Intellectual Property Law Implementation in the Pharmaceutical Sector: The Influence of Pro-Stringent and Pro-Lax Actors

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Abstract

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Eric Veto

Intellectual Property (IP) has shaped the landscape in the pharmaceutical sector. In this industry, these protections have resulted in varying sentiments ranging from pro-lax proponents like advocacy groups supporting less stringent IP so that medicines can be made affordable and widely available in emerging countries, such as in the form of generic drugs, while pro-stringent actors encompassing multinational pharmaceutical corporations and trade representatives espouse more IP safeguards for political and economic leverage. India and China are two emerging economies, yet they have achieved varying results in implementing IP law. This thesis examines the roles of international and domestic pro-lax and pro-stringent actors that have shaped the political and legal landscape surrounding IP in the pharmaceutical industry, analyzing their influence based on the theoretical underpinnings of framing, lobbying, venue shopping, and agenda-setting, with a focus on landmark court cases in both regions. Findings demonstrate that, given the greater influence of pro-lax actors in India domestically and internationally, there is less stringent implementation of IP law. In contrast, given the more pronounced influence of pro-stringent actors in China domestically and internationally, IP law implementation in the pharmaceutical sector contains greater IP legal protections.

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Chapter 1: Introduction

In the era of globalization, intellectual property law has become a pivotal aspect in the struggle of emerging countries to balance their international commitments with the demands of domestic stakeholders. Intellectual property rights (IPRs) have been a crucial legal development in protecting creations and innovations in the global trade regime, particularly over the past few decades. In 1994, the Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") was adopted by the World Trade Organization (WTO) to protect intellectual property innovations (Su, 2000, p. 185). IPRs protect intangible elements, including patents, copyrights, and trademarks (Goans, 2003, p. 2). TRIPS laid the groundwork for enhanced international IP protections. To improve access to medicines, the WTO Ministerial Conference adopted the Doha Declaration in 2001, based on the TRIPS agreement, to support public health. This initiative enables countries to circumvent patent protection, ensuring that drugs are more accessible (Harris, 2010, p. 385).

Enforcing strict IP laws can bring substantial benefits, including encouraging foreign direct investment (FDI), incentivizing technology transfer, and stimulating innovation (Maskus, 2000a, p. 2). Nonetheless, stringent IP can also block access to affordable medicines and other essential technologies, especially for the public health sector within countries (Bauza, 2019, para. 1). Hence, there is a trade-off between the economic benefits of strong IP laws and the social costs of reduced access to lifesaving treatments. In addition to access to medicines, one of the critical motivations behind flexibility in IP laws involves similar concerns around fostering technological advancement through technology transfer and enabling economic development. Technology transfer, where developing countries can learn and adopt technologies from other countries, can create financial and legal barriers to accessing these existing technologies (Schiappacasse, 2003, p. 171).

Given these trade-offs, there is a need to understand how and why countries differ in their approaches toward IP law. Despite shared international obligations, there is considerable variation in the stringency of their domestic IP laws. What is the explanation for this divergence? This is a crucial question for academic inquiry, providing insight into global policy debates and the intersection between IP law, innovation, and public welfare.

This research examines the stringency of IP law in India and China's pharmaceutical sectors, highlighting the differences across industries and national contexts. Although both countries are members of the WTO and are bound by TRIPS, India is perceived as having lower stringency in pharmaceuticals to safeguard public health concerns (Médecins Sans Frontières, 2012a, para. 1; Oxfam, 2006b, para. 6), whereas China has more IP stringency based on complying with IP from international pressures (Cao et al., 2021, p. 3719). Examining two distinct countries in the pharmaceutical sector provides insights into how domestic and international pressures influence the implementation of IP law.

In India, a robust domestic generic pharmaceutical industry, supported by advocacy groups and international non-governmental organizations (INGOs) such as Médecins Sans Frontières (MSF), is part of a sustained pro-lax mentality that likely contributed to shaping national IP outcomes. The Cancer Patients Aid Association advocacy group, represented by its lawyer Anand Grover, was involved in the landmark *Novartis v. Union of India & Ors* Supreme Court ruling, which advocated for a more lax approach to IP (Supreme Court of India, 2013). Judicial and administrative authorities, including the Supreme Court of India and the Indian Patent Office, interpret IP law in a manner that prioritizes access to medicines over strict IP implementation. In contrast, China's stronger IP stringency stemmed from a top-down, state-led approach. Pro-stringent IP actors, such as domestic pharmaceutical firms and the United States Trade

Representative, seek greater enforcement of IP rights. The central government led legal reforms, expanded IP courts, and promoted patenting as part of an economic modernization strategy, including the Healthy China 2030 policy and forming national innovation agendas (Chen, 2023). There was also discretion in implementation through selective enforcement and pragmatic judicial interpretation, which will be seen in the Chugai Pharmaceutical Co., Ltd. v. Wenzhou Haihe Pharmaceutical Co., Ltd. case (Xiaohui, 2023).

The Chinese example, complemented by India's unique perspective on IP issues, provides a platform for exploring in more detail the common problems and prospects of emerging countries in navigating IP law issues in the globalizing world, between safeguarding innovation and ensuring the public availability of medicines.

I aim to address the research question: *What factors explain the variation in the stringency of intellectual property (IP) law implementation in emerging countries? Why do certain countries end up with stricter domestic IP laws than others*? Understanding this divergence, focusing on the pharmaceutical sector is significant for policymakers in the context of ongoing debates about global justice, public health advocacy, and the influence of multinational companies on national policies (Hassoun, 2014, p. 231). India's less stringent patent legislation has attracted criticism from multinational pharmaceutical companies seeking access to its market (Bennett, 2014, p. 545).

I argue that the difference in emerging countries' choices about IP law can be explained by unravelling the interaction between pro-lax IP and pro-stringent IP advocates at both international and domestic levels. These coalitions comprise foreign multinational corporations (MNCs) and their local subsidiaries, professional associations and business groups such as the Organisation of Pharmaceutical Producers of India (OPPI) and the China Pharmaceutical Innovation and Research Development Association (PhIRDA), public health nongovernmental organizations (NGOs),

domestic advocacy groups, and international nongovernmental organizations (INGOs), all of whom seek to pressure key stakeholders to amend their patent laws to varying extents and with varying degrees of success, Pro-stringent actors often mobilize around economic and trade interests in favour of stronger IP protections to secure benefits in investment and innovation such as the OPPI and PhIRDA (Organisation of Pharmaceutical Producers of India, 2024, p. 1; China Pharmaceutical Innovation and Research Development Association PhIRDA, n.d., para. 1). In contrast, pro-lax IP coalitions promote more flexible IP rules to favour public health policies for gaining cheap and accessible access to medicines.

These influences can help explain why some countries adopt strict IP laws while others prefer lenient approaches to accomplish their social, economic, and political objectives. This thesis examines the evolution of pharmaceutical patent laws in China and India, which has been shaped by key actors over time. The pharmaceutical sector is a highly contested area where tensions between innovation and public welfare are sharp, offering insights into broader IP policymaking, including in fields like biotechnology and software, where similar trade-offs between access and protection arise.

1.1 Methodology

This thesis employs a qualitative, comparative case study methodology to examine how international and domestic actors have shaped the evolution of pharmaceutical patent law in India and China. The study specifically investigates the roles of U.S. pressure, transnational advocacy networks, and local actors in influencing pharmaceutical intellectual property reforms in both countries, with a particular focus on the implementation of IP following the TRIPS agreement and judicial patent challenges.

Data Sources

The analysis draws on primary and secondary sources.

- Legal texts and court judgments, including landmark rulings such as *Novartis AG v. Union of India & Ors* (Supreme Court of India, 2013; Madras High Court, 2007), and patent cases, help trace how courts have interpreted pharmaceutical patent provisions, such as Section 3(d) of India's Patents Act and China's patent linkage system. Laws, amendments and trade documents from official Chinese and Indian patent authorities were examined. The China National Intellectual Property Administration (CNIPA), the Indian Patent Office, the 2005 Indian Patent Amendment Act, and the Fourth Amendment to China's Patent Law are sources analyzed for understanding legislative and policy dimensions of IP.
- Government and intergovernmental reports: Key documents include USTR's Special 301 Reports, publications from the World Intellectual Property Organization (WIPO), and national policy documents.
- Industry and NGO publications: Sources from Indian and Chinese pharmaceutical companies (e.g., Cipla, Dr. Reddy's, BeiGene, Jiangsu Hengrui), industry associations (Indian Pharmaceutical Alliance, Organisation of Pharmaceutical Producers of India, Pharmaceutical Innovation and Research Development Association of China), and activist groups (Médecins Sans Frontières, Oxfam, Cancer Patients Aid Association) are used to trace their influence and strategies used. Advocacy group campaign materials served as evidence of mobilization.
- Academic literature and peer-reviewed journals provided the theoretical grounding and historical context (e.g., Basheer & Reddy, 2008b; Mueller, 2007; Deere, 2009; Brander et al., 2017). Studies analyzing patent reform, advocacy networks, and political institutions

(Farrand, 2015; Heiss & Johnson, 2016) helped frame the interaction between external actors and domestic politics.

- Media reports and archival news: Outlets such as The Economic Times, Business Standard, BBC, The Guardian, and LexisNexis archival database provided details on policy changes, lobbying campaigns, and international trade negotiations.

Data Collection Strategy

This research employed a document analysis approach, encompassing legislative records, judicial decisions, industry statements, policy briefs, advocacy group reports, and academic articles. Sources were collected through academic databases, including JSTOR, ProQuest, SSRN, Concordia University Library Sofia Discovery Tool platform and Google Scholar; legal repositories (Indian Kanoon and Global Health Rights); organizational websites (WIPO, USTR, MSF, and OPPI) and news sources.

1.2 Research Approach and Methodological Application

Hypothesis:

Countries where pro-stringent intellectual property coalitions, such as multinational pharmaceutical companies, business associations, and state actors, hold greater interests relative to pro-lax actors, are more likely to implement stricter pharmaceutical IP protections aligned with global patent standards. Conversely, where pro-lax coalitions, such as public health NGOs, access-to-medicine advocates, and INGOs are more influential, countries are more likely to adopt flexible IP regimes that prioritize access to affordable medicines.

To test my argument, I examined how both domestic and international actors influenced the implementation of pharmaceutical IP law in India and China through framing, lobbying, agenda-setting, international pressures, and venue shopping. I began by identifying key

amendments to both nations' pharmaceutical IP laws, such as India's 2005 Patent Amendment Act and China's Fourth Amendment to its Patent Law. I matched these with periods of advocacy activity. I considered court cases, such as *Novartis v. Union* and *Chugai v. Haihe*, to observe the outcomes of court litigation, the influence of the judiciary, and the participation or indirect influence of pro-lax and pro-stringent IP stakeholders. I compared advocacy campaigns based on campaign documents and reports, such as from Médecins Sans Frontières, the Cancer Patients Aid Association, and Oxfam, as well as industry perspectives derived from the websites and reports of organizations such as OPPI, PhIRDA, and pharmaceutical companies like Cipla and BeiGene.

Focused keyword searches on LexisNexis and Google Scholar (e.g., "advocacy," "petitions," "campaign strategies") were employed to identify connections between advocacy activity and legal change, particularly where legislative or judicial change was underway. While direct causality was hard to prove, especially in court decisions driven by precedent or independent judicial rationale, I argue that the timing and strategies of pro-lax and pro-stringent-IP actors shaped the overall policy climate and public discourse, indirectly influencing outcomes. The main challenging task I faced was attributing direct influence to specific actors, especially from court decisions, which are typically driven by legal and independent rationale. Courts, such as in the India case, did not mention any praise for advocacy initiative influence in my searches, so it is challenging to prove that results were directly affected by advocacy influence. For example, while groups like Médecins Sans Frontières and Cancer Patient Aid Association (CPAA) engaged in cases like *Novartis v. Union*, their influence is not visible in formal judgments. To address this, I gathered evidence from various sources, including legal records, advocacy materials, news outlets, and policy reports. By comparing the timing and content of court decisions with ongoing

campaigns, I identified plausible links between advocacy and legal changes, even where causation could not be definitively established.

Thesis Structure

This thesis is organized into five chapters. Following the introduction, Chapter 2 presents the literature review, focusing on existing explanations of IP law stringency in emerging countries. It engages with international influences, such as U.S. trade pressure and TRIPS compliance, and extends its insights by incorporating both international and domestic actor influences, including NGOs, courts, and industry associations. Chapter 3 introduces the India case study, examining how pro-lax and pro-stringent IP actors influenced key pharmaceutical IP landmarks such as Section 3(d), the *Novartis AG v. Union of India & Other cases,* along with the *Bayer Corporation v. Natco Pharma Limited* case. Chapter 4 proceeds to the China case study, examining how the central government, supported by pro-stringent IP actors such as PhIRDA and the United States Trade Representative (USTR), shaped IP reforms, including the patent linkage system outlined in the Fourth Amendment. The final chapter concludes by contrasting the two countries, integrating the findings, and examining broader implications for our understanding of IP law in other sectors, such as technology. It also highlights the broader significance of the pharmaceutical industry and suggests how this research may inform discussions on innovation, access, and global justice.

Chapter 2: Literature Review

This chapter aims to provide background on the implementation of IP law, specifically examining why countries align with the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement. It begins with an overview of compliance with the TRIPS Agreement, followed by an analysis of international pressures stemming from TRIPS, and then an examination of the roles of domestic actors in shaping the implementation of IP law. This analysis will examine key scholars

in the literature to provide a foundation for implementing IP law in the country case chapters, thereby enhancing our understanding of these international influences and the role of domestic actors. The following section of the chapter examines my theoretical framework, which includes not only international influence from the literature but also domestic pressures. I categorize pro-lax and pro-stringent IP groups for conceptualization. I then explain how influence is garnered through framing, lobbying, agenda setting and venue shopping. In the final section, I outline my hypothesis for the conditions that lead to stringent or lax IP, examining the factors that influence pro-stringent and pro-lax IP laws, including political sovereignty, multinational pressure, international agreements, and social movements.

The TRIPS agreement sets minimum IP protection standards that the World Trade Organization (WTO) members must follow (Yu, 2009, p. 980). The multilateral intellectual property system culminated in the TRIPS Agreement. The negotiations focused on the substantive standards for the protection of intellectual property rights, mechanisms for achieving IPR protection within national legal systems, and rules for resolving disputes between parties under the TRIPS Agreement. They also addressed the relationship between GATT (General Agreement on Tariffs and Trade) and other relevant international organizations, such as WIPO, in relation to TRIPS, as well as the interplay between a potential agreement in the Uruguay Round of trade negotiations and existing intellectual property conventions (Yu, 2009, p. 983). The negotiations were contentious, as developed and developing regions disagreed on how IP should be incorporated into their respective nations (Yu, 2009, p. 980). Due to diverging views, pressures towards its implementation became an issue among WTO members.

A) 2.1 Compliance with TRIPS

While TRIPS allows some flexibility for emerging countries, it largely pressures developing countries to align with the IP standards of developed countries. One key flexibility is compulsory licensing, which permits governments to authorize the production or importation of generic versions of patented products without the consent of the patent holder (Wong, 2020, p. 1). To improve access to medicine, the WTO Ministerial Conference adopted the Doha Declaration, which extended the TRIPS agreement for public health purposes in November 2001 (Harris, 2010, p. 385; Rodrik, 2018, p. 76). The Doha Declaration sparked discussions on how developing regions can leverage greater bargaining power in negotiations over IPR. As IP rights expand, access to generics becomes essential. Article 31 of the TRIPS agreement allows members of the World Trade Organization to be granted a compulsory license for pharmaceutical products; developing regions have discretion over what constitutes a 'national emergency' (Abbott, 2002, p. 498). Article 31 states that in public health emergencies, developing regions are not required to negotiate with patent holders (Matthews, 2004, p. 77). The Doha Declaration's flexibility enables developing countries to use compulsory licensing to provide low-cost drugs (Sun, 2004, p. 148). When public health is at risk, this mechanism can be used to maintain weaker IP protection. Nevertheless, ambiguity in the Doha Declaration has limited the options available for developing regions. Paragraph 5 of the Agreement aimed to clarify the term 'national emergency' in Article 31 (Kobori, 2003, p. 78). Since TRIPS lacked clear rules for compulsory licensing, the Doha Declaration lets members define 'national emergency' and 'public health crisis' (Murthy, 2001, p. 1324). This openness can create a sense of confusion due to the vagueness in defining key terminology.

A common theme in the literature is how international commitments shape domestic IP laws. Cardwell & Ghazalian (2012) note that while TRIPS allows flexibilities, such as parallel importation, their ambiguity causes uncertainty in dispute settlements (p. 24). Parallel imports are

goods that have initial IP protections under a trademark, patent or copyright but are then imported in a second market without permission from the owner of the IP holder (Maskus, 2000b, p. 1269). For example, TRIPS permits parallel importation; however, unclear rules have made it difficult for developing countries to meet the strict industrialized-world IP standards (Cardwell & Ghazalian, 2012, p. 35). Developed countries face fewer changes given their compliance with international IP norms. Developed nations and multinational corporations have created leverage to affirm their ambitions. Despite Doha flexibilities, the U.S. continued to push its IP agenda as developing countries resisted Western efforts. This U.S. ambition was achieved through the TRIPS-Plus provisions, meaning that the U.S. altered its approach to concentrate on bilateral and regional negotiations (Mercurio, 2006, p. 215). Through these avenues, the U.S. also sought to affirm IPRs by making TRIPS-Plus provisions mandatory for free trade agreement (FTA) partners. Those provisions commonly contain the new scope of IPRs, the implementation of more stringent requirements for IP protection than those stipulated by TRIPS, or the abolishment of TRIPS flexibilities (Mercurio, 2006, p. 219). These requirements highlight the limits faced by emerging countries within the global IP regime.

B) 2.2 International Pressures Towards TRIPS

The implementation of TRIPS in emerging countries is shaped by international pressures from MNC lobbying, advocacy from international organizations, and diplomatic and economic leverage exercised by industrialized nations. Deere (2009) provides a comprehensive framework for understanding the role of pro-stringent and pro-lax IP actors in influencing IP laws, illustrating the mechanisms through which multinationals apply economic pressure to drive legal reforms in developing countries. She argues that multinationals exert economic pressure on developing countries to reform their IP laws to comply with the global pro-stringent IP agenda. This pressure

has been used to threaten sanctions or create diplomatic intimidation (Deere, 2009, p. 162). Multinational corporations used the threat of withdrawing or withholding foreign investment as a lever to influence the regulation of intellectual property law. For example, in the Philippines, Microsoft and its trade association, Business Software Alliance (BSA), a global trade organization with software companies, exerted pressure on the government to modify its legal procedures to enable law enforcement agents to engage in search warrants to cope with software piracy (Deere, 2009, p. 164). These business lobbyists claimed that such reforms were essential to maintaining foreign investment. The assertion was a persuasive tactic to facilitate the integration of developing countries into the global economy. Fueled by a desire to expand its data processing and business services industries, the Philippine authorities eventually yielded to the demands (Deere, 2009, p. 164). Conversely, international organizations such as the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), and the Joint United Nations Programme on HIV/AIDS (UNAIDS) advocate for developing regions to utilize the TRIPS flexibilities to exercise discretion over public health (Deere, 2009, p. 185). These organizations have employed strategies such as using policy briefs to emphasize the importance of promoting citizens' well-being by developing measures that ensure the effective and accessible delivery of essential medicines and health services. These international organizations have emphasized the need to use TRIPS flexibilities to ensure that developing countries can prioritize public health over the inflexible rules of the intellectual property regime. These organizations sought to strengthen the capabilities of national government agencies beyond just IP offices. For instance, the WHO supported health ministries by offering guidance and information, often through seminars and meetings, on the patent status of essential medicines and the policy options available under the TRIPS agreement (Deere, 2009, p. 185).

