patent system is characterized by strong statutory protection, robust litigation, and a willingness to experiment with extraterritorial doctrines. Section 271(f) of the U.S. Patent Act,[615] for example, imposes liability on those who supply components from the U.S. for assembly abroad, closing loopholes that previously allowed infringers to evade domestic enforcement.[616] The Supreme Court's decision in *WesternGeco LLC v. ION Geophysical Corp.* further expanded the reach of U.S. patent law by allowing recovery of damages for certain foreign sales lost due to domestic infringement.[617]

However, the U.S. approach has been criticized for prioritizing the interests of patent holders and the pharmaceutical industry over global health equity. The absence of a general compulsory licensing regime and the high cost of litigation can impede access to affordable medicines, particularly for developing countries.[618]

European Union

The European Union's Unified Patent Court (UPC) and unitary patent system represent the most advanced experiment in supranational patent enforcement. The UPC enables patent holders to obtain pan-European injunctions and damages in a single proceeding, reducing costs and legal uncertainty.[619] However, the UPC's reach is geographically limited, and its mechanisms do not extend to developing economies outside the EU.[620] Moreover, the EU's aggressive border enforcement measures, as seen in the seizures of Indian generics, have sometimes conflicted with its own commitments to public health and global trade norms.[621] The EU model offers efficiency and legal certainty within its borders but fails to address the needs of the Global South.

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[615] 35 U.S.C. § 271(f) (2022).
[616] Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972).
[617] WesternGeco LLC v. ION Geophysical Corp., 138 S. Ct. 2129, 2137–38 (2018).
[618] Supra note 602 at 317, 319–20.
[619] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[620] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.
[621] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

China

China's approach to pharmaceutical patent enforcement is marked by rapid judicial specialization, administrative innovation, and a pragmatic assertion of sovereignty. The establishment of specialized IP courts and the use of anti-suit injunctions in global licensing disputes reflect China's determination to shape the international patent landscape on its own terms.[622]

While China's system is still maturing in terms of transparency and predictability, its willingness to assert jurisdiction over cross-border disputes contrasts with India's more public health-centric model. China's focus on building institutional capacity and technical expertise offers important lessons for India as it seeks to modernize its own enforcement mechanisms.[623]

C. India's Balancing Act

India's legal framework, as interpreted in *Novartis AG v. Union of India* and *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*,[624] has emerged as a global benchmark for reconciling the competing imperatives of innovation and access. By strictly applying Section 3(d) to prevent evergreening and embracing compulsory licensing under Section 84, India has demonstrated that patent law can be tailored to serve constitutional mandates for public health without entirely sacrificing innovation incentives.

The judiciary's willingness to weigh public interest in granting or denying injunctions, as seen in *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*,[625] has further entrenched the principle that patents are privileges, not absolute rights. This approach has inspired similar reforms in other developing countries and has positioned India as a leader in the global movement for access to medicines.

However, significant systemic vulnerabilities remain. India's legal framework does not adequately address cross-border contributory infringement, leaving loopholes for entities that facilitate infringement from within India without directly violating domestic patents.[626] Outdated border measures, limited technical capacity among customs officials, and the absence of a centralized digital enforcement infrastructure further hamper effective cross-border enforcement.

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[622] Huawei v. Conversant, (2019) Supreme People's Court, China.
[623] Patent Law of the People's Republic of China art. 71 (2020).
[624] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del).
[625] Id
[626]Supra note 472 at. 1032, 1034–36.

These gaps underscore the need for legislative and institutional reform. As India's pharmaceutical industry becomes more integrated into global supply chains, the challenges of enforcing patent rights-while upholding public health commitments-will only intensify. The Indian experience thus offers both a model and a cautionary tale for other countries grappling with the demands of globalization and the imperatives of equity.

5.3 Contributions to Literature and Policy

The findings of this dissertation contribute significantly to both the academic literature on cross-border pharmaceutical patent enforcement and to the evolving policy discourse, especially from an Indian vantage point. This section delineates the theoretical advances and policy innovations that emerge from the research, situating India's experience within the broader global context.