Alternatively, Deere (2009) also discusses how framing by pro-stringent IP actors, such as the WIPO Secretariat, seeks to influence the international discourse on IP through media campaigns and agenda-setting (p. 167). Therefore, external actors attempt to influence countries' domestic policies to align with their own goals. NGO transnational networks provide an alternative frame to the effects of TRIPS patent law on the HIV/AIDS epidemic. In contrast to those business networks that blame the crisis on poverty and poor governance, NGOs attribute the problem to overly rigorous intellectual property rights laws, making HIV/AIDS drugs unaffordable and thereby undercutting public health efforts (Deere, 2009, p. 145). In an attempt to do this, civil society organizations campaign for developing countries to adopt compulsory licensing as a mechanism for allowing local production of patented HIV/AIDS drugs at reduced prices (Deere, 2009, p. 145). On the other hand, business networks argue that such attempts infringe upon their patent rights. Nonetheless, through NGOs campaigning with the "Access Campaign," networks were formed to ensure affordable medicines. Agenda setting was a way NGOs established framing. The NGO network bridged the gaps between the policy realms of trade and investment, as well as public health, by introducing the issues of intellectual property rights into the international public health agenda on HIV/AIDS (Sell & Prakash, 2004, p. 163). It also emphasized the link between stringent IPR laws and the crisis, pitching its narrative to influential policymakers and the international community. The NGO network deliberately framed the problem, claiming "greedy" pharmaceutical companies were causing thousands of avoidable deaths (Sell & Prakash, 2004, p. 163). Achieving a successful advocacy strategy focused on the pandemic's social impact, highlighting the pandemic's victims, and building a clear and convincing causal narrative that assigned accountability (Sell & Prakash, 2004, p. 163).

Industrialized countries pressure emerging regions to adopt stringent IP laws. Whether regions support or resist international pressures significantly contributes to the literature on the stringency of IP law. An example is the United States Congress, which has leveraged the Special 301 report and bilateral investment treaties (BITs) to pressure developing countries to strengthen their IP laws (Shadlen et al., 2005, p. 65). There is an incentive for countries to sign BITs with the U.S. to enhance their standards of IP protection, as BITs may provide preferential trade terms or access to investment (Shadlen et al., 2005, p. 65). This links IP protection and broader trade and investment agreements, as countries would be incentivized to implement stronger IP laws to realize these economic benefits (Shadlen et al., 2005, p. 65). This dynamic provides a lens for understanding how the interaction between trade agreements and the implementation of IP law can create a strategic context in which emerging countries must weigh economic incentives against domestic considerations. Accordingly, the tightening of IP laws is often less about whether it is a state's domestic policy objective and more about the pressure from industrialized nations, thus emphasizing the tension between international pressure and national sovereignty in implementing these laws. Although BITs can provide developing countries with more favourable terms of trade and investment, these BITs can unfairly benefit developed countries because they can force these regions to have even stronger legal protection of intellectual property, which often suits the interests of developed countries.

C) 2.3 Domestic Actors: NGOs, MNCs, and the Judiciary

While international actors exert significant pressure, domestic actors—including NGOs, MNCs, and the judiciary—also shape IP implementation. While the literature has been critical in highlighting the United States' role in promoting the expansion of IP protection, it tends to overlook the domestic dynamics of emerging countries. My research aims to fill this lacuna by

examining the relationship between international pressures on the one hand and domestic actors represented by the courts, MNCs, and advocacy groups on the other hand. This would provide a more nuanced understanding of how domestic actors and international pressures influence the stringency of IP laws across countries.

Courts interpret IP laws and function as arenas where international and domestic pressures shape IP and pharmaceutical policy. Following the 2001 Doha Declaration, India adopted compulsory licensing in 2012 to deal with high drug prices. Bayer Corporation, a German multinational pharmaceutical and life sciences company, was involved in the case of compulsory licensing for its drug Nexavar in India. Natco Pharma, an Indian pharmaceutical company, was granted a compulsory license to manufacture a generic form of Bayer's Nexavar, a medication used to treat liver and kidney cancer (Onderkova, 2021, p. 8). The license was granted because the patent drug produced by Bayer U.S. was not manufactured in India (O'Connell & Guggenheim, 2016, p. 4). The cost of Nexavar, at 3200 Euros per month, was beyond the reach of many people in India. Producing a generic version through a compulsory license, via Natco Pharma, allowed the drug to become affordable and accessible. Nevertheless, Bayer continued to receive royalties, with Natco paying 6% of its sales to Bayer (Onderkova, 2021, p. 8).

Following the landmark case, another significant challenge to pharmaceutical patents emerged in India. A coalition of generic pharmaceutical companies and advocacy groups, such as the CPAA, sought to contest Novartis' patent application for its drug Glivec. The coalition argued that the company's modification to Glivec did not significantly improve its therapeutic efficacy over its previously existing form, which had already been patented outside India. Novartis' patent application, initially intended to be examined in 2005, was rejected by the Indian Patents Office in 2006 under Section 3(d) of the Indian Patents Act. The rejection was based on the argument that

the modification lacked substantial therapeutic advancement, thereby preventing Novartis from obtaining exclusive patent rights for Glivec in India (Gabble & Kohler, 2014, p. 3). This ruling was a landmark case for India's strategy in balancing public health concerns with international IP practices, once again affirming the nation's resolve to facilitate affordable access to lifesaving drugs for its people.

NGOs like the CPAA opposed pharmaceutical patents, which may have contributed to the courts issuing a compulsory license. This illustrates the roles of domestic actors in relation to the stringency of IP in the pharmaceutical sector. By extending the interplay between international and domestic players, it is crucial to demonstrate the significance of local courts in mediating between these external and internal pressures on the policies concerning IP. In this example from India, the courts may have interpreted and applied patent law by considering their international obligations under the TRIPS Agreement, the influence of the CPAA, and domestic priorities, particularly those related to public health and access to essential medicines. The 2012 Natco ruling exemplifies how domestic law shaped by public health advocacy can counter the influence of multinational firms. The court case reflects a broader trend of emerging countries using legal tools to assert national priorities amid global pressures.

BRICS, comprising Brazil, Russia, India, China, and South Africa, are emerging regions with significant economic influence and considerable potential in the global economy (Radulescu et al., 2014, p. 606). Despite foreign pressures, BRICS nations exhibit more autonomy in IP policymaking due to their economic power and political influence. India’s Natco case demonstrates how national courts can resist multinational influence and prioritize public health. This trend of employing national regulatory instruments to address global pressures is part of a broader trend among emerging countries to prioritize national interests. However, the extent of

this trend will vary beyond the BRICS group depending on economic dependencies, regulatory space, and the strength of domestic industries.

Courts help shape IP laws by reconciling international commitments with domestic concerns. Courts may be influenced by NGOs, advocacy groups, and public health agencies pushing for affordable medicines. These actors can shape rulings through public support and legal arguments. However, a court's ability to mediate pressures depends on its independence and adherence to the rule of law. In weak or politicized systems, this balance can break down. Thus, courts serve both as a link between global and local forces and as platforms for national IP policies. Choudhry & Stacey (2013) mention that judicial independence reflects democratic principles, such as the rule of law and separation of powers (p. 1). Moreover, the authors declare that "judges are tasked to uphold the rule of law. To ensure that they do so without improper influence, they must be independent from the executive and legislative branches of power" (Choudhry & Stacey, 2013, p. 1). This idea emphasizes how judicial independence, when compromised by political influence, can undermine the courts' ability to mediate effectively between international and domestic pressures.

Pharmaceutical MNCs often hold strong influence over governments at both national and local levels, thereby shaping policies through their monopolistic control of IP. Their control of key sectors enables them to influence regulatory decisions, while their potential to exit markets gives them bargaining power in securing favourable government policies (Batok, 2024, para. 5). These power dynamics help MNCs push for stronger IP protections to secure profits and market dominance. They lobby, litigate, and use international agreements to enforce and protect patent rights.

Conversely, NGOs, especially in the health sector, advocate for weakening strict IP rules to improve access to affordable medicines. Deere (2009) shows how these actors organize to counter pharmaceutical corporations' efforts to strengthen IP rights (p. 177). These NGOs support compulsory licensing and public health initiatives to increase access to medicines in low- and middle-income countries. My project compares the strategies of both advocacy groups and MNCs, analyzing how opposing actors, with their interests, preferences, and actions, interact with government agencies and local subsidiaries of MNCs to shape the implementation of IP laws.

2.4 **Theoretical Framework**

Who are the Actors? At the Domestic and International Levels

This chapter outlines the theoretical framework for identifying and analyzing key actors shaping pharmaceutical IP policy in emerging economies. I draw on academic literature to theorize how various actors, such as multinational corporations, local firms, non-governmental organizations, and advocacy groups, are likely to behave based on their structural positions and political-economic incentives. This literature helps identify the expected interests and preferences of different types of actors, such as MNCs' desire for strong IP protections to secure returns on innovation, or NGOs' prioritization of access to medicine. I incorporate empirical research demonstrating how these actors engage with IP law (e.g., Adams, 2010; Deere, 2009; Bauza, 2019). To examine how these actors pursue their goals in my case study chapters, I use descriptive case studies, such as Novartis' push for patent protection and the CPAA's opposition to pharmaceutical patents in India. Although I start by drawing inferences about expected preferences based on theory and prior behaviour, the empirical chapters will test and sharpen these hypotheses.

1. International Actors

A) Pro-Stringent IP Actors: International Pharmaceutical MNCs

Developed nations promote international IP standards through international organizations, such as the WTO, and agreements like TRIPS. They push for stronger IP to protect the interests of foreign MNCs, which rely on IP to secure innovations and investments. Strong IP laws help attract knowledge-intensive products, which might otherwise be inaccessible to the local market without foreign direct investment. Foreign direct investment also supports technology transfer (Adams, 2010, p. 202). Thus, there can be a sharing of technical expertise and skill from IP. From a pro-stringent IP view, stringent IP laws in emerging countries help regions integrate into the global economy and attract foreign investment. Government protection and recognition of intellectual property drive innovation in the pharmaceutical field. Gilead Sciences epitomizes how international operations of MNCs demand strong IP protection to cover their pharmaceutical treatments and ensure monopoly rights for new drugs. In the absence of patent protection, pharmaceutical companies were unable to secure the necessary upfront investment to sustain R&D for new medicines targeting unmet patient needs (Gilead Sciences, Inc., 2014, p. 1). These companies may struggle to attract early-stage funding for their research and development (R&D) objectives (Gilead Sciences, Inc., 2014, p. 1). Hence, having stringent IP protections can enable a robust patent system and strengthen a country's global competitiveness in the pharmaceutical sector.

Merck, a research-focused biopharmaceutical company, is committed to improving global health by developing innovative medicines and vaccines at an affordable cost. The company argues that strong IP frameworks are essential because IP implementation encourages the lengthy, costly, and high-risk undertaking of developing new and better medicines and vaccines (Merck & Co., Inc., 2024, p. 1). IP rewards innovation and enables scientists to build upon each other's work, fostering collaboration and partnerships (Merck & Co., Inc., 2024, p. 4). Merck views IP not as a

constraint, but as a facilitator of access and affordability, making novel products accessible to patients worldwide through its voluntary licenses and other IP-based collaborations (Merck & Co., Inc., 2024, p. 1). Hence, Merck views IP as essential for both innovation and access. As a U.S. multinational, it frames IP as key to advancing science, collaboration, and global health.

B) Pro-Lax IP Actors: Advocacy Groups Prioritizing Public Health

International health organizations, advocacy groups, and emerging economy coalitions can resist the imposition of strict IP laws. Médecins Sans Frontières (MSF) advocate for affordable medicines across European countries and beyond (Bauza, 2019, para. 1). They argue that IP protection raises drug prices and limits access to lifesaving medicines in developing countries (Bauza, 2019, para. 2). Pro-lax actors promote weaker IP laws to prioritize public health over corporate patent rights. Their goal is to prioritize patient needs over corporate patenting interests. Public health advocacy efforts can drive national policies toward less stringent IP protections.

2. Domestic Actors

A) Pro-Stringent IP Actors: MNCs and their Local Subsidiaries, Domestic Firms with Innovations

MNCs and their local subsidiaries often support stronger IP protections to boost competitiveness (Brander et al., 2017, p. 917). In addition to the subsidiaries of foreign companies, large domestic corporate firms with valuable innovations in emerging countries may prefer strict IP regimes like their counterparts in developed countries. A strict IP preference may develop in the pharmaceutical industry after firms have acquired valuable IP technology and seek protection to maintain a competitive advantage. Therefore, their incentives would alter towards desiring stricter IP implementation. Local firms in developing nations often play a central role within their technological markets (Zhou & Xin, 2003, p. 133). Local firms frequently collaborate with

domestic subsidiary MNCs to equip them with organizational and technical advantages, thereby bolstering their market network and innovative capabilities in the domestic market (Zhou & Xin, 2003, p. 133). With this advantage, local firms may support strict IP laws to shield themselves from competition. As their innovation grows, so can their demand for stronger IP protections. Innovation levels within local firms thus shape their IP policy preferences.

B) Pro-Lax IP Actors: Domestic Firms Seeking Technology Transfer, Patient Advocacy and Public Health Interest Groups

Domestically oriented firms can oppose stringent IP protection, especially in the pharmaceutical industry. The intention in technology transfer for domestic firms is to acquire, adapt, and enhance foreign technologies to build local capacity and enhance innovation. In such a situation, fewer IP safeguards can limit the opportunity for reverse engineering, modification, or innovation of existing technologies, limiting domestic innovation. To counter this, such firms may ally with public health groups. For instance, advocacy groups such as the CPAA in India collaborated with generic pharmaceutical manufacturers to file pre-grant oppositions to IP patents. In the Novartis case, there was such pre-grant opposition because the patent application was not novel and obvious and did not meet the patentability criteria under Section 3(d) (Mani et al., 2017, p. 31). These collaborations help ensure access to affordable medicines by circumventing strict patent implementation. According to India's Patents Act, Section 3(d) provides a legal framework wherein merely incremental improvements to pre-existing drugs are not patentable, except when such improvements or modifications significantly enhance their therapeutic efficacy (Sohrabji & Maloney, 2022, p. 65). Such legislative steps are taken in the pharmaceutical sector because the stakes are high for public health. Pro-lax actors gain influence when public welfare is at risk. Section 3(d) ensures access to lower-priced generics, except when new patents are justified by

genuine innovation (Basheer & Reddy, 2008b, p. 234). Thus, pro-lax actors resist strict IP to foster innovation and accessible medicines.

What are the Mechanisms of Influence?

Pro-stringent and pro-lax IP actors, such as MNCs and NGOs, can use strategies like lobbying, framing, agenda-setting, and venue shopping to shape IP policy. However, their impact varies due to differences in strategy, resources, political access, and institutional openness.

Agenda-Setting

Agenda setting can incentivize grassroots mobilization. Shaping early legislative changes (agenda-setting) and the degree of political significance attributed to an event are essential for successful lobbying (Farrand, 2015, p. 487). Proposal power refers to ensuring that ideas or initiatives are available for consideration within an international nongovernmental organization (Heiss & Johnson, 2016, p. 534). While Heiss & Johnson focus on agenda-setting within INGOs, similar dynamics apply in policymaking institutions—such as national courts or the WTO—where actors use venue shopping to push their agendas. Enforcement power allows vetoing decisions and ensuring compliance. Finally, implementation power executes the agenda (Heiss & Johnson, 2016, p. 534). These powers shape an INGO's focus, coherence, and effectiveness. Agenda setting, as will be explored, is also important for corporate interests, such as MNCs, seeking to shape IP law implementation.

According to Stevens & Willems (2024), "interest groups can gain agenda-setting influence by strategically highlighting different types of information in their interactions with policymakers" (p. 581). Specifically, groups that emphasize audience support over expert information are more likely to shape policy agendas, such as in the European Commission, especially on politically charged issues (Stevens & Willems, 2024, p. 581). As the authors note,

"the EC is largely driven by concerns about its reputation for responsiveness when making decisions about its policy priorities" (Stevens & Willems, 2024, p. 579). Thus, credibility and perceived legitimacy are key assets in agenda-setting (Stevens & Willems, 2024, p. 581). Therefore, different groups can tailor their strategies to the institutional venue they seek to influence. NGOs may focus on public support, while MNCs often emphasize technical and economic expertise.

Framing

Advocacy groups use framing to shape policy discussions, while business entities have framed the TRIPS agreement ''patents = free trade + investment = economic growth'' (Sell & Prakash, 2004, p. 145). Transnational NGOs counter this by linking TRIPS-related patent rules to the HIV/AIDS crisis. Business coalitions attribute the epidemic to poverty and ineffective governance, while the NGO networks reframe the issue to declare that strict IP blocks access to life-saving medicines (Sell & Prakash, 2004, p. 145). From the NGO perspective, strong IP enforcement is detrimental to public health. NGOs promote policies such as compulsory licensing that empower developing countries to produce generic versions of patented HIV/AIDS drugs locally and at a lower cost. Business groups oppose this, claiming it violates patent rights. The NGO network bridged trade and public health by introducing IPR concerns into HIV/AIDS debates, framing strict IP laws as a root cause of the crisis. They employed a normative framework to inform policymakers through international forums. The intentionalist frame blames profit-driven pharmaceutical companies for millions of deaths among vulnerable populations using emotional narratives (Sell & Prakash, 2004, p. 163). One of the NGO network's first agenda-setting moves was shaping a revised drug strategy at the 1998 World Health Assembly (WHA), where it introduced its normative frame linking concerns for IPR to medicine access. The WHA's

resolution urged member states to ensure access to drugs and utilize TRIPS flexibilities. The network then pushed its message globally, issuing an open letter to WTO members. It called for public health to take precedence in TRIPS implementation, extended grace periods for developing countries, and the use of Articles 7 and 8 of TRIPS for more flexibility in IP. This strategy used an international forum (the WHO) to influence the WTO (Sell & Prakash, 2004, p. 163).

Transnational advocacy networks increasingly influence states and international institutions. They are driven by both ethical values and strategic goals. These networks utilize framing to simplify complex issues for key audiences and align with institutional settings most receptive to their causes (Keck & Sikkink, 2014, p. 11). They introduce new narratives, ideas, and norms into global policy debates, acting as credible experts. Transnational networks promote and enforce new norms (Keck & Sikkink, 2014, p. 11). They pressure actors to adopt reforms, monitor adherence to global standards, and seek to maximize influence. Their efforts reframe how states and societies understand their interests, responsibilities, and identities, shifting the way policies are crafted and discourse is conducted (Keck & Sikkink, 2014, p. 12). These networks communicate with diverse policy stakeholders holding varied institutional and ideological views (Keck & Sikkink, 2014, p. 12). Importantly, advocacy networks also function as political arenas where actors define and negotiate social, cultural, and normative meanings that drive collective action. Hence, in international forums such as the WTO or the WHO, networks can employ moral frames centered on public health crises or human rights violations that resonate with humanitarian mandates. In domestic courts, advocacy groups may frame arguments based on legal equality and justice narratives to challenge restrictive IP laws.

Naming and shaming is a strategy to enforce laws and human rights norms. It involves NGOs, the media, and international bodies publicizing violations by countries and calling for

change (Hafner-Burton, 2008, p. 689). The “mobilization of shame” refers to targeted actions seen as problematic and are therefore held to international scrutiny. Activists in advocacy networks apply moral pressure by appealing to a government's concern for its international reputation (Keck & Sikkink, 2014, p. 31). By exposing instances where a state falls short of its international commitments or contradicts its stated principles, advocacy networks aim to erode its credibility and encourage policy reform.

Framing is thus a persuasive mechanism employed by both MNCs and NGOs to push for the stringency of IP law in the pharmaceutical sector, as I will analyze in the following chapters. By identifying the scope of the debate, such actors can help shape policymaking toward solutions to achieve their goals. For example, MNCs may have more influence when framing IP enforcement as essential for economic development, especially in global governance forums within the WTO. NGO advocacy may gain more leverage when framing issues as a human rights concern, particularly where IP restricts access to essential medicines and public health.

MNCs and NGOs can frame IP issues to resonate with the public or with policymakers. IP laws could be presented as a constraint on introducing affordable medicines by NGOs or as a gatekeeper of innovation and economic development by MNCs. The complex global IP system, comprising numerous international players, provides these actors with numerous platforms to promote their framing. Framing is consequential, as NGOs reshape interests, identities, and emotional responses. For instance, the effects of land use rights in the Amazon had an approach with people who viewed policies through the deforestation frame, while others framed land use through the prism of social justice or regional development frames (Keck & Sikkink, 2014, p. 25). During the 1970s and 1980s, several states recognized, for the first time, international human rights promotion as an effective foreign policy lever and a manifestation of national interest, partly

influenced by their engagement with a growing global human rights network (Keck & Sikkink, 2014, p. 25). As NGOs can change perceptions by reframing issues like land use rights, advocacy groups and other stakeholders can impact the stringency of IP laws by appealing to public health, economic growth, or innovation. Activists typically share facts and personal stories, portraying issues as a matter of right and wrong to motivate people and encourage action (Stroup & Wong, 2017, p. 26). Effective persuasion hinges on a strong frame that presents a situation as something that can be changed, identifies who is responsible, and suggests viable solutions. Clear, value-driven messages are crucial for achieving these objectives and often have a greater influence on state policies than technical advice from experts (Stroup & Wong, 2017, p. 26). INGOs seek to serve the needs of the public. INGOs claim moral authority through representation or universalism, helping them speak on behalf of global public interests (Stroup & Wong, 2017, p. 28). They also represent marginalized voices, reinforcing democratic ideals (Stroup & Wong, 2017, p. 28). This dual authority enables INGOs to engage with global issues through advocacy efforts and democratic ideals. In contrast, domestic NGOs may rely more on grassroots support, legal standing, or national democratic discourse. The distinction between INGOs and NGOs thus opens additional framing strategies and tensions over who can legitimately speak on behalf of affected communities, particularly in contentious areas like pharmaceutical IP law, where global norms and local realities collide.

Lobbying

Dellmuth & Bloodgood (2023) argue that domestic political opportunity structure (POS) and institutional arrangements play an important role in shaping the lobbying methods of corporate entities and advocacy organizations such as MNCs, INGOs and NGOs. Advocacy groups in democratic countries tend to have a higher likelihood of participating in lobbying with

policymakers at both national and global levels, due to their proximity to such individuals (Dellmuth & Bloodgood, 2023, p. 11). This is particularly the case for MNCs from developed democracies, which will likely enjoy privileged access to policy arenas due to their wealth, expertise and legal resources. Conversely, INGOs will likely rely on normative legitimacy—founded on ideals such as universalism or human rights—to gain access to global governance forums (Stroup & Wong, 2017, p. 28). However, their influence may be more limited in authoritarian regimes. Domestic NGOs, particularly in the developing world, tend to operate based on grassroots legitimacy and domestic legal frameworks (Makoba, 2002, p. 60). The manner in which NGOs function may grant them easier entry into more open political systems, but provides them with less room to act in closed systems.

Risse-Kappen (1995) declares: "On the one hand, the more the state dominates the domestic structure, the more difficult it should be for transnational actors to penetrate the social and political systems of the 'target' country. Once they overcome this hurdle in state-dominated systems, however, their policy impact may be profound, as coalition-building with relatively small groups of governmental actors appears to be comparatively straightforward. On the other hand, the more fragmented the state and the better organized civil society, the easier should be the access for transnational actors" (pp. 6-7). Lobbying is more difficult if the state is more powerful than the advocacy groups seeking change. Concerning the USSR historically, Evangelista (1995) states that: “certain aspects of the domestic structure of the Soviet Union—in particular the domination of a weak, fragmented society by a strong, hierarchical party-state apparatus—made it difficult for new ideas to find their way to the top of the policy process” (p. 147). This portrays how a hierarchical state that faced fragmentation in its society resulted in sentiments not garnering attention. Evangelista (1995) further declares: “with the removal of the Communist Party’s

political monopoly, more actors will participate in policy-making, including in the security sphere" (p. 154). Without a rigid hierarchy, lobbying and advocacy can gain traction. Access varies depending on regime type, institutional openness, legal status, and the character of actors' constituencies. These factors can help explain why lobbying for pharmaceutical IP differs in India and China.

Venue Shopping

Venue shopping involves selecting the most suitable institutions—such as courts, legislatures, or international bodies—to promote policy goals (Ley & Weber, 2015, p. 703). Adaptive Venue Shopping (AVS) theory posits that groups consider three imperative considerations when determining their course of action: their assets, their adversary's strength, and the receptiveness of the chosen venue (Ley & Weber, 2015, p. 704).

Advocacy groups select venues to achieve policy aims and maintain their identity and organizational needs (Pralle, 2003, p. 234). This selection portrays why different groups of people would prefer different venues. Beliefs are also important towards the self-image: "Advocacy groups are apt to prefer some venues to others depending on their beliefs about the most effective means of policy change or the suitability and sustainability of certain kinds of policy solutions" (Pralle, 2003, p. 241).

Issue framing affects venue accessibility: "Groups often have to redefine an issue to suit the discourse and norms of the institutions they are soliciting for support. If environmentalists hope to involve the courts, for example, they must invoke the discourse of rights or otherwise reframe their argument in ways that engage the legal system. Or, if an advocacy group wants to move an issue to the subnational level, it must highlight the local origins or impacts of the policy problem so as to engage policymakers and publics at the local level. In short, issue redefinition is a tactic

designed to shift an issue from one venue to another" (Pralle, 2003, p. 242). Successful venue access is therefore about institutional availability and about an actor's ability to adapt their framing to align with the norms and expectations of the chosen venue. Actors with greater framing ability are better positioned to capitalize on institutional openings.

In IP, venue shopping can refer to the practice of choosing between international institutions and domestic actors to maximize influence. An idea can be framed differently depending on the forum in which it is presented. For example, advocacy groups may challenge patents on public health grounds in domestic courts, as seen in the *Novartis v. Union* case, to shape national law. Meanwhile, multinational firms can bypass domestic constraints by appealing to international institutions, such as the WTO, and framing disagreements in terms of TRIPS compliance to influence governments through trade mechanisms. Thus, venue shopping serves as both a legal strategy and a means to influence policy at international and national levels.

Domestic venue preferences vary by group identity, capacity, and goals. Business coalitions and multinational corporations may prefer to collaborate with legislatures and executive regulatory agencies to influence lawmaking through lobbying and expertise. These venues may allow them to shape the IP regimes. Civil society groups and advocacy NGOs often turn to the judiciary, as will be seen with the CPAA in India, particularly when they lack access to policymakers. Courts can serve as a more neutral or sympathetic venue for asserting rights-based or normative claims, such as access to cheap medicines, especially when framed within a human rights discourse.

Expectations: Under What Conditions Will IP Law Be Stringent or Lax? Hypothesis

The strength of IP laws in emerging countries is shaped by the interactions between domestic and international actors, influenced by political institutions, public health pressures, and

the strength of both domestic and international institutions. The strategies actors take, and the resulting outcomes for the IP strength of IP laws, are contingent upon specific circumstances.

Conditions for Pro-Lax and Pro-Stringent IP Strategies and Expected Outcomes

Political Sovereignty and National Priorities

High political sovereignty, where the nation can set its domestic priorities, allows for more flexibility in implementing policies that can minimize the impediments of IP laws in healthcare. Such states can weigh international trade pressures against local innovation and public health needs. As Chalmers (2013) notes, access to decision-makers depends more on how the message is delivered than on what the message is: "The medium is more important than the message" (Chalmers, 2013, p. 51). Lobbying includes position papers, face-to-face meetings, and legal memoranda (Chalmers, 2013, p. 52). These inside tactics are institutionalized and can be used by both MNCs and NGOs. MNCs can frame IP as essential for innovation and investment. Groups possessing resources perceived as valuable by decision-makers are more inclined to engage with bureaucratic institutions than other groups. (Binderkrantz, 2005, p. 709).

NGOs and civil society actors, although typically less resource-rich, often compensate by using external tactics that circumvent internal political pressure, such as public campaigns and media interventions. These outside tactics are resource-intensive but vital for gaining attention and conveying urgency (Chalmers, 2013, pp. 52–54). As Binderkrantz (2005) emphasizes, *"*groups competing intensely for members rely more heavily on indirect strategies" (pp. 710-711). This can include the media and mobilization efforts. Binderkrantz (2005) declares that "groups with a privileged position vis-à-vis decision makers have high levels of activities targeting these decision makers, but the lack of a privileged position does not lead groups to pursue indirect strategies" (p. 694). This suggests that outside strategies are effective in open policy environments where

multiple channels exist. The type of issue area further shapes strategy. In contested issue areas such as pharmaceutical IP, advocacy groups favour public mobilization. As Chalmers (2013) similarly argues, "outside tactics are not necessarily 'outsider' tactics" (p. 54). These strategies can be a powerful tool to pressure decision-makers, especially in sovereign states where civil society retains the space to act.

Klüver et al. (2015) emphasize that the institutional context shapes the extent to which interest groups can access decision-makers. They note that interest groups within political systems are vertically and horizontally decentralized, offering opportunities to shape policymaking in their home country (p. 455). This indicates that a country's political sovereignty and institutions influence the incentives for group mobilization. Klüver et al. (2015) argue that "interest group lobbying varies with regard to two different characteristics: the distribution of powers and the patterns of interest intermediation" (p. 455). This links the political context to the effectiveness of lobbying. In open, sovereign states with strong civil societies, public mobilization tactics can pressure decision-makers, especially in highly contentious issue areas, such as pharmaceutical IP.

Dür and Mateo (2013) demonstrate that business groups are more likely to engage in inside lobbying than citizen groups (p. 660). However, this gap narrows in regulatory issue areas, where decision-making access is competitive and issues are highly salient (Dür & Mateo, 2013, p. 677). Their work suggests that the policy domain shapes lobbying strategy as much as actor resources. Hence, political sovereignty creates the opportunity structure, but effective access for MNCs or NGOs depends on how strategically they use insider and outsider channels to influence policy, especially in the disputed domain of the pharmaceutical sector involving intellectual property.

Multinational Firms' Pressure and International Agreements

In increasingly integrated countries within the global trade regime, multinational firms and developed nations will likely pressure governments to adopt stronger IP laws through international agreements, such as the TRIPS. We can expect the government to enact stricter pharmaceutical IP laws, particularly in areas where MNCs have significant investments. The enforcement would be spurred on by the need to remain competitive and attract foreign investment.

Social Movements or Public Health Crises

Pro-lax IP players, like public health organizations, traditionally support lenient IP laws during health crises or grassroots movements. Pro-lax IP players demonstrate how strict IP law blocks access to affordable medicine and frames IP rights as an impediment to public health or social justice. We can expect these actors to advocate for policy responses such as compulsory licensing, parallel imports, or shortened patent durations during emergencies or public health crises.

2.5 Gaps in the Literature and My Research Contributions

While existing literature is informative on the international pressures for IP law stringency, much of this literature tends to be one-dimensional, which focuses more on TRIPS compliance and international trade pressure (Cardwell & Ghazalian, 2012, 2015; Shadlen et al., 2005). Although TRIPS includes flexibilities like compulsory licensing, scholars have pointed out that ambiguities in its language, particularly regarding what qualifies as a 'national emergency,' create uncertainty for developing countries (Abbott, 2002; Matthews, 2004; Kobori, 2003). The expansion of TRIPS-Plus provisions through bilateral trade agreements increased external pressures and often limited the scope for local legal discretion (Mercurio, 2006). While the role of pro-stringent IP actors like MNCs and industrialized nations is studied (Deere, 2009; Shadlen et al., 2005), less attention has been given to how domestic actors, such as advocacy groups, affect

the implementation of IP laws in response to international pressures. Literature bridging international and domestic influences remains limited, and studies examining the lobbying, framing, venue shopping, and agenda-setting strategies of domestic interest groups in the health sector are still understudied (Deere, 2009; Sell & Prakash, 2004; Yu, 2009). Further research to help explain the stringency of IP laws will provide nuanced insights into IPRs. My research aims to fill these gaps by examining how domestic and international actors interact and how their strategies influence the adoption of IP law in India and China, rather than providing an overall understanding across many countries, as Deere (2009) does. The focus on the pharmaceutical sector enables my research to provide a more nuanced understanding of how different interests are played out in the context of IP law reform. This helps explain how emerging countries adopt IP laws and how domestic actors resist or cooperate with international pressures.

Cardwell & Ghazalian (2015) state that the TRIPS Agreement shows how powerful industrialized regions can push emerging economies to strengthen IP laws (p. 271). Nonetheless, they emphasize that regional responses to coercive threats of trade retaliation under TRIPS are far from uniform (Cardwell & Ghazalian, 2015, p. 272). My research builds on Cardwell & Ghazalian (2015) to explain how domestic actors, including corporate stakeholders such as domestic subsidiaries of MNCs and public health NGOs as advocacy groups, respond to international pressures and shape IP law stringency domestically, moving beyond a preoccupation with trade sanctions and diplomatic threats. I will extend Deere's (2009) work by considering how domestic pro-lax IP actors in the pharmaceutical sector use strategies such as framing to influence policy. Similar to Deere (2009), I examine how pro-stringent IP actors are influential in emerging countries. However, I take this further by gauging the domestic strategies of both the pro-stringent and pro-lax actors for public health, to connect it to the international realm of IP and the actors

involved. These insights will enable a more comprehensive understanding, and this mobilization, viewed through the lens of different actors, can explore tactics and help comprehend the strategies deployed to push for more or less stringent IP laws. Analyzing the strategies and tactics of competing and complementary interest groups will exemplify how they frame their positions, mobilize support, and influence policy debates around IP law.

The TRIPS Agreement has reshaped IP laws in both emerging and industrialized economies. While it provides flexibility for emerging countries, it is vulnerable to external pressures such as bilateral investment treaties and international trade agreements. Internal limits and external pressures from interest groups restrict how fully these flexibilities can be used. Though TRIPS sets a shared baseline, its implementation has largely benefited industrialized nations. This creates challenges for emerging countries, especially in reconciling international obligations with public health needs.

Chapter 3: India

This chapter examines India's pharmaceutical industry, characterized by its substantial generic drug sector. It examines the actors, coalitions, and impact of pro-stringent and pro-lax IP actors, which are composed of domestic and international advocacy groups, as well as pharmaceutical companies and U.S. pressure. I will explain the 2005 legislation and how it created a pathway for more flexibility in IP. The chapter then examines key actors on both sides of the IP debate. I then examine coalitions for pro-lax and pro-stringent IP and how they demonstrate influence. I will describe their mechanisms of influence through lobbying, agenda setting and framing. The U.S. will be discussed in relation to American perceptions of India's patent standards. Landmark cases, such as *Novartis v. Union of India & Others* (2013) and *Bayer v. Natco* (2012),

highlight India's resistance to stricter patent rules, reinforcing its public health approach. I then provide my explanations in contrast to alternative explanations.

Pharmaceutical IP in India is closely tied to public health outcomes. The trajectory of this sector has reflected concerns about public health. As illustrated in Table 1 below, the 1970 Patents Act of India, which provided for process patents in the pharmaceutical sector, laid the foundation for the country's expansive generic drug industry. This Act was pivotal for compulsory licensing, as it allowed the issuance of licenses permitting the production of pharmaceutical drugs in India without violating patents held in other countries, if the versions were made and sold solely within India (Papaioannou et al., 2016, p. 73). The 1970 law permitted patents based on the manufacturing process (process patents) but not for the pharmaceutical products themselves (product patents) (Grover, 2018, p. 308). This allowed Indian firms to produce drugs using alternative methods without infringing on product patents held abroad. As a result, generic versions of patented drugs became available in India more quickly (Batra, 2022, p. 1). This legal framework laid the foundation for the expansion of India's domestic pharmaceutical sector, positioning the country as a global supplier of affordable generic medicines. This chapter argues that India's pharmaceutical IP regime reflects the country's commitment to public health, strategic use of legal safeguards, and the influence of both domestic and international actors. It examines this evolution by reviewing the 1970 Patents Act, the TRIPS Agreement, the 2005 Amendment, and key court cases and stakeholders that have promoted a laxer IP regime.

From the 1970s through the 1990s, India's generic pharmaceutical industry grew under the 1970 Patents Act, which permitted only process patents and explicitly excluded product patents. Process patents protect the methods for making a product, allowing others to produce the same product through a different process since only the method is protected. In contrast, product patents

protect the final product, preventing others from making or selling that product (Chaudhry, 2011, p. 7). This made it possible for Indian companies to legally produce generic versions of patented medicines by developing alternative processes, and drugs became available at affordable prices for domestic consumption. In the 1990s, pressure from the WTO mounted for India to adopt TRIPS-compliant product patents. India held out against such changes until 2005, when it enacted the Patent (Amendment) Act to become compliant with TRIPS. This amendment was a dramatic change, as it revived product patents for drugs, but with safeguards such as Section 3(d) to prevent evergreening and preserved compulsory licensing. Evergreening is a method that extends the duration of a patent through artificial improvements, thereby maintaining high prices while making minimal alterations to the patented medicine (Rompaey, 2018, p. 315). This meant that patenting new forms of drugs was not granted unless the latest form was more effective than the original. Evergreening helps propel market exclusivity. Preventing evergreening was framed in TRIPS-compliant language to ensure public health protection (Liu, 2015, pp. 213-214). These reforms were significant because they represented India's effort to reconcile its international obligations with public health priorities. This tension characterizes the country's adaptive approach to pharmaceutical IP, framing the argument of this chapter. I characterize India's IP regime as flexible due to the incorporation of TRIPS-compliant flexibilities in the 2005 Patent (Amendment) Act, including restrictions on evergreening, the introduction of a pre-grant opposition system, and provisions for compulsory licensing. These mechanisms help India protect access to medicines while complying with international law.

Table 1 - Timeline of Major Reforms in India's Pharmaceutical IP Regime

Date	Law/Policy Instrument	Summary/Significance
1970s	1970 Patents Act (process patents only), introduction of compulsory licensing	Growth of the generic drug industry, lower drug prices
1980s-1990s	Expansion of the generic sector, IP negotiations leading to TRIPS	Rising pressure from international actors for product patents
2005 (The Main Focus)	Third Amendment to the 1970 Patents Act (TRIPS-compliant)	The introduction of product patents for pharmaceuticals, accompanied by key public health safeguards (e.g., Section 3(d) to prevent evergreening and provisions for compulsory licensing), sparked legal and political battles, marking a shift from India's process-patent era while retaining flexibilities to protect access to medicines.

Post-2005	Ongoing implementation of the amended 1970 Patents Act (especially compulsory licensing provisions)	India strategically utilizes TRIPS-compliant compulsory licensing, particularly for lifesaving drugs (e.g., the 2012 *Bayer v. Natco* case), affirming its role as a global supplier of affordable generics and garnering international scrutiny and praise from health advocacy groups.

The Function of the Judiciary: Its Specialized Tribunals and Regulatory Agencies

Despite being a federal state, India has a unified judiciary (Lee, 2008, p. 287). The Supreme Court has the highest authority, followed by state high courts and lower courts (Lee, 2008, p. 287). The Supreme Court handles appeals and disputes between the central and state governments. Each state and union territory has a high court that holds appellate authority and, in some cases, original jurisdiction (Lee, 2008, p. 287). The Intellectual Property Appellate Board (IPAB) was established in 2003 to hear IP-related appeals (Lee, 2008, p. 287). The IPAB operates from Chennai, with branches in Mumbai, New Delhi, Kolkata, and Ahmedabad (Lee, 2008, p. 287). Unlike other tribunals, the IPAB has both legal and technical members (Lee, 2008, p. 287). Section 83 of the Trade Marks Act of 1999 established the IPAB (Mani et al., 2017, p. 32). These reforms aimed to ensure India's compliance with the TRIPS agreement and improve IP dispute resolution through specialized expertise.

Two critical regulatory agencies in India oversee the regulation of drugs and patents. The first entity is the Indian Patent Office (IPO), which manages and grants patents under the Controller

General of Patents, Designs, and Trademarks (The Law Codes, n.d.-a, para. 4). The second entity is the Controller of Patents, who holds judicial oversight (The Law Codes, n.d.-b, para. 15). This office handles the patent process, ensures compliance with the 1970 Patents Act, and resolves patent disputes for integrity and fairness of the patent system (The Law Codes, n.d.-b, para. 2). The Office of the Patents, Designs and Trade Marks (CGPDTM) operates as a subordinate body within the Department for Promotion of Industry and Internal Trade (DPIIT) (Department for Promotion of Industry and Internal Trade, 2023, para. 1). The appeals against decisions to be possibly overruled can be filed with the Intellectual Property Appellate Board (Lee, 2008, p. 287).