A. Theoretical Contributions

1. Reconciling TRIPS with National Priorities

One of the dissertation's most salient theoretical contributions is its nuanced analysis of how India's invocation of TRIPS flexibilities fundamentally challenges the prevailing neoliberal orthodoxy in international intellectual property (IP) law. The TRIPS Agreement, while setting minimum standards for patent protection, was often interpreted by developed countries as a vehicle for harmonizing IP enforcement to the benefit of multinational patent holders.[627] However, India's strategic use of compulsory licensing (Section 84), the anti-evergreening provision (Section 3(d)), and parallel importation (Section 107A) demonstrates that TRIPS is not a straitjacket but a framework that accommodates national priorities-especially public health.[628]

This dissertation shows that India's approach is not merely defensive or exceptionalist; rather, it offers a replicable model for other Global South nations seeking to balance innovation incentives with access to medicines. The analysis of landmark cases such as *Novartis AG v. Union of India* and the Natco-Bayer compulsory license illustrates how TRIPS flexibilities can be operationalized in a manner that is both legally robust and ethically defensible.[629] By foregrounding constitutional commitments to the right

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[627] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299.

[628] The Patents Act, No. 39 of 1970, §§ 3(d), 84, 107A, India Code (1970).

[629] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India).

to health (Article 21 of the Indian Constitution) and leveraging international law (Doha Declaration on TRIPS and Public Health), India has carved out a normative space for equitable enforcement that resists the hegemony of transnational pharmaceutical interests.[630]

2. Regionalism as a Stopgap: The Promise and Limits

The dissertation also advances the literature by critically evaluating the role of regionalism as a pragmatic response to the limitations of territorial patent enforcement. The European Union's Unified Patent Court (UPC) and unitary patent system are analysed as the most ambitious experiment in supranational patent enforcement.[631] The UPC reduces costs, streamlines litigation, and minimizes forum shopping within the EU, offering a blueprint for efficiency. However, as the research demonstrates, such regional solutions are ultimately bounded by geography and political will; they cannot substitute for a truly global enforcement mechanism.[632]

The proposed SAARC and BRICS frameworks, discussed in Chapter 5, illustrate how regional cooperation among developing countries can provide actionable solutions-such as mutual recognition of judgments, harmonized border measures, and shared patent databases-to reduce enforcement costs and enhance legal certainty.[633] These models, while insufficient for full globalization, represent important incremental progress and underscore the value of South-South solidarity in IP governance.

B. Policy Innovations

1. Ethical Licensing: Aligning Enforcement with Human Rights

A key policy innovation explored in this dissertation is the concept of ethical licensing, particularly in the context of vaccines and biologics. India's experience with voluntary licensing for hepatitis C drugs, and its advocacy for open-access frameworks during the COVID-19 pandemic, provide a template for aligning patent enforcement with the right to health.[634]

By incorporating access-oriented conditions-such as royalty waivers for low-income countries, technology transfer requirements, and commitments to affordable pricing-

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[630] India Const. art. 21; WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[631] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.

[632] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.

[633] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998; BRICS Framework Agreement on Intellectual Property Cooperation, 2022.

[634] Supra note 602 at 317, 324–25.

ethical licensing bridges the gap between innovation and equity.[635] The Medicines Patent Pool and the Open COVID Pledge are cited as global exemplars, but India's proactive role in negotiating such licenses for generic manufacturers demonstrates how national policy can drive global change.[636]

The dissertation argues that ethical licensing should be institutionalized through statutory mandates for publicly funded research and public-private partnerships, ensuring that life-saving innovations developed with public resources are accessible to all.[637] This approach not only fulfils India's constitutional and international obligations but also enhances its soft power as a leader in global health governance.

2. Digital Infrastructure: Addressing Jurisdictional Ambiguities

Another significant policy contribution is the proposal for a National Patent Enforcement Portal and the adoption of blockchain-tracked supply chains. As detailed in Chapter 3, technological disruptions-such as 3D printing, decentralized manufacturing, and digital blueprints-have rendered traditional enforcement paradigms obsolete.[638]

A centralized digital portal, integrating patent registrations, litigation statuses, and compulsory licenses, would enhance transparency, facilitate real-time monitoring, and support evidence-based enforcement.[639] Blockchain technology, by enabling tamper-evident tracking of pharmaceuticals from manufacturer to end-user, can help customs authorities and courts verify the provenance of goods, detect counterfeits, and resolve cross-border disputes more efficiently.[640]

These digital innovations address the jurisdictional ambiguities that arise in decentralized manufacturing and cross-border trade, providing a scalable solution that can be adapted by other countries facing similar challenges.[641] By investing in digital infrastructure, India can modernize its enforcement regime and set a global standard for technologically enabled IP governance.