Pharmaceutical Sector Case Overview

India's role as a leading manufacturer of generic drugs in emerging economies is undeniable, particularly as the "pharmacy of the developing world" (Bazzle, 2011, p. 786). India exports most of its generic medicines to developing countries, serving as their main supplier. Following the TRIPS agreement, economic liberalization began to take shape in India.

The legal case of Novartis, a Swiss multinational pharmaceutical company, was initiated in 2006 when the firm challenged India’s rejection of its 1998 patent application for the beta crystalline salt form of imatinib mesylate (Glivec) (Gabble & Kohler, 2014, p. 5). Novartis holds patents in the United States, Europe, the UK, and Australia (GreyB Insights, n.d.). The Indian Patent Office denied the patent application under Section 3(d) of the 2005 Patent (Amendment) Act. Lawmakers designed this provision to prevent 'evergreening,' which allowed for a modification of existing drugs without providing significant therapeutic benefits.

In 2006, the Patent Office rejected Novartis’s patent for Glivec (an anticancer medicine) under Section 3(d), requiring significant therapeutic value. The Madras High Court upheld the rejection in 2007. Novartis appealed, and the case eventually reached India's Supreme Court,

which upheld the denial in 2013 (Abbott, 2013, p. 1). This landmark ruling reinforced India's stance against evergreening and its support for affordable medicine. Throughout the case, campaigning organizations such as Médecins Sans Frontières led the "Drop the Case" campaign, generating global pressure to protect India's role as a major manufacturer of generic medicines.

This chapter will review the key actors, coalitions, and strategies that shaped IP in India's pharmaceutical industry, from the 2005 Patent Amendment Act to the 2013 Novartis case. I argue that despite sustained pressure from external actors—including multinational pharmaceutical firms and the U.S. Trade Representative (USTR)—leveraged through bilateral trade negotiations, WTO forums, and diplomatic channels, India has maintained a flexible IP regime. By a flexible IP regime, I refer to a legal framework that complies with TRIPS while preserving strong public health safeguards, such as strict patentability criteria including Section 3(d), compulsory licensing, and judicial enforcement. If this argument holds, we should see repeated international pressure for stricter IP laws met with political mobilization by domestic actors, public health activism, and judicial interpretations that reinforce India's pro-lax stance on IP for pharmaceuticals.

The Basis of the 2005 Legislation that Set the Stage for Court Cases in India

To meet WTO TRIPS obligations, India provided product patent protection for medicines as of January 1, 2005. While this aligned with TRIPS, which mandates minimum standards such as 20-year patent terms for new inventions and requires WTO members to grant patent protection for pharmaceutical products and the processes used to make them (Sundaram, 2014, p. 83), it raised concerns about access to affordable medicines in India and the developing world (Gopakumar, 2010, p. 326). Policymakers needed to harmonize patent protection with India's public health and economic goals. In response, India utilized TRIPS flexibilities to tailor IP laws to local needs by embedding safeguards into the 2005 amendment. These included Section 3(d), which prevents

evergreening by requiring enhanced therapeutic efficacy for patents on new forms of known substances, and compulsory licensing provisions, which permit generic production of patented drugs in cases of public health necessity or unaffordability. Backed by the 2001 Doha Declaration, these safeguards enabled India to fulfill its TRIPS obligations while maintaining access to low-cost medicines (M, 2010, p. 326). Henceforth, the 2005 Patent Law served dual purposes. The importance of India complying with the 1995 TRIPS agreement and ensuring public health safeguards led to the creation of the 2005 Patent Law, which introduced further flexibilities for access to medicines through Section 3(d). This demonstrated the importance of India's Patents Act with the pivotal incorporation of Section 3(d). Groups like MSF opposed the initial 2005 bill, arguing that product patents would benefit MNCs and restrict generic companies from producing low-cost versions of drugs to promote public health (World Generic Markets Pharmaceuticals, 2005, para. 2). Section 3(d) aims to protect access to essential medicines and avoid misuse of IP protection for commercial gain.

There are clashes of interest between international pro-stringent IP pharmaceutical firms and pro-lax IP firms. During the 2005 Patents Act discussions, Ranjit Shahani, managing director of Novartis India, supported the initial 2005 Act, as patents incentivized innovations and investment in R&D (Ramesh, 2005, para. 16). To the contrary, Yusuf Hamied, in charge of Cipla, a prominent generic drug manufacturer of HIV drugs commented that India could "not afford monopolies" (Ramesh, 2005, para. 17).

Nonetheless, India introduced lax IP safeguards because the initial 2005 Act focused more on IP safeguards for WTO compliance. India continued to utilize compulsory licensing to address public health crises, adopting a flexible approach to pharmaceutical IP that could bridge global commitments with domestic public health imperatives.

Civil society actors challenged TRIPS early on, including India's National Working Group on Patent Law during the Uruguay Round of negotiations (Rangnekar, 2006, p. 412). An international coalition of 189 NGOs, known as the "TRIPS Action Network," pressured WTO members to reform TRIPS (Rangnekar, 2006, p. 412). This network advocated for loosening IP stringency to support public health. Such civil society groups played a role in shaping amendments to India's 2005 Patent Law, which resulted in more flexible IP provisions, including the creation of Section 3(d). The All India Drug Action Network (AIDAN) pursued legal action to compel the Indian government to regulate drug prices by ensuring that all medicines listed on the National Essential Medicines List 2003 were made available and affordable for low-income populations through price control measures (Srinivasan, 2004, p. 13). While AIDAN did not directly influence India's TRIPS compliance, its advocacy for price controls contributed to the broader policy climate that emphasized public health over strict IP protections. This alignment with civil society efforts helped shape discussions that influenced amendments to India's 2005 Patent Law. Therefore, through the creation of Section 3(d), civil society groups advanced the narrative of public health as the initial Act aimed to protect intellectual property in compliance with TRIPS. Courts upheld these provisions to protect access to medicines in later rulings.

India introduced the 2005 Patents Act to meet TRIPS obligations. However, due to domestic priorities for public health and civil society group activism, India exercised greater discretion over IP and enacted less stringent laws. The 2005 Patents (Amendment) Act marked a shift in India's IP regime, paving the way for important court decisions that ruled in favour of access to medicines and a more lenient IP regime, as will be explored later with the Novartis court case.

India's Political and Economic System

Building on India's political framework and economic openness, its political opportunity structures have enabled civil society organizations to influence policy outcomes. India's more democratic ethos, characterized by its bicameral parliamentary system, coalition-driven governance, and active judiciary, provides a conducive environment for advocacy groups to engage with policymakers.

India's party system and electoral system operate on a single-member constituency basis, utilizing a First-Past-the-Post plurality voting system, with a bicameral parliament (Mitra & Enskat, 1999, p. 125). The President of India has primarily a ceremonial role as the constitutional head of state. There are some deviations, but these conventions closely approximate those of British parliamentary democracy (Mitra & Enskat, 1999, p. 125).

India’s economy is driven by its industrial, service, and agricultural industries. India is currently the fifth-largest economy, with a value of USD $4.112 trillion (Mandal, 2024, p. 10). India's economy grew 8.2% in the fiscal year 2023-2024, propelled by strong demand for its services and products, as well as high industrial output. India, having previously relied on British trade, now has a significantly diversified economy, with services contributing to growth (Page, 2024, para. 2). Following its independence in 1947, India adopted a centrally planned economy with an emphasis on industries (Page, 2024, para. 4). In 1950, India adopted their democratic Constitution. Economic liberalization in 1991, however, expanded the private sector, transforming India into a mixed economy (Page, 2024, para. 5). The government retains control over key sectors, such as defence and banking, while citizens have the freedom to choose their occupations and businesses. India's GDP rose from $288 billion in 1992 to $3.42 trillion in 2022 (Page, 2024, para. 6). Agriculture, the primary source of revenue, now accounts for approximately 17.6% of the GDP, reflecting the growth of industry and services. India is a major producer of food crops. The

manufacturing-based industry, particularly chemicals and pharmaceuticals, is significant. The petrochemical industry in India experienced substantial growth after the 1970s, producing a range of chemicals, pharmaceuticals, and machinery (Page, 2024, para. 11). Foreign direct investment (FDI) is a crucial element of globalization, demonstrating India's openness in economic terms. Since India's economic liberalization in 1991, foreign direct investment has driven growth via foreign capital, technology, and expertise. FDI has improved investment, employment, innovation, consolidated industries, and increased GDP (Sadashiv, 2023, p. 45). While some people believe that it benefits foreign investors at the expense of domestic firms, FDI is one of the key drivers of modernization and development in India (Sadashiv, 2023, p. 45). FDI has a positive impact on India's growth by facilitating employment, increasing government revenue, and ensuring economic stability. These investments enhance infrastructure, connect companies to international markets, and foster competition, thereby increasing efficiency and innovation. Foreign direct investment also reduces poverty by providing income opportunities (Sadashiv, 2023, p. 46). Apart from FDI, the government encourages Foreign Institutional Investors (FIIs) to deepen the depth of financial markets. Hence, India is a more open economy driven largely by FDI and FIIs.

India’s economic and political institutions help explain its approach to pharmaceutical IP law. Democratic openness, an active civil society, and a mixed economy allow advocacy groups and domestic firms to shape IP policy. India's focus on affordability and export-led growth favours a flexible IP regime. These institutional features explain why India has strategically embraced TRIPS flexibilities to balance innovation incentives against public health imperatives. The next section analyzes how these tendencies are institutionalized in India's IP regime and shaped by key actors.

India’s Legal System and Intellectual Property Landscape

India's legal system is based on British common law, adapted to Indian values. The Constitution establishes the three branches of government: the executive branch, the judicial branch, and the legislative branch. Precedent-setting cases in common law jurisdictions are essential because, as the following section will explore, court rulings impact future IP disputes in India. India's first patent law came into effect in 1856 under British rule, giving inventors 14-year rights. (Bennett, 2014, p. 539). It evolved into the Inventions and Designs Act of 1888 and ultimately into the Indian Patents and Designs Act of 1911, which remained in effect until 1972 (Bennett, 2014, p. 539). The 1911 Act allowed product patents, permitting foreign firms to block Indian drug production. Domestic drug production, however, remained largely inactive until World War I (Bennett, 2014, p. 540). After independence in 1947, India struggled to provide affordable healthcare, prompting a re-examination of patent laws (Bennett, 2014, p. 540). The Patent Enquire Committee (1948-50) and the Patents Revision Committee (1957-59) aimed to harmonize patent laws with national concerns, which led to the 1970 Patents Act (Bennett, 2014, p. 540). This Act, which came into force in 1972, focused on process patents rather than product patents, allowing Indian manufacturers to produce generic drugs. The Act facilitated the growth of the local pharmaceutical industry and spurred technological development (Bennett, 2014, pp. 541-542). Product patents led to a momentous shift in India's corporate interests, which clashed with advocacy groups over how IP protections should evolve, as illustrated by IP concerns that necessitated court proceedings. It had consequences in India, as will be explained in the *Novartis v. Union* case, where patent protection was at odds with IP flexibilities. Since product patents made IP more stringent, it was difficult to produce generics legally, and this resulted in advocates of lax IP altering the IP environment to provide for flexibilities which went against the interests of pro-stringent IP advocates.

Under TRIPS, India was required to provide patent protections for inventions in all fields of technology, including pharmaceutical products, and to establish enforcement mechanisms to ensure a 20-year patent term (Kamiike, 2020, p. 96). These protections grant exclusivity to patent holders. However, a transition period was allowed until 2005 for pharmaceutical patents (Tenni et al., 2023, p. 170). India complied in a three-stage process: first, the 1999 amendment introduced a "mailbox" system to receive pharmaceutical patent applications (Tenni et al., 2023, p. 170). Secondly, the 2002 Amendment extended the patent term from 14 to 20 years (European Patent Office, n.d.). Finally, the 2005 Patent (Amendment) Act implemented complete product patent protection for pharmaceuticals, in accordance with the TRIPS obligations (Basheer, 2005, p. 31). To balance patents with public health, India retained TRIPS flexibilities like Section 3(d), which only grants patents for new drug forms with proven therapeutic benefits (Fyan, 2010, p. 209).

3.1 Key Actors in India's Pharmaceutical IP Landscape

India’s pharmaceutical industry is divided into two main camps: the pro-stringent IP actors, who push for stronger patent rights to protect the economic interests of multinational corporations and domestic innovators, against the pro-lax IP actors, who promote a more flexible IP regime to ensure affordable medicines. This section first covers the pro-stringent side, followed by the pro-lax advocates. Understanding these dynamics will help grasp the international and domestic influences shaping India’s pharmaceutical IP regime.

Pro-Stringent IP Actors: Proponents of Stricter Patent Laws

International Actors

Pro-stringent IP actors argue that strong patent rights are vital for innovation and protecting R&D investments (Gilead Sciences, Inc., 2014, p. 1; BeiGene, 2022b, para. 19). Hence, IP grants MNCs benefits.

MNCs advocate for more stringent IP protections. An IP monopoly can be created by MNCs (Dolcerocca, 2016, p. 234). Harmonized intellectual property regimes enable MNCs to coordinate production, distribution, and sales across borders without risking the loss of IP protections (Nayyer, 2002, para. 28). An important proponent advocating for more rigorous IP protections is Novartis. This Swiss MNC challenged India's patent law in the landmark case *Novartis AG v. Union of India & Ors (*2013), which was pivotal in shaping the enforcement of pharmaceutical patents. This case, along with the 2005 Patent Amendment, is explored next to show how courts addressed such pressures.

States, with their corporations, exert diplomatic pressure through their trade representatives. Mennis (1978) reviews Gilpin's work titled *U.S. Power and the Multinational Corporation: The Political Economy of Foreign Direct Investment* (1975). Mennis (1978) states that Gilpin discusses how the U.S. government and its national interests share overlapping interests with corporate and business entities (p. 790). Mennis (1978) suggests that Gilpin states that America shapes its strategy of direct investments through their transnational corporations (p. 790). Thus, the U.S. backs MNCs to maintain economic dominance and further its national goals. States seek what MNCs want since it allows the U.S. to remain economically strong. In India, these interests diverge since pro-lax actors want to ensure access to medicines through generics, which involve less IP protection. The USTR represents the U.S. national interests to push for IP protections. The USTR, as a U.S. government agency, protects IP stringency for their market share, wealth and power: "An important part of the mission of the Office of the United States Trade Representative (USTR) is to support and implement the Administration's commitment to protect American jobs and workers and to advance the economic interests of the United States. USTR works to protect American innovation and creativity in foreign markets employing all the tools of

U.S. trade policy, including the annual Special 301 Report" (Office of the United States Trade Representative, 2024a, p. 9).

Domestic Pharmaceutical Firms

A segment of domestic biopharmaceutical firms actively supports stronger IP protections in India. These domestic firms seek to incentivize IP.

Domestic firms like Dr. Reddy's Laboratories and Biocon have contributed to novel drug development and argue that stronger patent controls are necessary for their R&D (World Intellectual Property Organization, 2010, para. 9). Biocon, a leading biotechnology firm in India, strategically checked existing patent documents to identify where product patents were out of date, but processes of manufacture remained protected. With human insulin, Biocon had a chance in the patent space: while nearly all patented processes used E. coli or baker's yeast, Biocon utilized a different strain, Pichia yeast, licensed from an American company (World Intellectual Property Organization, 2010, para. 9). This provided the firm with a way to create a new, patentable manufacturing process, circumventing existing process patents. The result was Insugen, a recombinant human insulin launched in the Indian market in 2004 and later sold in countries like China and Germany (World Intellectual Property Organization, 2010, para. 10). Biocon's use of patent innovation demonstrates how firms can innovate when faced with IP restrictions by searching for appropriate legal channels to develop proprietary technologies. Insugen marked the first recombinant insulin using Pichia yeast, marking Biocon's entry into the diabetes market. Biocon's IP approach is to "strengthen our IP portfolio by filling all possible patent applications for innovations covering product, process of preparation, formulation, route of administration, various indications, etc." (Jamil, 2017, para. 4). Biocon values the innovation and strategies

utilized in IP creation. They protect their brand names, designs, and copyrightable elements to maintain their competitive edge (Jamil, 2017, para. 4).

` Biocon leveraged IP flexibility to become pro-stringent in regulation. The company made use of India's patent regime, such as not having product patents and lenient process patent rules, to innovate beyond existing protections and enter the insulin market. Nevertheless, as Biocon initiated proprietary technologies like Insugen and expanded globally, it formed a pro-stringent position, securing and defending a large IP portfolio. This stemmed from their innovation positioning, whose growing technological prowess and global ambitions drove Biocon to adopt stronger IP protections to safeguard its competitive advantage.

Dr. Reddy's Laboratories (DRL) began drug discovery in 1994, becoming India's first firm to do so. With its headquarters in Hyderabad, it employs over 21,000 people worldwide. Between 1995 and 2009, DRL developed twenty-seven compounds, with twelve entering clinical development (Differding, 2017, p. 789). The company has filed 4,592 patents worldwide, with 1,125 granted. Over 40% of its patents remain active, signifying its ongoing innovations. India is its main patent market, followed by the U.S. and Europe. Out of twenty-seven compounds identified between 1995 and 2009, DRL pursued patent protection for several of them, including Balaglitazone, an anti-diabetic molecule (Differding, 2017, p. 789). Patents for this treatment were filed in the U.S., EU, and under the Patent Cooperation Treaty (World Intellectual Property Organization, 2010). Stronger IP protections can propel innovation and returns on R&D investments. In an interview, Sohini Das asked Chairman Satish Reddy about the industry's requests to the Indian government for R&D funding and policy support. Satish Reddy emphasized that funding for R&D is crucial for innovation. Satish Reddy advocated for a mix of policy incentives and financial mechanisms, including the restoration of weighted deductions in R&D

expenditure, expansion of the patent box's scope, and the establishment of special innovation funds (Dr. Reddy's Laboratories, n.d., para. 6). Beyond regulatory frameworks, alternative financial mechanisms such as corporate tax reductions and tax credits for R&D-linked deductions play a vital role in financing pharmaceutical innovation ("Budget 2025: Pharma sector," 2025, paras. 2-7). These financial benefits enable firms to reinvest tax savings into research and drug development. A patent box is a tax incentive that reduces corporate taxes on profits earned from patented inventions, making R&D financially viable (Hájek, 2024, p. 70). DRL's emphasis on these policy measures reflects its support of stringent IP for innovation and R&D in the pharmaceutical domain.

The government promotes pharmaceutical research through initiatives like the National Policy on Research and Development and Innovation in the Pharma-Med Tech Sector (Department of Pharmaceuticals, 2024), aimed at strengthening drug discovery and providing financial grants for pharmaceutical R&D efforts. Additionally, direct government investment supports collaborative R&D, with agencies such as the Department of Science & Technology supporting collaborative R&D through the Drugs and Pharmaceutical Research Program (Department of Science & Technology, 2018). These combined efforts—policy incentives, tax benefits, direct government funding, private-sector investment, and industry partnerships—underscore India's commitment to advance pharmaceutical research. At the same time, firms continue to push for stronger financial and regulatory backing to sustain long-term growth.

Pro-Lax Actors: Advocating For Flexible Patent Protections

International Advocacy Groups

The pro-lax IP coalition encompasses a wide range of advocacy groups. INGOs, such as Médecins Sans Frontières and the Third World Network (TWN), among others, aim to prevent

patents from blocking access to affordable medicines. Unlike local NGOs based in India, these international NGOs (INGOs) have headquarters outside India. Therefore, their advocacy is wide-ranging, encompassing access to medicines worldwide.

MSF treated cases of drug-resistant tuberculosis (TB) in Mumbai in coordination with local health authorities to reduce the incidence of tuberculosis. In Bihar, MSF provides care for HIV, while in Chhattisgarh, mobile clinics provide essential healthcare in remote areas. MSF offers mental health services in Jammu and Kashmir (Médecins Sans Frontières, n.d.-a). In 2023, MSF employed 797 staff and spent €16.4 million to enhance healthcare in various parts of India, with work ongoing since 1999 in the areas of tuberculosis, HIV, and public health in regions where individuals require care. They advocate for a laxer IP regime, considering public health over corporate profits. The advocacy group's stance is to ensure that people in need have affordable access to medicines. MSF argues that IP monopolies hinder access to lifesaving medical products, particularly during public health emergencies (Médecins Sans Frontières, 2023, p. 1). MSF advocates for stronger public health safeguards to ensure equitable access to healthcare when patent protections restrict affordability (Médecins Sans Frontières, 2023, p. 4).

The Third World Network, an advocacy organization, argues that strong IP protection limits drug affordability and access. TWN advocates for flexibility in TRIPS as evidenced by their reports on the dysfunctions of IP laws and their impact on public health outcomes. They argue that patenting already-known pharmaceutical substances creates monopolies, leading to inflated drug prices and reduced access to essential medicines, particularly in developing countries (Third World Network, 2019). Furthermore, TWN criticizes the prevalent issuance of secondary patents (newer versions of existing patents) and the practice of evergreening. They mention that such a strategy unduly limits generic competition and extends high drug prices to benefit corporate interests over

public health. TWN's global advocacy aims to challenge restrictive patent regimes and positively enhance global health access.

The Gates Foundation

The philanthropic Bill and Melinda Gates Foundation contributes to global health through financing international institutions and financial contributions (Mahajan, 2018, p. 1357). It began work in India in 2002–2003 with a $200 million grant to launch Avahan, targeting HIV/AIDS prevention and establishing prevention programs for at-risk communities (Mahajan, 2018, p. 1359). Between 2013 and 2019, the foundation collaborated with Indian health agencies to improve TB care models (Bill & Melinda Gates Foundation, n.d., para. 25). They also implemented technologies like 99DOTS and the Medication Event Reminder Monitoring Systems (MERMs) to boost treatment adherence and improve TB monitoring systems (Bill & Melinda Gates Foundation, n.d., para. 27). Pilot projects in Mumbai, Patna, and Mehsana showed how to engage with private providers better and improve disease surveillance while also leveraging technology for care delivery. Pilot projects demonstrated the benefits of outreach and private partnerships in TB treatment (Bill & Melinda Gates Foundation, n.d., para. 28). The company has continued to collaborate with India's Central Tuberculosis Division to expand these initiatives and to scale digital tools and personalized support in states like Gujarat and Bihar (Bill & Melinda Gates Foundation, n.d., para. 29).

Domestic Pharmaceutical Firms

Pro-lax IP actors argue that strict patent laws block access to affordable medicines, crucial for countries relying on low-cost generics. These actors believe that pursuing strong patent protection, usually driven by multinational corporations, undermines public health through high drug prices and limited generic competition.

Indian generic manufacturers like Cipla are key pro-lax IP actors, basing their business on producing affordable versions of patented drugs. Cipla gained global recognition for manufacturing low-cost HIV/AIDS medicines distributed throughout the world and thus treating millions unable to afford brand-name treatments. In the early 1990s, as AIDS cases rose in India, Cipla introduced the antiretroviral Zidovudine at one-tenth the international price (Cipla, n.d., para. 3). This was followed by the introduction of Lamivudine and Stavudine. In 2001, Cipla was the first to introduce a 3-in-1 combination of Nevirapine, Stavudine, and Lamivudine in India, aiming to reduce the costs of AIDS treatment (Cipla, n.d., para. 2). Cipla sought to ensure that patients in need of care received the necessary support and treatment.

Similarly, Natco Pharma supports public health and was founded in 1981. It is one of India's fastest-growing pharmaceutical companies, with eight manufacturing facilities nationwide and approximately 4,500 employees (Natco Pharma Limited, n.d.). The company emphasizes pharmaceutical research and new drug development, favouring affordable access to medicines over strict IP protections. Natco introduced the generic oral tablet teriflunomide in India in 2018 to treat multiple sclerosis (MS) and introduced a generic version of posaconazole in the country. MS is a chronic autoimmune inflammatory disease that affects the central nervous system, specifically the spinal cord and brain (Goldenberg, 2012, p. 175). Posaconazole treats serious fungal infections, particularly in immunocompromised patients, including those undergoing transplantation and chemotherapy (Katragkou et al., 2012, p. 111).

Natco's strategy of IP protection and pricing reflects a public health focus. For chronic diseases like multiple sclerosis, long-term affordability is crucial because patients require continuous treatment. In contrast, for acute conditions such as fungal infections treated with posaconazole, immediate access to lifesaving medication is more urgent, making accessibility and

affordability more important than market exclusivity. As part of its mission, Natco aims to deliver breakthrough specialty medicines while addressing public health needs. Its approach is driven more by the idea of health as a human right than by profit.

Domestic NGOs: Advocacy Groups

Unlike international advocacy groups concerned about global health, domestic actors in India prioritize access to medicines. The CPAA, founded in 1969, is a non-profit dedicated to a holistic approach to cancer care with its unique philosophy of 'Total Management of Cancer' (Cancer Patients Aid Association, n.d.). Working with the medical community focuses on awareness, early detection, treatment, counselling, rehabilitation, research, and advocacy. The CPAA mainly supports low-income patients and mentors other healthcare organizations across India. It operates in Mumbai, New Delhi, and Pune. Instead of overall influencing global health access across countries, which is a vital driver of groups such as MSF and TWN, the primary focus is on patient care in India for domestic advocacy groups. The CPAA primarily advocates for low-income patients who lack access to treatment across India. As institutions such as MSF and TWN focus on global health initiatives, CPAA is specifically targeting patient care and affordability within India.

The CPAA has opposed patents that threaten patient access and has supported the Indian government in the *Novartis v. Unio*n case, opposing stringent patent protection for cancer drugs. This position will be expanded further in the second half of the chapter. The CPAA has collaborated with generic firms to challenge monopolies on essential medicines.

Domestic Political Parties

Left-wing parties, particularly the Communist Party of India (Marxist) (CPI(M)), have played a significant role in shaping India's patent policy. They pushed for public health protection

in the 2005 Patents (Amendment) Act. These included provisions against evergreening under Section 3(d) and extending the pre-grant opposition period from two to nine months, thereby strengthening the ability of civil society and generic firms to challenge patents (World Generic Markets Pharmaceuticals, 2005, para. 2). CPI(M) leaders, such as Prakash Karat, defined these amendments in clear terms as imperative for preserving public interests through legislation. The party claimed credit for 10 of the 12 amendments, asserting its influence in the patent reform process.

3.2 Coalitions and Political Alliances in India

India's pharmaceutical IP landscape comprises coalitions of pro-lax and pro-stringent IP actors at both the domestic and international levels, working together to shape IP outcomes.

Pro-Stringent IP Coalitions

Multinational corporations, foreign governments, and domestic innovators form strong pro-stringent IP lobbying networks. Industry trade coalitions, such as the Organisation of Pharmaceutical Producers of India, play a central role in these efforts. The OPPI includes forty-three members. Apeejay Stya Svrán Group, Medreich, and Indegene are examples of Indian pharmaceutical firms that are part of the coalition. International firms with headquarters located outside of India, such as Pfizer, Bayer, and Novartis, are also part of the coalition (Organisation of Pharmaceutical Producers of India, n.d.). The OPPI represents foreign pharmaceutical companies operating in India, actively pushing for patent protection (Organisation of Pharmaceutical Producers of India, 2024, p. 1). Members collaborate on global trade negotiations and individually advocate for an environment that aligns India's IP laws with international standards. OPPI argues that stronger IP fosters innovation and R&D for unmet medical needs (Organisation of Pharmaceutical Producers of India, 2024, p. 7). The organization views India as evolving from a

leading source of generic medications to a global pharmaceutical powerhouse, promoting public health and economic growth (Organisation of Pharmaceutical Producers of India, 2024, p. 7). In addition, embracing value-based care models, strengthening manufacturing standards, and enhancing intellectual property protection are imperative to improving India's global pharmaceutical footprint and maintaining a competitive advantage (Organisation of Pharmaceutical Producers of India, 2024, pp. 9-12).

Pro-Lax IP Coalitions

The Indian Pharmaceutical Alliance (IPA) represents twenty-three leading research-based pharmaceutical companies in India, focusing on advocacy, regulatory interfaces, and advancing the common cause of patients' well-being (Indian Pharmaceutical Alliance, n.d.), unlike pro-stringent IP coalitions, such as the OPPI, which advocates for stricter patent protections. The IPA adopts a middle-ground policy by promoting substantial R&D investment while safeguarding access through price controls. This two-way approach reflects its unique position in India's IP regime, facilitating collaboration across the pharmaceutical industry to drive both innovation and affordability. IPA members contribute 85% of private R&D, 80% of exports, and 62% of price-controlled drugs in India (Indian Pharmaceutical Alliance, n.d.). IPA members account for 64% of India's total pharmaceutical sales, underscoring their market influence (Indian Pharmaceutical Alliance, n.d.). Founded in 1999 by companies such as Cipla, Dr. Reddy's, Lupin, Piramal, Ranbaxy, and Wockhardt, the Indian Pharmaceutical Alliance has since played an active role in representing the Indian pharmaceutical sector and promoting improved manufacturing standards and quality assurance (Indian Pharmaceutical Alliance, n.d.). Later, it expanded to include Natco and Sun Pharmaceutical Industries, thereby playing a leading role in the development of India's pharmaceutical industry. By balancing innovation incentives with affordability concerns, IPA

shapes IP outcomes in ways that differ from more hardline pro-stringency IP coalitions. The next section explores how such collaborations shape pharmaceutical IP policy.

3.3 Mechanisms of Influence in India

Pro-Stringent IP Mechanisms: Lobbying and Diplomatic Pressure

Foreign governments and multinational pharmaceutical companies lobby and apply trade pressure to shape India's IP and regulatory policies. Trade pressure is exerted particularly from the USTR through mechanisms such as tariff adjustments, market access restrictions, and threats of economic sanctions, to push India toward stricter international IP standards. These pressures can involve direct engagement with Indian policymakers, not just abstract threats. Frontline organizations, such as the OPPI, comprising leading multinational pharmaceutical firms, have advocated for policy changes to accelerate the approval and introduction of new medicines in India.

To expedite drug availability, OPPI has urged India's drug regulatory authority, the Central Drugs Standard Control Organization, to allow parallel approvals in alignment with global markets ("Pharma lobby bats for drug approvals," 2023, para. 1). OPPI claims that India's current system delays new drug launches by up to four years compared to the U.S. and EU, limiting timely medicines access ("Pharma lobby bats for drug approvals," 2023, para. 2). The lobbying group, which contains pharmaceutical giants such as Novartis, Roche, AstraZeneca, Sanofi, and Merck among its members, blames India's burdensome clinical trial regulations for these delays and calls for reforms for approval acceleration ("Pharma lobby bats for drug approvals," 2023, para. 3). These firms engage directly with Indian regulatory bodies, such as the Drug Controller General of India (DCGI), through meetings and forums to push for regulatory reforms. In response, the DCGI

holds discussions with domestic and international pharmaceutical groups on issues pertaining to clinical trials (“Pharma lobby bats for drug approvals 2023,” para. 4).

OPPI calls for clear, predictable regulations to speed up access to new treatments in India (“Pharma lobby bats for drug approvals,” 2023, para. 5). By participating in global clinical studies and pursuing parallel Marketing Authorization filings, OPPI believes the industry can reduce the current time lag of approximately 18 months—sometimes extending to three or four years—for introducing innovative therapies to Indian patients (“Pharma lobby bats for drug approvals,” 2023, para. 6). Referring to the OPPI, Matai (2024) states: "There's a continuous emphasis on the protection of intellectual property… the focus is now on tightening the implementation to ensure robust IP protection" (para. 5). This demonstrates that the OPPI is an active advocate for stronger IP implementation and pushes for legislative clarity. It also reflects OPPI's strategic lobbying in the post-2005 TRIPS-compliant regime, working to shift India's IP standards closer to international norms, aligning with the TRIPS frameworks advocated by multinational pharmaceutical companies and Western trade partners. This shows that pharmaceutical firms use lobbying not just for profits, but to speed up innovation capabilities through more stringent IP regulation.

U.S. diplomatic leverage over India has increased significantly due to enhanced strategic, defence, and economic ties. Despite Cold War-era distance, "the bilateral ties have seen a massive turnaround" in the post-Cold War period (Borah, 2024, p. 379). A key driver has been China’s rise as a strategic rival, prompting the U.S. to view India as a regional counterweight. This shift was evident in the 2018 renaming of the U.S. Pacific Command to the Indo-Pacific Command (Borah, 2024, p. 379). India’s growing economic and demographic weight has strengthened ties, making it a top purchaser of U.S. defence equipment, with purchases nearing $20 billion in 2020 (Borah, 2024, p. 379). The 2016 designation of India as a ‘Major Defence Partner’ further advanced

bilateral defence collaboration through greater technology-sharing and co-development (Borah, 2024, p. 380). Closer ties have also strengthened U.S. influence on Indian IP policy, as stronger economic links may give India more reasons to abide by U.S. trade demands.

Diplomatic pressure is present in India, as shown in the USTR Special 301 Report. Such views echo the patent waiting periods, as depicted by the OPPI. India is listed on the USTR's Special 301 Report for what the U.S. considers inadequate IP protection. The USTR is a U.S. government trade agency that applies trade pressure through the Special 301 Report, which frequently critiques India's pharmaceutical intellectual property regime. This report serves as a strategic instrument to pressure India into implementing more stringent patent laws, often through the threat of trade sanctions or other economic penalties. In a recent United States Trade Representative statement for 2024, the USTR has portrayed India's IP regime as having weak enforcing mechanisms with high online piracy, a large backlog of trademark opposition cases, and insufficient protection of trade secrets under the law (Office of the United States Trade Representative, 2024b, para. 10). The WTO monitors compliance with TRIPS through mechanisms like the Dispute Settlement Body (DSB), which operates under the authority of the WTO General Council to resolve disputes (Luthfiah & Oppusunggu, 2024, p. 241). In 1997, the U.S. filed a WTO dispute WT/DS50 against India regarding insufficient patent protections for pharmaceuticals. According to the USTR, India lacked a proper mechanism for filing patents and obtaining exclusive marketing rights for pharmaceutical products (World Trade Organization, 1997, p. 1). However, no WTO dispute has been initiated against India's pharmaceutical IP policies since the country amended its Patents (Amendment Act) in 2005.

In the 2024 Special 301 Report, India remains on the USTR's Priority Watch List. Over the past years, USTR has seen minimal progress by India in IP protection and enforcement. Still,

the USTR notes some positive bilateral engagement on IP issues with India (Office of the United States Trade Representative, 2024a, p. 54). For instance, India has taken steps to streamline patent opposition processes and reduce burdensome reporting requirements (Office of the United States Trade Representative, 2024a, p. 56). However, major concerns from past reports remain unresolved, according to the USTR. These include (1) the threat of patent revocations after the grant through the broad use of post-grant oppositions, (2) subjective patentability standards under the Indian Patents Act, particularly the application of Section 3(d), and (3) the absence of a mechanism for early resolution of pharmaceutical patent disputes (Office of the United States Trade Representative, 2024a, p. 54). The USTR believes that India continues to lack protection and enforcement of IPRs. This belief stems from the USTR feeling that India has persistent structural issues, including a lack of transparency, lengthy patent application backlogs, excessive documentation demands, weak enforcement at the police and judicial levels, and fragmented coordination among enforcement bodies (Office of the United States Trade Representative, 2024a, p. 54). Section 3(d), which blocks patents on known substances without improved efficacy, is a core issue according to the USTR. Originally intended to prevent 'evergreening' by pharmaceutical firms, Section 3(d) has also created ambiguity for innovators seeking to patent incremental innovations, thus deterring investment and technology transfer. In the pharmaceutical industry, the United States continues to closely monitor the limitations that it believes are imposed by Section 3(d) of the Indian Patents Act, and it believes that these restrictions affect patent eligibility. Pharmaceutical industry stakeholders have raised concerns about the perceived absence of an efficient mechanism in India to resolve patent disputes in advance (Office of the United States Trade Representative, 2024a, p. 54). For instance, the U.S.-based trade association, the Biotechnology Innovation Organization, values an early resolution of disputes for patents to ensure

that a jurisdiction's regulatory agency does not unknowingly infringe on patent rights (Biotechnology Innovation Organization, 2024, p. 33). The USTR argues that India lacks an entity to notify patent owners before the marketing of follow-on medicines, resulting in limited transparency (Office of the United States Trade Representative, 2024a, p. 54). Despite some reforms, the USTR claims India still does not meet U.S. IP standards. The USTR views India as needing to enhance its IP protections, placing it on a Priority Watch List. Nonetheless, India has discretion based on domestic law and its legal obligations under TRIPS, which includes the flexibilities India can take for IP enforcement.

India's inclusion on the Special 301 Report means that U.S. trade sanctions may follow, given its inclusion on the Priority Watch List. These could include suspending or altering trade benefits. Import duties and restrictions may apply to goods and services from countries such as India (Puckett & Reynolds, 1996, p. 678). Section 301 of the U.S. Trade Act authorizes the USTR to address trade practices it considers unfair, including through measures like tariffs, import restrictions, or the suspension of trade benefits. Section 301 grants the U.S. significant unilateral leverage, but it does not compel compliance; targeted countries, such as India, can resist or negotiate, especially on public health grounds. The USTR can negotiate binding agreements in which the foreign government agrees to eliminate or phase out a problematic policy, remove trade barriers, or provide the United States with compensatory trade benefits (Puckett & Reynolds, 1996, p. 678). Investigations and sanctions can be initiated by the USTR directly or in response to domestic industry petitioning for redress. Sanctions require a finding that a foreign policy is unreasonable or discriminatory and harms U.S. commerce, and that U.S. action is justified (Puckett & Reynolds, 1996, p. 678). This demonstrates the requirements for the USTR to impose sanctions

on India, depicting U.S. limitations for complete influence. The U.S. uses such trade pressure to push India toward stricter IP implementation and enforcement.

India was on the USTR Priority Watch List from 1989 to 2007 (International Intellectual Property Alliance, 2014). This served as a negotiation tactic to pressure India on IP reforms. Earlier reports focused less on online piracy but shared the same issues on IP as the 2024 report. For example, the 2007 report—issued after the 2005 Patents (Amendment) Act—called for stronger patent protections, better enforcement, and implementation of the WIPO Internet Treaties (Office of the United States Trade Representative, 2007, p. 26). The USTR opposed the flexibilities introduced in India's 2005 Patent Law, maintaining India's spot on the Watch List. The USTR placed India on its Special 301 Priority Watch List in 1989, but India's generic pharmaceutical industry continued to expand rapidly throughout the 1980s and beyond. This reflects India's resistance to U.S. pressure and contrasts with China's response, discussed in the next chapter.

Pro-Lax IP Mechanisms: Public Advocacy and Agenda Setting

Agenda setting is an important mechanism used by INGOs such as Médecins Sans Frontières, known as 'Doctors without Borders'. Advocacy groups have employed agenda-setting strategies to portray IP as a barrier to public health and to depict the benefits of access to medicines that can be achieved through lax IP. Concerning IP being described as a hindrance to public health, MSF declared that pharmaceutical monopolies limit generic competition, raising drug prices and restricting access to HIV/AIDS, Hepatitis C, and Tuberculosis treatments (Médecins Sans Frontières, 2021, p. 1). These arguments support MSF's push for fairer distribution of medicines in low- and middle-income countries. Regarding the benefits that can be gained from less strict IP, MSF points to IP/C/W/673, a document submitted to the WTO for the TRIPS agreement and questioned how the current IP system is not conducive to the development of quick, affordable

medicines and access to health technology, which results in compulsory licensing being difficult to employ. MSF declares that “the cumulation of decades of experience and evidence of intellectual property being a barrier and having a chilling effect on competition, scaling-up manufacturing, and ensuring affordable access to medicines, vaccines, and other health technologies is a solid argument for supporting the proposed TRIPS waiver” (Médecins Sans Frontières, 2021, p. 1). This illustrates how MSF aims to relax TRIPS-based IP rules to promote broader access to pharmaceuticals.