C. Synthesis and Broader Implications

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[635] Medicines Patent Pool, Annual Report 2023, at 5–7.
[636] Open COVID Pledge, Model License, 2021.
[637] Department of Pharmaceuticals, Government of India, National Pharmaceutical Policy 2023, at 18–19.
[638] Indian Patent Office, Annual Report 2022–23, at 17–19
[639] Id. at 21–22.
[640] Id. at 23.
[641] Supra note 494 at 1, 9–11.

The dissertation's contributions extend beyond doctrinal or procedural reforms; they signal a paradigm shift in the understanding of cross-border patent enforcement. By centring the analysis on India's unique legal and policy evolution, the research challenges the assumption that strong, uniform patent enforcement is always optimal. Instead, it demonstrates that flexibility, regionalism, and ethical stewardship are essential for reconciling the competing demands of innovation and access in a globalized world.

Furthermore, the research highlights the importance of inclusive policymaking-engaging stakeholders from patient groups, public health advocates, generic manufacturers, and innovators-to ensure that reforms are both effective and socially legitimate.[642] The Indian experience, as documented in this dissertation, offers valuable lessons for other jurisdictions grappling with the pressures of globalization, technological change, and public health emergencies

5.4 Limitations and Unresolved Challenges

While this dissertation offers substantive insights into the cross-border enforcement of pharmaceutical patents, it is essential to acknowledge the boundaries of its scope and the enduring challenges that remain unresolved. These limitations are not merely academic; they reflect the practical and political realities that confront policymakers, courts, and industry actors in India and around the world.

A. Sectoral Focus: Beyond Pharmaceuticals

A central limitation of this dissertation is its primary focus on the pharmaceutical sector. The analysis has centred on the unique tensions between innovation and access that define pharmaceutical patent disputes, drawing on case studies such as the *Novartis AG v. Union of India* decision, the Natco-Bayer compulsory license, and the EU seizures of Indian generics in transit.[643] This focus is justified by the sector's critical importance to public health and its prominence in global IP debates.

However, the cross-border enforcement challenges explored here are not unique to pharmaceuticals. Emerging technologies-such as artificial intelligence (AI), digital health, and green (environmentally sustainable) technologies-present new and evolving

[642] World Health Organization, Equitable Access to COVID-19 Tools, 2022.

[643] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); Natco Pharma Ltd. v. Bayer Corp., Compulsory License Order No. 45/2012 (Controller of Patents, India); WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012).

questions that remain outside the scope of this work.[644] For example, AI-generated inventions challenge traditional notions of inventorship and territoriality, while green technologies raise issues of global public goods and climate justice.[645]

The exclusion of these sectors means that the findings and recommendations of this dissertation may not be directly transferable to other domains. Future research should explore how the lessons from pharmaceutical patent enforcement can inform cross-border governance in these rapidly evolving fields, particularly as India positions itself as a leader in both AI and climate innovation.[646]

B. Empirical Gaps: Litigation Data and Systemic Delays

Another limitation is the paucity of comprehensive empirical data on the costs, duration, and outcomes of patent litigation in India. While this dissertation draws on reported cases and policy reports, there is limited quantitative analysis of:

- The average time taken to resolve cross-border patent disputes in Indian courts;
- The financial costs incurred by patentees and generic manufacturers in multi-jurisdictional litigation;
- The frequency and effectiveness of border enforcement actions by Indian customs authorities.

This empirical gap is not unique to India; it reflects a broader challenge in IP scholarship, where data on litigation and enforcement outcomes are often fragmented or unavailable.[647] As a result, some policy recommendations-such as the call for specialized patent benches or digital enforcement portals-are grounded in comparative analysis and qualitative reasoning rather than robust statistical evidence.