While Novartis challenged India's lenient IP regime, civil society groups pushed back. International NGOs, such as MSF and TWN, emphasize India’s role in exporting generics that support global public health, particularly in low-income countries. Domestic groups focus on ensuring access and affordability of generics for Indian patients, as seen with Cipla and Natco. Both international and domestic advocacy groups support flexible IP policies. Still, with varying aims, international actors seek to achieve global health benefits. In contrast, domestic agencies tailor their approach to maintain local accessibility and price affordability for Indian consumers.

The pro-lax IP coalition uses media campaigns and agenda-setting to counter stringent IP policies. Health organizations such as MSF and TWN led extensive media campaigns, organized grassroots petitions, and lobbied directly to brand restrictive IP protections as a threat to public health. During the global HIV/AIDS epidemic, MSF advocacy mobilized support for India's compulsory licensing to expand access to generics. Their campaigns span across India, North America, Europe, and Africa (Paul, 2019, p. 1). Campaigns can become amplified through news coverage, interviews, social media mobilization, and petitions, as illustrated below.

One significant advocacy effort was the 'Drop the Case Campaign' in response to the Novartis legal case (Médecins Sans Frontières, 2012a, para. 1). In 2006, the pharmaceutical

company Novartis sued the Indian government over its patent laws, challenging Section 3(d) of the Indian Patents Act after the company sought to patent Glivec, a leukemia drug. India's Patent Office rejected the application because it did not contain significant therapeutic advancements over existing versions (Gabble & Kohler, 2014, p. 5). Novartis legally challenged the implementation of Section 3(d). This challenge favours their patents to prevent generic companies from producing cheaper alternatives to their products. Novartis argued that the enhanced efficacy requirement of Section 3(d) was ambiguous, unclear, and arbitrarily enacted (ESCR-Net, 2020, para. 3). Novartis's attempt to overturn the provisions of the law constitutes a legal challenge. The counterreaction of MSF was the "Drop the Case" campaign, in which almost half a million people signed an online petition through the MSF Access Campaign. If Novartis were to win the case, the distribution of generic medicines to people in need would be hindered, as India would not be allowed to manufacture these generics. MSF warned that patents would hinder Indian production of affordable HIV/AIDS drugs, risking millions of lives. In a 2007 campaign video, MSF showed a patient about to take a pill, only for gloved hands to snatch it away, symbolizing how Novartis was taking medicines from those who needed them (Sismondo & Greene, 2015, p. 251). The message challenged the idea that the company owned the drugs, instead portraying patients as the rightful holders being robbed of lifesaving treatment. The case proceeded to India's Supreme Court, where in 2013, the court rejected Novartis's patent application. Before this, MSF renewed its campaign, again requesting Novartis to put an end to their legal case against generic medicines (Médecins Sans Frontières, 2012b, para. 2). The petition, which gained the signatures of Archbishop Desmond Tutu, the author John Le Carré, and former Swiss President Ruth Dreifuss, among others, was highly publicized and brought attention to India as the "pharmacy of the developing world" (Médecins Sans Frontières, n.d.-b, paras. 1-3). Although Novartis did not drop its case, in

August 2007, the Madras High Court rejected the company's case (Médecins Sans Frontières, 2012b, para. 8). This campaign illustrates the advocacy efforts of MSF and the media attention they have garnered from seeking to uphold integrity over access to medicines through their public health agenda-setting, emphasizing that generic drugs are vital to the health of individuals. The campaign garnered global media attention, highlighting India's role as a leading supplier of generic medicines (Médecins Sans Frontières, n.d.-b, para. 3). Through on-the-ground campaigning, MSF brought public health concerns to the public's consciousness, effectively framing the Novartis case as a threat to access to medicines. This advocacy likely influenced public opinion and helped shift the narrative in favour of protecting India's patent law provisions. The courts, even as a neutral entity, may have been influenced by the public discourse created by advocacy efforts, such as the petitions of MSF, which garnered vast signatures, as well as the overall public sentiment in India, which was a significant promoter of generic medicines. On the ground, awareness raising was evident through signs that read "Novartis: Making a killing in profits" (Médecins Sans Frontières, n.d.-b). Henceforth, lax-IP is pivotal in providing flexibility in India's patent regime.

3.4 Pharmaceutical IP Law Trajectory in India: The 2005 Patents (Amendment) Act and Landmark Cases—*Novartis v. Union* and *Bayer v. Natco*

With the amendments to the 2005 Patents (Amendment) Act, the alignment of shared interests between advocacy actors, MNCs, and political entities shaped the outcome of the legislation and influenced landmark court cases such as *Novartis v. Union of India* and *Bayer v. Natco*.

The final version of India's 2005 Patents (Amendment) Act incorporated critical legislative changes, such as restrictions on evergreening and expanded opportunities for patent opposition, that were introduced in response to political pressure and advocacy, aimed at preserving public

health safeguards from TRIPS flexibilities. The Lok Sabha (Lower House of the legislative branch) passed the 2005 Patent Ordinance on March 22, 2005, followed by the Rajya Sabha (the Upper House) the following day (Bhattacharya, 2008, p. 401). The final version of the law incorporated amendments from the initial proposal, mainly in response to pressure from the Indian government, its Left allies, and the National Democratic Alliance (Bhattacharya, 2008, p. 401). Section 3(d), excluding "evergreening," became central to safeguarding generics. The pre-grant opposition period extension, embedded in the 2005 Act, allowed stakeholders to challenge patent applications before they were granted (Abbas, 2021, p. 62). This legal tool allows third parties, particularly generic manufacturers, INGOs and NGOs, to challenge patent applications before approval, reinforcing TRIPS flexibilities. The amendment reinstated an extended period for filing opposition, thus expanding opportunities to contest monopolistic claims. Generic companies such as Cipla, Ranbaxy, and Cadila, which had vested interests in maintaining market access, supported this flexibility. For instance, they had filed around 45 pre-grant oppositions towards the Controller of Patents. Much of this opposition targets mailbox applications, including Novartis's anti-asthma compound (Mueller, 2007). A mailbox application refers to a pharmaceutical or agrochemical patent application that was filed in India during the country's TRIPS transition period (1995-2004), but was not examined until after January 1, 2005, following TRIPS implementation. These applications were stored in a symbolic “mailbox”, meaning they were not reviewed or published until India implemented complete pharmaceutical patent protection in 2005 (Mueller, 2007). Therefore, patent applications for these agrochemicals can be accepted before national laws grant the patent by being stored in a “mailbox" pending evaluation. Left-leaning political groups in India, notably the Communist Party of India (Marxist) (CPI(M)), asserted their role in securing late-stage changes to the bill, including amendments that reflected Médecins Sans Frontières' concerns over

access to generic medicines (World Generic Markets Pharmaceuticals, 2005, para. 2). The left-wing parties noted that the government accepted a majority of the requested amendments, 10 out of 12 of which were subsequently included in the legislation. Prakash Karat from the CPI(M) said these changes were vital for protecting public interest. The bill's amendment included provisions on evergreening that aimed to limit what can be patented. Moreover, another amendment overturned a prior limitation on the duration for which a patent can be opposed (World Generic Markets Pharmaceuticals, 2005, para. 2). The legislation initially limited the time from nine to two months. Still, through the new amendment, the 9-month duration was reinstated, and the deadline to file an opposition was extended from three to six months. The CPI(M) concerns were aligned with those of MSF (World Generic Markets Pharmaceuticals, 2005, para. 2). The amendments to the legislation were a testament to the Left parties' dedication to public interest and the impact of MSF, as evidenced by the Left's alignment with the advocacy group. The 2005 (Amendment) Act was deemed a great accomplishment by CPI(M) leaders Nilotpal Basu and Rupchand Pal, telling reporters that the government changes would benefit developing countries and less affluent people (Patent Bill finally gets Left support, 2005, para. 2). The leaders said, “We are happy today because we told the government that we can support the legislation only if you accept our suggestions in national interest” (Patent Bill finally gets Left support, 2005, para. 5).

Through direct engagement with the legislature, the Left likely shaped the 2005 amendments by foregrounding concerns about access to medicines. By emphasizing public health priorities, they may have guided legal decisions toward provisions such as limits on evergreening and an extended pre-grant opposition period, aligning the reforms with broader health goals. Basheer (2005) claims that the Left Parties played a central role in shaping revisions to the patent ordinance to address concerns about drug patenting. The definition of an 'inventive step', which is

a critical threshold for patentability, was directly taken from the list of recommendations submitted by the Communist Party of India (Marxist) (CPI(M)), based on the Report of the Fourth People's Commission on Review of Legislations Amending Patents Act 1970 (p. 44). Collectively, the Left and MSF helped reconcile TRIPS compliance and influence access to affordable medicines in India's patent laws. Hence, the influence of the left-wing parties in India, such as the Communist Party of India (Marxist) (CPI(M)), with its alignment with INGO advocacy, advanced a public health narrative that shaped the 2005 Patents (Amendment) Act.

The 2005 Patents (Amendment) Act was introduced by the United Progressive Alliance (UPA) government led by the Indian National Congress under Prime Minister Manmohan Singh, with Kamal Nath as Commerce Minister. Nath provided assurance through a statement that the 2005 amendment would be made through setting up an expert committee (Mashelkar to head panel on patent law, 2005, para. 5). Nath wanted the government to uphold the safeguards to protect the interests of people requiring inexpensive medicines since they can better deal with drug price costs (Ahmad, 2005, p. 265). Dr. R. A. Mashelkar, Director General of the Council of Scientific and Industrial Research (CSIR), led the technical expert committee (Mashelkar to head panel on patent law, 2005, para. 1). The Commerce and Industry Minister of India assured Parliament that an expert committee would review the issues and report back. As a result, the Government of India established the Technical Expert Group (TEG) on Patent Law Issues (Report of the Technical Expert Group on Patent Law Issues, 2009, p. 2).

Ultimately, the TEG concluded that restricting patent creation solely to New Chemical Entities (NCEs) would not comply with TRIPS, as it would exclude an entire field of technology (Report of the Technical Expert Group on Patent Law Issues, 2009, p. 12). Nonetheless, the TEG emphasized the need to ensure affordable access to medicines and recommended strict guidelines

for the Indian Patent Office to follow, minimizing the possibility of granting frivolous patents and preventing evergreening (Report of the Technical Expert Group on Patent Law Issues, 2009, p. 12). Therefore, the TEC acts as an insider form of government influence as a venue actor. The Mashelkar Committee serves as a policymaking platform where stakeholders can effectively influence the direction of patent reforms. As a high-status expert committee, its recommendations carried both technical expertise and political weight. Thus, they functioned as an epistemic authority where knowledge production could shape the interpretation and enforcement of laws. This rendered it a place for insider advocacy, wherein the group acts through networks of specialists, policy briefs, or backroom lobbying rather than via public demonstrations, as exemplified through advocacy groups. Therefore, government officials promoted the 2005 amendments to expand access to medicines, and this aligned with the goals of advocacy groups. Government officials, including Kamal Nath, reinforced advocacy concerns by supporting safeguards against monopolistic patents (Ahmad, 2005, p. 265). The concerns of Kamal Nath were consistent with the demands from MSF, the CPI(M), and Indian generic manufacturers. The CPI(M)'s recommendations directly shaped amendments like the 'inventive step' clause, which was copied verbatim into legislation (Basheer, 2005, p. 44). Left-wing leaders credited their influence, emphasizing the law's public health benefits (Patent Bill finally gets Left support, 2005, para. 5).

Generic manufacturers filing 45 pre-grant oppositions reinforced restrictions on evergreening (Mueller, 2007). The positions of the generic manufacturing firms filing of pre-grant oppositions and the Left Parties positions shared the stance with MSF's widely publicized 'Drop the Case Campaign' during the Novartis litigation, which was an initiative that helped frame Section 3(d) as a public health safeguard and mobilized both domestic and international support

for India's flexible IP regime (Médecins Sans Frontières, 2012a, para. 1). India's generic drug industry supports lax IP, similar to the sentiments of advocacy groups. The Indian generic drug industry believes that the government, before the UPA, pushed for far-reaching IP protections, and the generic drug industry aimed to urge the new UPA government not to impose stricter rules as it reviewed the draft amendments. Yogin Majmudar, President of the Indian Drugs Manufacturers Association (IDMA), declared: "If the government has made that commitment [to a product patent], then we have no quarrel with that, but what we don't want to see are monopolies under the law. We want to see compulsory licensing. We have had this since the early 1970s –an automatic licensing right—and this needs to continue" ("Industry fears drugs law reversal," 2004). This demonstrates the advocacy efforts against strict patents in the pharmaceutical industry.

3.5 *Novartis v. Union*

The *Novartis v. Union* case was a landmark court case concerning IP in India's pharmaceutical sector. In 2003, Novartis sold the cancer drug Glivec for approximately $2,600 per patient per month in the U.S. (Plahe & McArthur, 2021, p. 1176). Glivec's active ingredient is imatinib mesylate. In 1998, Novartis submitted a patent application in India for the beta-crystalline form of imatinib mesylate. The Novartis application was examined in 2005, following India's amendment of its Patents Act to comply with the TRIPS agreement. In 2006, the Indian Patent Office denied the application because it lacked enhanced efficacy, as required under Section 3(d) of the Patents Act. Novartis filed two writ petitions before the Madras High Court: one against the denial of its patent application and another challenging the constitutionality of Section 3(d) because it was not in alignment with the TRIPS Agreement (Plahe & McArthur, 2021, p. 1176). The Novartis patent application pushed for stricter pharmaceutical IP protection.

In 1960, scientists Peter C Nowell and David Hungerford achieved the "Philadelphia chromosome" breakthrough, a mutation linked with Chronic Myelogenous Leukemia (CML), leading researchers to conduct investigations into potential treatments (Basheer & Reddy, 2008a, p. 133). Scientists developed imatinib during the 1990s, which was altered to its stable beta crystalline form used in Novartis' drug Glivec. Novartis patented this polymorphic form globally but was unable to do so in India due to the pre-2005 patent ban in the country. After India's 2005 patent law amendment, Novartis' "mailbox" patent application for the beta crystalline form was examined. Between 1995 and 2005, India had a system in place to maintain pharmaceutical and agrochemical patent applications without granting them, as the country transitioned to compliance with the TRIPS agreement. The applications were only to be reviewed in 2005. Generic pharmaceutical manufacturers and the CPAA opposed the application based on a lack of novelty, inadequate increased efficacy under Section 3(d), and a lack of obviousness (Basheer & Reddy, 2008a, p. 134). Hence, the modification was considered something a skilled person in the field could easily deduce, lacking the inventive step required for patentability. The Assistant Controller of Patents rejected the application, and Novartis appealed to the Madras High Court, believing that Section 3(d) was unconstitutional and violated the TRIPS agreement. The case was then transferred to the Intellectual Property Appellate Board (IPAB), which hears IP cases (Basheer & Reddy, 2008a, p. 135). Advocacy groups, including Médecins Sans Frontières, Oxfam, and Act Up, also mobilized public campaigns targeting Novartis shareholders, urging them to pressure the company to withdraw the lawsuit.

These efforts included demonstrations during Novartis shareholder meetings, intended to influence shareholders to oppose their company, thereby undermining the Novartis court case. In 2007, Novartis challenged the constitutionality under Section 3(d) and its conformity with the

TRIPS Agreement, but the Madras High Court dismissed the case, and no appeal was filed. The Madras High Court ruled that Novartis did not have jurisdiction and authority to determine whether Section 3(d) is TRIPS-compliant with Indian law, and that the court ruled that enhanced efficacy did not violate Article 14 of the Constitution of India (Du, 2014, p. 235). Instead of focusing more on Section 3(d) of the Indian Patents Act, which was rejected, Novartis then sought to challenge the rejection of its patent application, leading to the Indian Supreme Court hearing the case on April 1, 2013. The appeal was centered on the Indian Patent Office's decision to dismiss Novartis's application for a product patent on the beta-crystalline form of imatinib mesylate (Abbott, 2013, p. 1). The Supreme Court upheld the rejection, ruling that the beta crystalline form did not comply with Section 3(d) of the patent law.

Framing Strategies

In the *Novartis v. Union* of India case, framing was used during legal deliberations. Anand Grover was the lawyer representing the Cancer Patients Aid Association. Grover argued that efficacy, as defined in pharmacology, is a pharmacodynamic property, meaning it refers to a drug's ability to produce a therapeutic effect, not just how much of it reaches the bloodstream (Supreme Court of India, 2013, para. 183). Citing authoritative sources like the International Union of Pure and Applied Chemistry (IUPAC) Glossary, Goodman and Gilman, and Dorland's Medical Dictionary, Grover distinguished efficacy from affinity (how strongly a drug binds to a receptor), potency (the dose required for an effect), and bioavailability (how much of a drug reaches circulation). Grover emphasized that higher bioavailability does not necessarily mean better efficacy, as a drug must demonstrate an actual therapeutic improvement to qualify for a patent under Section 3(d) of the Indian Patents Act (Supreme Court of India, 2013, para. 184). Since Novartis' modification of Glivec (imatinib mesylate) mainly improved bioavailability relative to

its earlier non-crystalline form rather than demonstrating superior therapeutic benefits, Grover argued it did not meet the "enhanced efficacy" requirement for patentability. The Supreme Court of India ultimately agreed, ruling against Novartis and ensuring that affordable generic versions of Glivec remained available.

The CPAA's court proceedings in *Novartis v. Union of India* relied on framing and legal arguments to challenge Novartis' entitlement to a patent. Anand Grover delineated efficacy as a purely therapeutic attribute rather than the presence of enhanced bioavailability, using sources with key medical terminology to form the basis of argumentation for efficacy. The deliberations favouring lax-IP assisted in affirming Section 3(d) of the Indian Patents Act, which excludes the practice of evergreening. By contending that Novartis' Glivec alteration did not enhance efficacy, the CPAA could influence the Supreme Court's ruling, thereby ensuring the availability of low-cost generics and serving public health interests.

Most importantly, CPAA's efforts were not merely legal campaigning; they positively influenced the case by presenting detailed submissions and pooling expert scientific opinion in the service of their framing of efficacy. Anand Grover and CPAA tactically connected complex pharmacological definitions to larger issues of public health and the risk of patent evergreening, with the possible denial of access to cheap drugs to Indian patients. This framing may have resonated with the court, which was balancing India's TRIPS obligations against its constitutional guarantee of access to healthcare. Justice R. Balasubramanian and Sridevan delivered the deliberations in the Madras High Court. During the official judgement in the *Novartis AG v. Union* of *India and Ors,* it was mentioned by opposition senior counsels: “Every member country is given enough elbow room to bring in a local law in discharging their obligation under "TRIPS" having regard to the various needs of their citizens. India is a welfare country and it's [sic] first obligation

under the Constitution is to provide good health care to it's [sic] citizens. When that is it's [sic] priority commitment under the Constitution of India, the Union of India has every right to bring in any local law in discharging their obligations under "TRIPS" to suit to the needs and welfare of it's [sic] citizens" (Madras High Court, 2007, pp. 3-4). The CPAA's status as a patient-centered NGO added strength to their case, positioning it as one of social justice rather than a mere commercial patent case. Their multi-stakeholder campaigning effectively clarified the legislative intent of Section 3(d), convincing the Supreme Court to uphold the rejection of Novartis' patent application and, thus, the availability of generic alternatives. This illustrates how domestic civil society actors can wield significant power in shaping IP law through scientific, legal, and public interest advocacy. Since the CPAA was involved in the legal battles favouring lax IP, their advocacy—especially through Anand Grover—likely influenced the outcome. This highlights the role of domestic pro-lax actors in shaping the adoption of IP law. Without their framing strategy in court, the decision may have favoured Novartis' IP stringency.

As an international nongovernmental organization, Oxfam calls for action through its policy statement offering recommendations as it dichotomizes "patients over patents." (Oxfam, 2006a, p. 9). This distinction is a framing method that shapes views based on the impediments that IP creates for pharmaceutical access. For example, in the Doha Declaration, Oxfam reported that millions of people in developing countries struggle to afford the medicines their families need. Many people become poor due to expensive health treatments, mainly medications. Oxfam states that generic competition is the most effective way to make drugs more affordable (Oxfam, 2006a, p. 9). In Colombia, for instance, generics are two-thirds of the market; on average, they cost just one-quarter of the price of brand-name alternatives. However, the intellectual property rules of the TRIPS Agreement limit generic competition, making new medicines unaffordable for many people

in developing countries (Oxfam, 2006a, p. 9). Oxfam's report highlights inequities in medicine access between wealthy and low-income countries, using data and case studies to call for IP reform. It urges the protection of public health over IP in policy spaces while allowing for engagement with stakeholders, such as policymakers, media, and the public, in raising awareness and spurring action by effectively framing the issue.

Apart from the legal argumentation of framing in the Novartis case, tailored for the judicial process in India, Oxfam framed the potential limitations of Novartis' victory on global health access and the stability of generic pharmaceuticals. This target is aimed at a global audience, including the public, as well as policymakers in emerging countries and international advocacy groups focused on equitable access to medicines. Oxfam utilized a public advocacy framing strategy, whereby if Novartis were to win the case, India's export industry would suffer. Oxfam did not hold any legal standing in the case, nor did it submit legal briefs, but it played a strategic role outside the courtroom by shaping international discourse. In 2006, Oxfam released a policy statement under its "story" section on its website, warning that the Novartis victory would raise drug costs and threaten the Indian generic supply of medicines. Their text declared: "Not only would it increase the price of the drug it would also jeopardize India's generic export industry. India is the world's leading supplier of inexpensive generic medicines to developing countries, with approximately 67% of its exports going to developing countries. As a result, people needing cheaper versions of medicines in many developing countries would lose out" (Oxfam, 2006b, para. 6). This highlights the instability that generic manufacturers in India face, risking their ability to supply affordable medicines globally. Framing the issue this way helps build public pressure on trade negotiators to prioritize access. A 2001 Oxfam brief urged the UK Government and the EU to ensure that WTO-compliant patent laws would not restrict less affluent countries' access to

medicines, signalling Oxfam's long-term objective of maintaining access to Indian generics for global health needs (Oxfam, 2001, p. 4). These efforts reveal how Oxfam, as an international NGO, likely influenced the political and normative climate surrounding the case, not through legal participation, but by shaping public discourse with the CPAA and MSF, whose aligned messaging gained broad support.

Civil society groups like the CPAA and MSF in India used emotionally charged, global justice framing to depict patent disputes, such as the Novartis case, as threats to access to lifesaving medicines, thereby shaping both public opinion and legal outcomes through moral appeals.

Framing: Theoretical Linkages

Activists prefer using simple, direct words and communicating facts to frame issues regarding right and wrong, designed to mobilize individuals to act (Stroup & Wong, 2017, p. 26). Persuasion is more likely to be effective when the issue is formed using a strong frame highlighting the ability to change, identifying those who are accountable, and presenting viable solutions. Value-based messages are essential, and in most cases, they carry more power in influencing state policy than the professional advice of experts (Stroup & Wong, 2017, p. 26).

Oxfam and the CPAA framed the potential loss of India's legal victory as a moral crisis. They warned that a Novartis win would threaten access to medicines in developing countries. Unlike Oxfam, the CPAA was an intervenor and could participate in the court proceedings. Keck & Sikkink (2014) argue that identities and responsibilities are reframed to reshape the policy landscape and influence institutional and ideological perspectives through the strategic deployment of norms and ideas (p. 12). The CPAA and Oxfam effectively shaped normative sentiments by influencing stakeholders to align with their views on the importance of access to medicines. Naming and shaming, as (Hafner-Burton, 2008, p. 689; Keck & Sikkink, 2014, p. 31)

allude to, relates to the campaign in the Novartis case, for instance, that portrayed MNCs as evil, as signs read: "Novartis: Making a killing in profits" (Médecins Sans Frontières, n.d.-b). This institutional access may have allowed the CPAA to shape judicial reasoning more explicitly, especially in a political context where equitable access to medicines was a salient issue amongst advocacy groups. Although no direct evidence links the CPAA to explicitly shaping judicial decisions or the courts acknowledging its influence, it remains plausible that the CPAA affected the ruling, given the prevailing political climate. Oxfam, by contrast, operated outside the courtroom but engaged in widespread public advocacy, including online campaigns that helped frame the case as a threat to health justice. This public framing may have contributed to a broader political environment that reinforced judicial caution and delegitimized Novartis's attempt to narrow India's patent standards. By employing an international perspective, Oxfam and the CPAA established the discussion not merely as a court matter but as one of public health and economic stability across developing countries. They turned it into a matter of right and wrong, as well as India's ability to deliver affordable medicines. Oxfam placed their views within the theory of framing a problem as something that can be altered, with measurable effects and blame: "We fought for patients' rights in this litigation, and we are greatly relieved that the court has ruled in our favour, and recognized that patients need protecting more than patents," Y, K, Sapru, founder and chairman of the CPAA, mentioned following the court proceedings (Weissman, 2007, p. 15).

Agenda-Setting Strategies

MSF sought to garner attention from the masses in India by amplifying the issues of patented medicines, thereby gaining visibility and directing attention to the problematic outcomes they viewed that Novartis would create in the pharmaceutical sector for IP. In February 2012, MSF relaunched the "Drop the Case" campaign, "Stop Novartis" (Menghaney, 2013, p. 53). As the

initial campaign garnered attention through a petition, the Stop Novartis campaign utilized X (formerly Twitter) to achieve an international reach. MSF aimed to use the social media platform to request that people target the company themselves on the company's @Novartis profile, displaying the hashtag #STOPNOVARTIS (Menghaney, 2013, p. 55). The new form of campaigning prompted Novartis to respond with tweets that defended the company's record and sought to quell discord by presenting its perspective. MSF sought to mobilize public opinion and advance its public policy objectives to prevent Novartis from challenging the Indian Patents Law, as a win by Novartis would obstruct access to low-cost generics in the developing world (Vaughan & Arsneault, 2021, p. 372). Hence, there were two targets of MSF. Firstly, MSF directly targeted Novartis to discourage the company from appealing the decision that had rejected its patent application in India. Secondly, by raising the issues they disliked about Novartis, MSF aimed to create an ethos and influence public opinion on the importance of affordable medicines. By extension, MSF tactics likely contributed to the ruling indirectly as they shaped public opinion. The public voiced its sentiments through signs that read "Novartis: Making a killing in profits" (Médecins Sans Frontières, n.d.-b). Advocacy was expressed through media campaigns, which took part during the legal proceedings in 2012 before the 2013 court ruling, succinctly, by Leena Menghaney, Access Campaign Manager - India, Médecins Sans Frontières: "With this precedent-setting case nearing its end, we sincerely hope that the integrity and intention of India's patent law, and Section 3d in particular, is upheld. India's ability to continue producing affordable medicines for the developing world depends greatly on the country's patentability standards and how the courts in India interpret them. We will now wait for the judges' verdict to be released" (Médecins Sans Frontières, 2012d, para. 2). Timing was key—MSF's advocacy came just before the ruling, which may indicate their influence on the court's decision. The campaign was timed to influence

the court via public opinion. Furthermore, as the 2005 (Amendment) Act laid the groundwork for flexible IP in India, MSF exemplifies the mobilization that continued following 2005. Through my analytical exploration, I found no direct evidence that MSF had an explicit influence on court decisions. Nevertheless, it is noteworthy that public opinion was shaped and aligned with MSF's views, thereby creating a public health agenda that may have influenced the court ruling. The court did rule based on Section 3(d), and its legal formation was influenced in part by advocacy groups and pharmaceutical companies, which portrays how advocacy tactics may have indirectly shaped the Novartis case.

Oxfam employed agenda-setting in a statement featured on its website report. The organization drew public attention by framing the debate around the high cost of patented medicines, such as Glivec, for patients who cannot afford them. Oxfam argues that Glivec may apply for a new patent based on "new uses" in other countries, which would further give the company a monopolistic use of IP to delay the availability of generic versions of Glivec for individuals who rely on such medication (Oxfam, 2006b, para. 4). Oxfam highlighted the impediments India would endure if Novartis were to be successful in their legal case, reinforcing the urgency of less strict IP. Oxfam's policy statement challenged Novartis to raise awareness about IP if Novartis successfully receives approval for its patented medication in India. Moreover, during the Glivec trial, MSF and Oxfam expressed concern that if Novartis won, medicines would not reach hundreds of thousands of poor individuals. Due to campaigning, demonstrations took place in India, and over 500,000 people globally wrote to the CEO of Novartis, Daniel Vasella, to protest against the conduct of Novartis (European CEO, n.d., para. 4). As the agenda-setting strategy was driven in part due to Oxfam, there was a response as people expressed their frustration against Novartis since the company would impede cheap medicine provision.

Agenda Setting: Theoretical Linkages

As Oxfam and MSF employed an agenda-setting approach, this strategy echoes agenda-setting theory, since the political salience of an issue can be strategically leveraged by advocacy groups (Farrand, 2015, p. 487). MSF's use of public petitions and social media, especially the "Drop the Case campaign", did not directly influence the court, as the organization lacked formal standing in the legal proceedings. However, by strategically framing the case as a threat to global access to medicines, MSF shaped public discourse in a way that maintained political salience around India's patent law. According to Heiss and Johnson (2016), actions represent proposal power when advocacy groups introduce and sustain an issue in the public sphere (p. 534). While MSF did not directly influence the courts, the overall campaign contributed to a broader public environment that favoured strict patentability standards and equitable access to generic medicines, as evidenced by the signatures gained in favour of India's flexible IP regime (Heiss & Johnson, 2016, p. 534). Oxfam exercised its proposal power by strategically framing the problem as a threat to affordable medicines, ensuring that access to generics remained a vital concern in the public's view. Together, these advocacy tactics reflect elements of agenda-setting, ensuring that the implications of Novartis' legal challenge remain a focal point in public and policy discussions. Their ability to shape the discourse around IP law in India demonstrates how agenda-setting by INGOs can counter corporate influence and affect IP implementation, reinforcing the theory's argument that agenda-setting can be an important factor in legislative and policy outcomes. Stevens & Willems (2024) declare that audience support is important for agenda setting (p. 581). This suggests that MSF can target media and public venues to establish reputational credibility and mobilize support.

Lobbying Strategies

Advocacy groups lobbied to shift Novartis shareholders' views against the company's patent stance. Campaigners handed out leaflets to Novartis investors at the company's annual meeting in Switzerland to try to force the CEO, Daniel Vasella to drop the lawsuits warning it could weaken India's position as "the pharmacy of the developing world" (O'Connor, 2007, para. 2). Just before the 2013 ruling, civil society organizations such as Act Up, Oxfam and the Berne Declaration Group sought to influence a meeting outside the Novartis headquarters (Médecins Sans Frontières, 2012b, para. 8). As shareholders met in Basel, Switzerland, MSF urgently attempted to influence them through direct pressure to drop its ongoing court case against the Indian government (Médecins Sans Frontières, 2012b, para. 1). MSF feared the case would threaten affordable medicine access in developing countries. Dr. Unni Karunakara, MSF's International President, remarked: "Shareholders at this meeting need to know what the stakes are on this case and what the consequences will be…We are asking Novartis once and for all to stop this legal battle in India that is a direct attack on the pharmacy of the developing world. We will not stand by silently and watch our source of affordable medicines dry up in the future —we rely on these drugs to do our work in more than 60 countries today" (Médecins Sans Frontières, 2012b, para. 2). This statement served to inform and pressure shareholders of the broader implication for access to medicines in the developing world and shift the perspective of Novartis shareholders by applying pressure from within the company. Shareholders were aware of the lobbying efforts. According to HIV i-Base, activists from MSF, Oxfam and other groups showed videos and engaged with stakeholders. Numerous stakeholders expressed sympathy for the campaigner's protests against the Novartis lawsuit (Baker, 2012, para. 11).

Although MSF's campaign failed to get Novartis to withdraw the case, it helped shape the global debate on medicine access. This influence was demonstrated by the vast number of

signatories gained by the public to try to put an end to the Novartis proceedings. Campaigners protested with signs that read expressions such as "Patent Kills Patient" and accused Novartis of asserting influence over "the pharmacy of the developing world" (O'Dea, 2012, para. 16). New Delhi Healthcare campaigners also welcomed the rejection of Novartis' patent for a new version of the cancer drug Glivec. MSF aid agency responded to the case by saying the ruling would save lives across the developing world and that the verdict is "a victory for poor patients not just in India but across the world" ("Healthcare campaigners hail Novartis patent rejection," 2013, para. 3). This shows MSF's message aligned with domestic healthcare campaigners. Media and public attention from MSF, Oxfam, and the CPAA likely increased the visibility and political weight of the 2013 Supreme Court ruling, reinforcing its status as a landmark verdict on IP rights against access to medicines.

Lobbying: Theoretical Linkages

My section on lobbying strategies aligns with my theoretical framework, with elements mentioned by Dellmuth and Bloodgood (2023) and Risse-Kappen (1995) regarding how political opportunity structures and institutional access shape lobbying efforts. Advocacy groups' direct engagement with Novartis shareholders at the company's annual meeting in Basel exemplifies how NGOs and INGOs leverage institutions available to them, such as shareholder meetings, to influence corporate decision-making. Lobbying efforts were made during an important court case, and its results have political ramifications for India's pharmaceutical sector. This demonstrates how, despite the limited formal power of transnational actors, they can strategically engage with private sector actors to advance their policy goals, consistent with Risse-Kappen's (1995) argument that access depends on the fragmentation of state and society (pp. 6-7).

Additionally, the mobilization of global supporters through social media and public campaigns reflects the reliance on normative legitimacy and grassroots mobilization described by Stroup & Wong (2017) and Makoba (2002). These groups expanded their influence beyond traditional policymaking institutions by targeting shareholders, demonstrating an adaptation of lobbying strategies to different institutional contexts. This aligns with Dellmuth & Bloodgood's (2023) argument that lobbying extends across various arenas depending on political opportunity structures and capabilities of actors.

These examples support the theoretical claim that lobbying tactics are shaped by the accessibility of political and institutional venues, the nature of actors' constituencies, and the overall political environment (Dellmuth & Bloodgood, 2023; Risse-Kappen, 1995). Lobbying is not limited to formal state channels but can also involve strategic engagement with private corporate stakeholders to influence international intellectual property laws and outcomes.

Pro-Stringent IP Actors in the Novartis Case

Novartis executives have denounced the court ruling in the landmark case. Former vice-chairman and managing director of Novartis India Ltd Ranjit Shahani told reporters in Mumbai following the court ruling that the pharmaceutical company would alter its R&D from India to more "favourable destinations" (Shift in Novartis strategy, 2013, para. 2). Shahani noted that: "This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options" (Cancer Patients Aid Association, 2013, para. 8). Furthermore, a U.S. industry trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA) mentioned in a statement pertaining to the verdict of Novartis that: "To solve the real health challenges of India's patients, it is critically important that India promote a policy environment that supports continued research and development of new medicines" (Cancer Patients Aid Association, 2013, para. 7).

Thus, there were no strong pro-stringent actors in the Novartis case to influence the court ruling in their favour. Instead, there were just minimal remarks following the verdict of PhRMA and from the former Novartis chairman, whose views diverged from those of advocacy groups. This helps to comprehend that the influence of pro-lax IP actors was greater due to their tactics of seeking to form a cohesive narrative surrounding the importance of access to medicines, which may have shaped the courts due to the inside and outside tactics of these advocacy groups that do not support stringent IP implementation. Pro-stringent IP actors may have believed the case would succeed on statutory grounds alone, especially given their arguments about Section 3(d) being inconsistent with TRIPS. This could have led to underinvestment in public mobilization, assuming the judiciary would prioritize such legal interpretation over public sentiment.

3.6 *Bayer v. Natco*

The *Bayer v. Natco* case exemplifies the first instance of compulsory licensing, which is a legal flexibility that counters strict IP protection. India granted its first-ever compulsory license for Nexavar (sorafenib tosylate), a patented cancer drug developed by Bayer, on March 9, 2012 (Nedumpara & Misra, 2012, p. 326). Natco had first applied for a voluntary license from Bayer in 2008 to manufacture sorafenib but was unsuccessful. Later, Natco applied for a compulsory license with the Controller General of Patents, allowing an entity to produce and market a patented drug without the patent holder's consent. Sorafenib, the drug involved in this case, is used for treating late-stage kidney and liver cancer. Bayer's branded version, Nexavar, was priced at INR 2,84,428 (approximately USD $5,700) for a month's supply and was imported rather than manufactured locally (Nedumpara & Misra, 2012, p. 326). As part of the compulsory license terms, Natco was required to pay Bayer a royalty of 6% of Nexavar's net sales every quarter (“India orders first compulsory license,” 2012, para. 5). The license also stipulated that Natco could only manufacture

the drug at its facility in Hyderabad and was prohibited from outsourcing production. Moreover, the drug could be sold solely for the treatment of kidney and liver cancers within India ("India orders first compulsory license," 2012, para. 5). Additionally, Natco was obligated to provide Nexavar free of charge to at least 600 patients facing economic hardships each year.

At the time, a generic form of sorafenib was also available for less from another Indian generic company, Cipla, under the name Soranib, at an estimated monthly cost of INR 30,000 (approximately USD $600). Bayer initiated an infringement case against Cipla in the Delhi High Court (Nedumpara & Misra, 2012, p. 326). The *Natco v. Bayer* case arose from the initial challenges between Cipla and Bayer. Bayer argued that the Indian drugmaker Cipla had breached its patent rights by significantly reducing the price of a generic version of its patent-protected cancer drug Nexavar ("Cipla breached patent," 2012, para. 1). Bayer declared that its generic sorafenib constituted a clear patent infringement. Bayer did not grant Cipla consent for their life-extending kidney and liver cancer drug ("Cipla breached patent," 2012, para. 2). With the Natco case, Bayer referred to Cipla to provide a foundational argument against Natco. Bayer argued in an appeal that the new price of Natco's drug will render the price unreasonable and undermine the intent of compulsory licensing (Singh, 2012, para. 4). Bayer said in its appeal to the IPAB that "in view of the fact that Cipla is now selling at Rs 6,840 (with discount, for Rs 5,400) for a month's treatment, i.e. at much lesser price as that of Natco, the very objective of grant of compulsory license has been defeated, thereby making the grant thereof as infructuous" (Singh, 2012, para. 5). Furthermore, Bayer argued that Natco's drug will not 'be able to meet reasonable requirements of public' as preferred by the government order. Hence, the Nexavar patent can be revoked following two years of compulsory licensing, which would result in proprietary loss for the patent holders, not due to their fault (Singh, 2012, para. 6). This is based on Section 85 of the Indian Patents Act

that states that a patent may be cancelled two years after a compulsory license is granted if the invention does not meet the reasonable needs of the public or remains inaccessible due to high cost (Singh, 2012, para. 7).

Bayer argued that since Cipla would sell its drugs for less than Natco, which would be granted a compulsory license, the compulsory license would not meet public demands by being priced too high. From that, Natco's compulsory license can be ineffective and undermine Bayer's patent. The statutory foundation for issuing compulsory licenses is found in the Indian Patents Act of 1970. Any interested person may apply to the Controller of Patents for a compulsory license after three years from the date that a patent is granted. A license may be granted if the public's needs for the invention are not being met, if the invention is not available at an affordable price, or if it is not being produced or used in India (Nedumpara & Misra, 2012, pp. 327-328). Natco's application was based on all three grounds. The Controller of Patents ruled that Bayer's Nexavar did not work in a manner that met the reasonable needs of the public, relying on WHO estimates that around 30,000 patients needed the medication. The drug cost of INR 2,84,428 (USD $5,700) for a monthly dose was also ruled out of reach for the public. Natco argued that even the lowest-paid government servant would need three and a half years' salary to afford the treatment, an argument the Controller accepted (Nedumpara & Misra, 2012, pp. 327-328). The Controller noted that Bayer's Nexavar was imported rather than manufactured locally. Section 83(b) of the Patents Act stipulates that patents should permit the holder to import a product and produce it within India to meet local demand. The Controller of Patents argued that Bayer's failure to produce Nexavar domestically violated this requirement, and thus, a compulsory license was granted to Natco (Nedumpara & Misra, 2012, p. 328).