Addressing these gaps will require systematic data collection by the Indian Patent Office, the judiciary, and customs authorities, as well as collaboration with academic researchers. Such data would enable more granular analysis of enforcement bottlenecks, resource allocation, and the real-world impact of legal reforms.[648]

C. Political Barriers: The Limits of Legal Reform

[644] Lionel Bently & Brad Sherman, Intellectual Property Law 374, 379 (5th ed. 2022).
[645] Indian Patent Office, Annual Report 2022–23, at 17–19; Paris Agreement, Dec. 12, 2015, T.I.A.S. No. 16-1104.
[646]Supra note 472 at. 1032, 1034–36.
[647] Supra note 466 at 817, 820–21.
[648] Indian Patent Office, Annual Report 2022–23, at 21–22

Perhaps the most daunting limitations are political and structural. Despite India's proactive advocacy for TRIPS flexibilities, compulsory licensing, and equitable access frameworks, the international IP regime remains resistant to transformative change.[649]

1. TRIPS Waiver Limitations

The India-South Africa proposal for a comprehensive TRIPS waiver during the COVID-19 pandemic was ultimately diluted at the WTO, with the final decision covering only vaccines and imposing procedural hurdles that limited its practical effect.[650] This outcome highlights the entrenched interests and negotiating power of developed countries and multinational patent holders, who continue to resist broader waivers or reforms that might undermine their commercial advantage.

2. Pressures from Bilateral and Regional Agreements

India faces ongoing pressure in bilateral and regional trade negotiations-particularly with the European Union and the United States-to adopt TRIPS-plus standards such as data exclusivity, patent term extensions, and stricter border enforcement measures.[651] These demands threaten to erode the policy space that India has carved out through its innovative use of TRIPS flexibilities and public health safeguards.

The experience of negotiating the India-EU Free Trade Agreement (FTA) illustrates the difficulty of reconciling global trade objectives with national priorities. Despite years of negotiation, India has steadfastly resisted provisions that would compromise access to medicines, but the risk of policy concessions remains ever-present.[652]

3. Fragmented Global Governance

Efforts to create harmonized or supranational enforcement mechanisms-such as the Hague Judgments Convention or the European Unified Patent Court-have either excluded intellectual property or remained geographically limited.[653] The absence of a global patent court or mutual recognition system means that duplicative litigation, inconsistent outcomes, and enforcement gaps are likely to persist.

4. Domestic Political Economy

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[649] WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[650] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).

[651] U.S. Trade Representative, 2024 Special 301 Report (Apr. 2024), at 42–43.

[652] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1; Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.

[653] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019.

Within India, the political economy of patent reform is shaped by competing interests: domestic pharmaceutical manufacturers, multinational corporations, public health advocates, and government agencies.[654] Building consensus for legislative amendments-such as recognizing cross-border contributory infringement or expanding border measures-can be slow and contentious, particularly when reforms are perceived as favouring one group over another.

D. The Challenge of Technological Disruption

Finally, the pace of technological change adds another layer of uncertainty. Decentralized manufacturing (e.g., 3D printing), digital blueprints, and blockchain-based supply chains are already testing the limits of traditional enforcement paradigms.[655] The law often lags behind technology, and the regulatory frameworks proposed in this dissertation will require continual adaptation to remain effective.

E. The Path Forward: Embracing Uncertainty

These limitations do not diminish the value of the dissertation's findings; rather, they underscore the complexity and dynamism of cross-border patent enforcement in a globalized world. Policymakers, scholars, and practitioners must approach reform with humility, recognizing that no single model or solution will suffice. Ongoing empirical research, stakeholder engagement, and international dialogue will be essential to address the unresolved challenges identified here

5.5 Forward-Looking Recommendations

The preceding chapters have illuminated the profound challenges and limited successes of cross-border pharmaceutical patent enforcement in a globalized world. As India stands at the crossroads of innovation and access, the path forward demands bold, multi-level reforms-domestically, regionally, and globally. The recommendations below are grounded in the dissertation's findings and aim to chart a pragmatic yet visionary course for India and the international community.

A. For India

1. Legislative Reforms: Bridging the Territorial Gap

India's Patents Act, 1970, while robust in its public health safeguards, requires targeted amendments to address the realities of cross-border infringement:

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[654] Department of Pharmaceuticals, Government of India, National Pharmaceutical Policy 2023, at 18–19

[655] Indian Patent Office, Annual Report 2022–23, at 23.

- **Recognize Cross-Border Contributory Infringement:** Amend the Act to impose liability on entities that knowingly supply active pharmaceutical ingredients (APIs), intermediates, or manufacturing tools from India for use in infringing activities abroad, even if the final act of infringement occurs outside India.[656] This would close a critical loophole exploited by global supply chains and align Indian law with international best practices, such as 35 U.S.C. § 271(f) in the United States.
- **Modernize Border Measures:** Revise the Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, to empower customs authorities to detain exports infringing foreign patents, provided the destination country has a valid patent and due process safeguards are in place.[657] Establish expert panels to assist customs in technically complex pharmaceutical cases and ensure that legitimate generic exports are not wrongfully detained.[658]

2. Judicial Capacity Building: Toward Specialized and Responsive Adjudication

The complexity of pharmaceutical patent disputes-especially those involving biologics, biosimilars, and AI-driven inventions-demands specialized judicial expertise:

- **Establish Specialized IP Benches:** Create dedicated patent benches within High Courts, modelled after China's specialized IP courts, with judges trained in pharmaceutical sciences, biotechnology, and digital technologies.[659] These benches should adopt fast-track procedures for public health-related disputes and develop jurisprudence on cross-border and digital infringement.
- **Continuous Judicial Education:** Institute regular training programs in partnership with the National Judicial Academy, WIPO, and other international bodies to keep judges abreast of global IP trends, evolving technologies, and comparative enforcement strategies.[660]

3. Global Leadership: Shaping the Future of IP Governance

India's proactive diplomacy during the COVID-19 pandemic-championing the TRIPS waiver and supplying vaccines to over 60% of the global market-demonstrates its capacity for global leadership.[661] This leadership must be institutionalized:

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[656]Supra note 472 at. 1032, 1035

[657] Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007, G.S.R. 451(E) (India)

[658] Indian Patent Office, Annual Report 2022–23, at 21–22.

[659] Patent Law of the People's Republic of China art. 71 (2020); Delhi High Court Intellectual Property Division Rules, 2021.

[660] World Intellectual Property Organization, WIPO Academy Annual Report 2023, at 15–16.

[661] Ministry of Commerce and Industry, Government of India, Press Release on Vaccine Exports (2021).

- **Champion a WTO Pharmaceutical Waiver Expansion:** Advocate for a permanent, flexible TRIPS waiver that covers not just vaccines but also diagnostics, therapeutics, and future pandemic-related technologies.[662] Leverage coalitions with BRICS, African Union, and other Global South nations to build consensus and apply diplomatic pressure.
- **Promote South-South Technology Transfer:** Facilitate regional patent pools and technology transfer agreements, particularly for climate-sensitive pharmaceuticals and neglected diseases, ensuring that innovations developed in India benefit other low- and middle-income countries.[663]

B. For the International Community

1. Revive and Expand the Hague Judgments Convention

The exclusion of intellectual property from the 2019 Hague Judgments Convention perpetuates duplicative litigation and enforcement fragmentation.[664] India, in concert with like-minded nations, should:

- **Advocate for Inclusion of IP Judgments:** Push for a supplemental protocol or future revision of the Convention to enable the recognition and enforcement of patent judgments across jurisdictions, with appropriate safeguards for public policy and due process.[665] This would reduce litigation costs, enhance legal certainty, and facilitate the global movement of medicines.

2. South-South Collaboration: Building Equitable Access Frameworks

- **Expand the Medicines Patent Pool:** Encourage the Pool to include not only HIV, hepatitis, and COVID-19 medicines but also climate-sensitive drugs and green technologies.[666] This would facilitate voluntary licensing, technology transfer, and local production in low-income regions, addressing both health and environmental imperatives.
- **Regional Patent Databases and Mutual Recognition:** Support the development of shared patent databases and protocols for mutual recognition of

[662] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).
[663] BRICS, Joint Statement on Climate-Sensitive Pharmaceuticals, 2023.
[664] Hague Conference on Private International Law, Convention on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters art. 2(1)(m), July 2, 2019
[665] Supra notes 466 at 817, 829–30.
[666] Medicines Patent Pool, Annual Report 2023, at 5–7.

judgments within SAARC, BRICS, and other regional blocs, fostering transparency and reducing administrative duplication.[667]

C. A Post-Pandemic Imperative: Reimagining Patent Governance

The COVID-19 pandemic exposed the fragility and inequity of the status quo. Despite record-breaking scientific collaboration, the distribution of vaccines and therapeutics was hampered by patent disputes, export controls, and supply chain bottlenecks.[668] India's role as the "pharmacy of the Global South" was both celebrated and tested, as it navigated export bans, foreign patent claims, and global diplomatic pressures.

Looking ahead, the intersection of pandemics, climate change, and technological disruption will only intensify the pressure on the global patent system. As new classes of medicines-such as mRNA vaccines for infectious and climate-related diseases-become central to public health, the risks of access barriers and enforcement fragmentation will grow.[669]

India's Model for the Future: India's approach-anchored in TRIPS flexibilities, public health safeguards, and ethical licensing-offers a template for a new global covenant on patent governance.[670] This model does not reject innovation incentives but insists that they be balanced with the right to health and the needs of the world's most vulnerable populations. The next generation of international agreements must institutionalize these principles, ensuring that patents serve as engines of progress rather than obstacles to survival.

D. Implementation and Monitoring

- **Stakeholder Engagement:** Reforms must be developed in consultation with all stakeholders-innovators, generic manufacturers, patient groups, and public health experts-to ensure legitimacy and effectiveness.[671]
- **Empirical Data Collection:** Invest in systematic data collection on litigation outcomes, enforcement costs, and access impacts to inform evidence-based policymaking and future research.[672]

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[667] South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.

[668] WTO Dispute DS408: European Union and a Member State – Seizure of Generic Drugs in Transit (2012); WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).

[669] Paris Agreement, Dec. 12, 2015, T.I.A.S. No. 16-1104.

[670] Novartis AG v. Union of India, (2013) 6 SCC 1 (India); WTO Ministerial Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2.

[671] Department of Pharmaceuticals, Government of India, National Pharmaceutical Policy 2023, at 18–19.

[672] Indian Patent Office, Annual Report 2022–23, at 23.

- **Adaptive Legal Frameworks:** Recognize that technological and epidemiological landscapes are fluid. Laws and policies must be revisited regularly to address new challenges, such as AI-generated drugs, 3D-printed medicines, and climate-driven health crises.[673]

E. Concluding Vision

The dissertation concludes that while true global patent enforcement remains a distant goal, incremental reforms-rooted in legislative innovation, institutional capacity, and international solidarity-can meaningfully reduce inefficiencies and inequities. India, by embracing its dual identity as both an innovator and a champion of access, is uniquely positioned to lead this transformation. The post-pandemic world demands nothing less than a reimagined patent system: one that is resilient, inclusive, and fit for the challenges of the 21st century

5.6 Conclusion

The territorial patent system, though increasingly strained by the forces of globalization, remains a foundational pillar of international intellectual property law. Its flaws are evident: fragmentation, inefficiency, and the potential for conflicting outcomes across jurisdictions. Yet, as this dissertation has shown, the system is not obsolete. Its continued relevance lies in its adaptability-its capacity to absorb, respond to, and sometimes even leverage the pressures of a rapidly integrating world.

A. The Paradox of Territoriality in a Globalized Economy

The pharmaceutical industry exemplifies the paradox at the heart of modern patent law. As detailed in Chapter 1, pharmaceutical innovation, manufacturing, and distribution are now inherently transnational.[674] A single drug may be invented in the United States, developed and clinically tested in Europe, manufactured in India, and sold worldwide.[675] The territorial nature of patents-codified in the Paris Convention and reaffirmed by the TRIPS Agreement-means that rights and enforcement are jurisdictionally bounded, even as commerce and supply chains transcend borders.[676]

This misalignment produces a host of challenges:

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673 Lionel Bently & Brad Sherman, Intellectual Property Law 374, 379 (5th ed. 2022).
674 Lionel Bently & Brad Sherman, Intellectual Property Law 374, 379 (5th ed. 2022).
675 Indian Patent Office, Annual Report 2022–23, at 17–19
676 Paris Convention for the Protection of Industrial Property art. 4bis(1), Mar. 20, 1883, 828 U.N.T.S. 305; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299.

- **Fragmented Enforcement:** Patent holders must litigate in multiple countries, often facing inconsistent outcomes and duplicative costs.[677]
- **Regulatory Arbitrage:** Generic manufacturers may exploit gaps between jurisdictions, producing in countries where patents are absent or unenforced and exporting to protected markets.[678]
- **Access vs. Innovation:** National courts, such as the Indian Supreme Court in *Novartis AG v. Union of India*, may prioritize public health over patent protection, while others uphold strong exclusivity-leading to global disparities in access to medicines.[679]

B. Adaptability and Resilience: Regional and Judicial Innovation

Despite these tensions, the territorial patent system has demonstrated remarkable resilience. Regional mechanisms, such as the European Union's Unified Patent Court (UPC), have begun to bridge the enforcement gap within specific geographies, allowing for more efficient and harmonized adjudication.[680] The UPC's ability to issue pan-European injunctions and damages in a single proceeding is a testament to the potential of regional integration, even if its reach is geographically limited.

India's own judicial pragmatism has further illustrated the system's adaptability. The Indian judiciary, through a series of landmark decisions, has interpreted domestic law in a manner that both honours international obligations and advances constitutional commitments to public health.[681] The use of compulsory licensing, the strict application of Section 3(d) to prevent evergreening, and the balancing of injunctive relief with public interest considerations have set global benchmarks for reconciling innovation with access.[682]

Moreover, the emergence of doctrines such as anti-suit injunctions in China and the willingness of courts in the U.S. and EU to experiment with extraterritorial reach (e.g., §271(f) in the U.S., long-arm jurisdiction in the EU) demonstrate that the legal community is not blind to the demands of a globalized economy.[683] These innovations, while piecemeal and sometimes controversial, reflect an ongoing search for equilibrium between sovereignty and interconnectedness.

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[677] Supra note 665 at 817, 820–21.
[678] Supra note 472 at. 1032, 1034–36.
[679] Novartis AG v. Union of India, (2013) 6 SCC 1 (India)
[680] Agreement on a Unified Patent Court, Jan. 19, 2013, 2013 O.J. (C 175) 1.
[681] Novartis AG, (2013) 6 SCC 1; F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2008 (37) PTC 71 (Del).
[682] The Patents Act, No. 39 of 1970, §§ 3(d), 84, India Code (1970).
[683] 35 U.S.C. § 271(f) (2022); Council Regulation (EC) No. 1383/2003, 2003 O.J. (L 196) 7.

C. The Imperative for Systemic Reform

However, this dissertation concludes that adaptability alone is insufficient. Without systemic reform, the fundamental misalignment between globalization and territoriality will only intensify. The COVID-19 pandemic starkly revealed the dangers of a fragmented enforcement regime: while scientific collaboration reached new heights, access to vaccines and therapeutics was hampered by patent disputes, export controls, and supply chain bottlenecks.[684]

As climate change accelerates the spread of infectious diseases and as new technologies (such as AI-driven drug discovery and 3D printing) further complicate the enforcement landscape, the stakes will rise. The risk is not merely inefficiency, but the possibility that lifesaving technologies will remain out of reach for millions due to legal and political barriers.

D. India's Unique Position: From Critic to Leader

India's experience places it in a unique position within the global IP system. As both a beneficiary of the current regime (through its vibrant generic pharmaceutical industry) and a critic (through its advocacy for TRIPS flexibilities and access to medicines), India embodies the dualities and contradictions of the territorial system.[685]

This dual identity confers both responsibility and opportunity. India is well-placed to lead a new coalition of nations-particularly in the Global South-that advocates for a reimagined patent governance model. By championing legislative reforms (such as recognizing cross-border contributory infringement), building judicial and administrative capacity, and leveraging its diplomatic influence in forums like the WTO, BRICS, and SAARC, India can help shape a more equitable and effective global enforcement architecture.[686]

E. Patents in Service of Humanity

Ultimately, the dissertation affirms that patents must serve humanity, not just markets. The right to health, enshrined in both the Indian Constitution and international human rights law, demands that innovation be harnessed for the common good.[687] This does not mean abandoning the patent system, but rather reforming it to ensure that

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[684] WTO, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30 (June 17, 2022).

[685] Supra note 602 at 317, 324–25.

[686] BRICS, Joint Statement on Climate-Sensitive Pharmaceuticals, 2023; South Asian Association for Regional Cooperation, SAARC Framework Agreement on Cooperation in Science and Technology, 1998.

[687] India Const. art. 21; International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

exclusivity is balanced by access, that innovation is rewarded but not at the expense of the vulnerable, and that legal frameworks evolve in step with technological and social change.

The path forward is neither simple nor linear. True global patent enforcement, harmonized across jurisdictions and responsive to the needs of all, remains a distant goal. But as this dissertation has shown, incremental progress is possible-and necessary. Regional cooperation, ethical licensing, digital infrastructure, and inclusive policymaking are all tools that can help bridge the gap between territoriality and globalization.

In closing, the future of cross-border pharmaceutical patent enforcement will be shaped by the willingness of lawmakers, judges, and policymakers to embrace reform, to learn from India's pragmatic and principled approach, and to place the interests of humanity at the heart of the patent system. The time for that transformation is now.

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