Framing Strategies

MSF framed the court ruling in favour of compulsory licensing in the Bayer and Natco case as a public health vs. patent right in their public statements. In their access campaign, MSF wrote that "this decision once again affirms that courts can and should act in the interest of public health" (Médecins Sans Frontières, 2012c, para. 1). This frames the issues as a health rights matter, rather than a legal or commercial dispute. There is also cost framing, as MSF stated that the cost of treating HIV in India is a major problem, as it is too costly and that compulsory licensing can help reduce such prices (Médecins Sans Frontières, 2012c, para. 1). Lastly, there is symbolic framing. MSF noted that the ruling is a "watershed for affordable access" (Médecins Sans Frontières, 2012c, para. 3) and vows for a "routine use of compulsory licensing" (Médecins Sans Frontières, 2012c, para. 2). These phrases cast compulsory licensing as a framing mechanism for cheaper medicines access and a moral imperative to shape how future challenges can be made for the better through this mechanism.

Agenda-Setting Strategies

Y K Sapru, CEO of the CPAA, sought to set the agenda in the Bayer and Natco dispute over the cancer drug sorafenib (Nexavar). According to DNA India, Y K Sapru mentioned that "the generic drug would be much more affordable to not only patients but also NGOs" (Golikeri, 2018, para. 7). Sapru reframes the issue from a legal or commercial dispute to one of public health and equitable access. This is a strategic attempt to reframe the discussion around drug pricing to center on the humanitarian costs and prioritize affordability over the enforcement of intellectual property rights. Rather than lobbying directly, Sapru exercises discursive power by shaping the policy discussion, emphasizing that access to affordable medication is a moral and social imperative. Setting this agenda within the broader context of the patent lawsuit and Cipla's controversial decision to introduce a generic version despite Bayer's patent contributes to a public

debate that legitimizes compulsory licensing and challenges the control of multinational pharmaceutical firms in setting the terms of access to medicine in India.

Lobbying Strategies

Pro-stringent actors have lobbied the Indian government in the *Bayer v. Natco* case, but the case has been shaped by the countervailing influence of pro-lax IP actors. The U.S. has lobbied the Indian government to impede the country's use of compulsory licensing ("US steps up lobbying efforts," 2012, para. 1). Teresa Stanek Rea, the US's deputy under secretary of commerce for intellectual property and deputy director of the United States Patent and Trademark Office (USPTO), stated during a U.S. House Committee meeting that the U.S. embassy in Delhi had a dedicated official who frequently engaged with Indian authorities to lobby against the issuance of compulsory licenses in cases where the U.S. deemed them unwarranted ("US steps up lobbying efforts," 2012, para. 2). Kalpana Reddy, first secretary, intellectual property, at the U.S. embassy in New Delhi was not available to provide comments ("US steps up lobbying efforts," 2012, para. 2). As pro-stringent actors like the U.S. government lobbied Indian officials to oppose compulsory licensing in the *Bayer v Natco* case, their efforts were countered by domestic opposition. Indian activists, legal experts, and pharmaceutical groups pushed back, framing compulsory licensing as a legitimate mechanism for public health. This portrays the influence of pro-lax IP actors in resisting external pressure and shaping India's IP discourse. Tapan Ray, director general of the Organisation of Pharmaceutical Producers of India, a lobby representing foreign drugmakers in India, said it was logical for the U.S. government to converse on the issue with actors in New Delhi ("US steps up lobbying efforts," 2012, para. 2). Activists and IP lawyers in India have opposed the U.S. campaign ("US steps up lobbying efforts," 2012, para. 1). Shamnad Basheer, an IP law professor at the National University of Juridical Sciences in Kolkata declared: "these unfortunate

comments by the deputy commissioner of the US PTO are reflective of a growing tendency by developed countries to demonize compulsory licensing-a perfectly legitimate legal tool… more importantly, compulsory licensing is not restricted to public health emergencies, as many would have us believe. In fact, the US itself routinely resorts to compulsory licensing, albeit through its courts which refuse to issue injunctions against infringers" ("US steps up lobbying efforts," 2012, para. 2). Moreover, the Indian Pharmaceutical Alliance (IPA) wrote to foreign secretary Ranjan Mathai questioning whether it was appropriate for diplomats in India to engage in lobbying efforts aimed at advancing the commercial interests of private corporations ("US steps up lobbying efforts," 2012, para. 2).

Venue Shopping

In India, venue shopping by advocacy groups such as INGOs and NGOs involved shifting their efforts across multiple institutional arenas to influence pharmaceutical IP policy. MSF turned to stakeholders in the Novartis case to influence individuals with direct relations to the company. MSF also targeted the public to shape opinions through online petitions, social media, and online statements, demonstrating the importance of affordable medicines. MSF did not have access to the courts, so targeting these stakeholders and the public was their outside form of advocacy. This advocacy can shape public opinion to raise awareness, and stakeholders can condemn the company. Therefore, this political ethos may have shaped the court ruling. The Cancer Patients Aid Association turned to the judiciary by leveraging the pre-grant opposition mechanism to challenge patent applications, as seen in the Novartis case, through their inside advocacy with their lawyer, Anand Grover. Advocacy groups, along with key government officials in India, were a more vocal group in pushing for pro-lax IP policies, which likely contributed to pro-lax policies being implemented and enforced in India.

3.7 **Comparisons Against Alternative Explanations for India**

Having examined the impact of advocacy groups on India's IP policy towards the pharmaceutical sector using the Novartis and Bayer cases, this section examines whether structural factors, as opposed to advocacy-driven influence, better explain India's IP policy stance. It compares advocacy-driven impact against two major structural explanations: market orientation and political regime type. These perspectives argue that open-market economies and democracies have a greater tendency to enact stronger IP protections. By comparing these with India's IP trajectory in empirical reality, this section tests whether the presence and mobilization of pro-lax IP forces yield a superior explanation for India's relatively lax patent regime than structural or institutional factors in isolation.

India's Market Orientation Landscape

Innovation Capacity

According to the Global Innovation Index (GII) 2024, India ranks 39th among 133 economies (World Intellectual Property Organization, 2024). The country ranks in the top spot amongst the 38 lower-middle-income group economies and first among the ten economies in Central and Southern Asia. They have improved their ranking from 48th in 2020.

Economic Integration: Trade and FDI

According to the 2022 Reserve Bank of India Annual Report, India's merchandise exports increased by 43.8% in 2021-2022 (Reserve Bank of India, 2022, p. 89). Since the 1990s, Indian firms have increasingly embraced outward foreign direct investment (OFDI) as a strategy to remain competitive in a more open and globalized economy. Cross-border investments surged from just $44 million in the 1980s to $700 million in the 1990s and then soared to $79 billion in the 2000s (Pradhan, 2017, p. 44). By 2014, India's OFDI stock reached 51% of its inward FDI,

6.4% of GDP, and 17% of gross fixed capital formation. The number of Indian firms investing abroad also grew sharply—from 60 in the early 1980s to nearly 7,800 in 2014 (Pradhan, 2017, p. 44).

Overall, India shows a strong and growing level of economic openness. Rapid export growth, rising innovation rankings, and a sharp surge in outward FDI, with thousands of Indian firms investing abroad, reflect a more robust integration into global markets. These trends highlight a strategic shift toward global competitiveness since the 1990s reforms.

Market Orientation Argument

With the economic model explanation for IP stringency, open economies tend to be more willing to align with IP protections. This argument is that the more open an economy is, the more IP protections there will be (Gould & Gruben, 1996, p. 324). Firms in a closed innovation model can generate ideas within their business, relying on IP rights to form innovation capabilities and capture the investment return from intangible property. In an open model of innovation, the role of IP rights is more strategic because innovation is catalyzed through cooperation with other actors like research institutions, businesses, and universities (World Intellectual Property Organization, 2021, para. 9). IPRs are more effective in promoting economic growth for countries well integrated into global trade and investment networks (Maskus, 2001, p. 471). Beyond the direct effects of higher productivity through trade and FDI, exposure to international competition incentivizes domestic firms to upgrade their technology and raise product quality (Maskus, 2001, p. 471). Firms in open economies are more willing to incur the costs of obtaining new technologies when strong IPRs ensure they can reap the benefits from such investments (Maskus, 2001, p. 471). This depicts how strong IP rights, combined with an open economy, are conducive to creating an environment ripe for technological advancement and competitive growth.

Based on this line of argumentation, India, being a more open-market economy, would demonstrate more stringent IP. Nonetheless, as portrayed, India has exemplified lax intellectual property protections due to the vocal and determined pro-lax IP advocates that support cheaper generic medicines, which contrasts with the market orientation rationale that would explain IP stringency. India is an open economy, yet the region is less aligned with strict IP in the pharmaceutical sector, which, as my argument highlights, is due to pro-lax IP entities.

India's Regime Landscape

India has been more democratic until the ascent of Narendra Modi to power in 2014. Democratic institutions remained in place during Modi's tenure while there was a decline in norms and practices that form the foundation of democracy (Tudor, 2023, para. 2). According to Freedom House, which ranks the degree of political rights and civil liberties, India is considered "partly free" with a rating of 66/100 (Freedom House, 2025). Compared to China, which will be explored in the next chapter, India ranks higher in terms of freedoms, where it is not severely restricted. As of 2024, India is categorized as an electoral autocracy, while China is classified as a closed autocracy (V-Dem Institute, 2025, p. 14). Therefore, this middle ground position, situated between democracy and autocracy, characterizes India's regime.

Regime Type Argument

Regarding the political regime in a country, the more democratic a country is, the greater the likelihood that the government will strive to conform to IP standards. Based on data from 42 countries between 2005 and 2008, Laplume et al. (2014) illustrate the political determinants of how IPR shapes the likelihood that entrepreneurs adopt technological mechanisms (p. 815). The stronger a country's democratic regime, the more positive the impact of IPR on the probability of entrepreneurs adopting the latest technologies in their businesses (Laplume et al., 2014, p. 815).

Rather than advocating for IP through advancements in pharmaceutical IP regulations, India maintains a lax IP stance. The regime-type argument does not hold in India, as this democratic nation actively supports affordable, generic medicines by resisting strong intellectual property protections mainly due to the efforts of NGOs, INGOs, government entities and pharmaceutical companies.

The classic regime-type argument assumes that more democratic regimes are more likely to uphold strong IP protections due to pressures for legal consistency, investor confidence, and innovation incentives. The implication is that less democratic regimes, such as autocracies, should be less responsive to advocacy groups and, more insulated from public health activism, and perhaps even more favourable to foreign IP holders due to centralized control. However, India as an electoral autocracy presents a puzzle: despite its democratic backsliding, it continues to resist strong IP protections in favour of public health, not necessarily because of democratic accountability, but due to strong domestic advocacy groups and nationalist industrial policy that persist even under a democratic autocracy.

While democracies and autocracies have different institutional preferences, I declare that policy outcomes depend less on regime type and more on the influence of pro-stringent and pro-lax IP interest groups within each country. Rather than assuming democracies inherently favour strong IP protections and autocracies act unilaterally, I demonstrate that both countries (India and China) yield results that run contrary to regime-type explanations. What matters is the relative strength and access of these groups, rather than whether a country is democratic or authoritarian. This adds nuance to the literature by highlighting that interest group dynamics, rather than regime type alone, shape IP policy outcomes.

Conclusion

This chapter has demonstrated that India's lax pharmaceutical intellectual property regime cannot be fully explained by structural factors such as market openness or regime type alone. Instead, the strategic efforts of domestic and international advocacy groups of INGOs like MSF, and NGOs such as the CPAA, and pro-lax pharmaceutical companies have played a decisive role in shaping policy outcomes (Médecins Sans Frontières, 2023, p. 1; Madras High Court, 2007, pp. 3-4).

By highlighting issues of access, affordability, and moral responsibility with framing, actors like MSF transformed the discourse, mobilizing public support and legitimizing resistance against strong patent protections (Médecins Sans Frontières, 2012c). Complementing this, agenda-setting efforts by key figures within civil society, such as CPAA's CEO Y K Sapru, shifted the policy conversation to center on equitable access and the social costs of high drug prices (Golikeri, 2018).

At the same time, lobbying dynamics were a contested policy domain, with pro-stringent actors such as the U.S. government actively opposing India's use of flexibilities like compulsory licensing ("US steps up lobbying efforts," 2012). Despite these pressures, Indian advocacy networks counterbalanced foreign influence, supported by legal and political structures to accommodate civil society engagement (Patent Bill finally gets Left support, 2005, para. 5; Médecins Sans Frontières, n.d.-b, para. 3).

This analysis challenges deterministic assumptions in the literature about the effects of economic openness and political regime type on IP policy. It reveals that policy outcomes depend largely on the relative strength of pro-lax and pro-stringent interest groups. India's case exemplifies how advocacy groups concerning pro-lax actors leveraging framing, agenda-setting,

venue shopping, and lobbying shaped the policy landscape in India more than pro-stringent actors to better serve public health objectives despite global pressures for stricter IP outcomes.

Chapter 4: China

Local pharmaceutical companies and Western actors use their influence to strengthen IP laws in China. For example, China's Jiangsu Hengrui Pharmaceuticals' extensive R&D and patent portfolio accentuates the strategic value of IP to domestic innovation. At the same time, multinational giants like Pfizer and AstraZeneca have tried to bolster IP, particularly in response to counterfeiting drug concerns (Bronshtein, 2008, p. 443). However, pro-lax IP actors, including advocacy groups, provide a counter-narrative by pushing for greater flexibility in IP law to address public health needs, especially in access to affordable medicine. The Chi Heng Foundation in China is an NGO seeking better access to care for children impacted by HIV/AIDS (Tatler Asia, n.d., para. 1). Domestic actors require approval from regulatory bodies such as the National Medical Products Administration (NMPA), the China National Intellectual Property Administration (CNIPA), and local pharmaceutical associations such as the China Pharmaceutical Innovation and Research Development Association (PhIRDA). In July 2021, China's National Medical Products Administration and the China National Intellectual Property Administration issued legal documents to ameliorate a mechanism first established in October 2020 under the amended Patent Law for the early resolution of pharmaceutical patent disputes. This mechanism links drug examination and approval with patent granting to address infringement violations before a drug is marketed. It includes adjudication agencies and standardized procedures that form the basis of a patent linkage system in China (China National Intellectual Property Administration, 2021, p. 48). The National Healthcare Security Administration (NHSA) oversees the procurement

of drugs and market access. Its coordination with IP authorities signals increasing stringency in China's IP regime, as patent protection is becoming more closely tied to drug procurement decisions. The NHSA and CNIPA released their Opinions on Strengthening the Protection of Intellectual Property in Centralized Drug Procurement and establishing a unified IP protection system for drug procurement on December 30, 2022. This system covers drug listing on provincial tendering platforms and volume-based procurement. It also allows drug procurement agencies to eliminate, exclude, and revoke IP rights-infringing products from bidding (European Union Chamber of Commerce in China, 2023, para. 12). The Joint Procurement Office is an example of a procurement agency along with the NHSA (Long et al., 2022, p. 4).

The 2020 U.S.-China Phase One Economic and Trade Agreement, which introduced stricter patent legislation and increased penalties for IP infringement, exemplifies how international and domestic pressures shape China's evolving IP landscape. The evolution of China's IP in the pharmaceutical sector illustrates the broader struggle between global IP norms and the local imperative of affordable medicines. This chapter argues that China's adoption of formal IP laws was primarily driven by international pressure from trading partners like the United States, while the actual enforcement and increasing stringency of these laws, especially in drug procurement, have been shaped by domestic administrative reforms, institutional capacity-building, and growing industrial policy concerns, as evidenced in the Haihe Biopharma case.

Historical Context

China's political system evolved from the totalitarian period of Mao Zedong. Under Mao, China was a one-party state with state control and repression. However, following Mao, Deng Xiaoping's reform period (1978-1992) introduced a "socialist market economy," which permitted partial marketization, private enterprise, and economic liberalization (Shi, 2008, p. 210). This

generated rapid economic development, with GDP per capita increasing exponentially from 1978 to 2002 (Shi, 2008, p. 210). Political freedoms remained tightly controlled, and pro-democracy demonstrations such as the 1989 Tiananmen Square protests faced repression (Shi, 2008, p. 210). Despite this, economic reform and limited social liberalization continued under Jiang Zemin (1989-2002) and the transition to Hu Jintao as the new leader in 2002. Although the Chinese Communist Party (CCP) maintained strong political authority, the economy diversified with the emergence of private and foreign enterprises. The CCP maintained large control over most sectors, including the government, the military, and the media, while allowing for modest institutional reforms, including elections in village committees and legislative participation (Shi, 2008, p. 211). The political system in 2002 continued to maintain its authoritarian structure, albeit with some liberalization in citizens' private and economic lives (Shi, 2008, p. 212). Economic opportunities increased. As China reformed its economy and trade expanded through negotiations, it became a member of the WTO in 2001 (Mavroidis & Sapir, 2021, p. 42). Due to legal and political restrictions, civil society participation in China is limited and less visible compared to India, where a broader space exists for civil society activism. For instance, in a 2017 speech, Xi Jinping, President of the People's Republic of China, called for an environmental governance system led by the government, including companies, civil society, and citizens. While this suggests broader participation, China's authoritarian system offers citizens only limited space to engage (Gao & Teets, 2021, p. 49). The model is often described as "authoritarian environmentalism," where experts dominate decision-making and the public is involved mainly through state-organized efforts. Though some cities saw successful citizen input in the 2000s, such involvement remains rare, and government responses tend to be case-by-case rather than part of a formal system (Gao & Teets, 2021, p. 49).

In the context of U.S.-China relations, where intellectual property was a key issue, China had compelling reasons to align with international agreements, particularly as a member state of the WTO. China wanted to be part of the WTO to gain access to new trading partners to provide the region with more favourable trade terms, improve the living standards within China and provide the country with "a seat at the table" in the global economic order (Council on Foreign Relations, 2025, para. 3). On the other hand, the United States wanted China to join the WTO because in their view, the U.S. believed that it would act as a check on communism in China and incentivize a quick transition to a market economy with global rules (Council on Foreign Relations, 2025, para. 6).

Historical Overview of Pharmaceutical Law in China

To align China's patent system with international practices, the Chinese Patent Law was first enacted in 1984 (Deng, 2010, p. 713). In 1992, under U.S. pressure, China amended its Patent Law in accordance with the Memorandum of Understanding between China and the United States. The scope of patent protections expanded to encompass foodstuffs, condiments, beverages, and, notably, pharmaceuticals (Cao et al., 2021, p. 3719). The length of patent protections increased from 15 to 20 years for invention patents and from 5 to 10 years for process patents, which include design patents (Yueh, 2009, p. 305). These formative years of international pressure led to further implementation of IP following the TRIPS agreement.

The Second Amendment was passed in 2000 to meet the requirements of the TRIPS agreement. As it sought to become a WTO member state, China implemented changes to align more closely with the TRIPS agreement’s higher IPR standards (Cao et al., 2021, p. 3719). The law was amended in 2000 to include the requirements of the TRIPS agreement while also preparing China for accession to the WTO in 2001 (Huang et al., 2023, p. 213). This depicts how China's

judicial and administrative protections were created, which expanded following the TRIPS agreement. Concerning statutory damages, Article 60 of China's Patent Law introduced a formula for calculating patent damages based on the patent holder's loss or the infringer's gain. If unclear, courts can use a multiple of royalty fees. Before this, damage awards followed vague general tort rules, often resulting in low compensation (Reed Smith, 2001, paras. 5-6). Preliminary injunctions were available. Article 61 added the ability to request a court injunction to stop or prevent infringement before a ruling, aligning with TRIPS rules on urgent remedies. Prior to this, China's law had no explicit provision for halting infringement in progress (Reed Smith, 2001, paras. 8-9).

The third amendment took place in 2008 to further improve IP implementation. This was a broad amendment that aimed to encourage patent exploitation, increase patentability requirements, address compulsory licensing matters, and establish protections for genetic resources (Yang & Yen, 2010, p. 4). The Fourth Amendment was a significant step forward in IP protections that reformed the system through specific provisions. A patent linkage system was formed whereby an infringement case would need to be resolved if a generic drug interfered with a branded version, hence safeguarding IP (Yao, 2024, p. 2). There were also patent term extensions and punitive damages for infringement (Feng & Yu, 2023, p. 196). This is significant not only because it introduced more detailed and targeted IP mechanisms but also because these changes increased the stringency of enforcement, limiting flexibility for generic competition and strengthening the position of patent holders in line with U.S. trade demands. This rising stringency was not incidental; it occurred in the shadow of escalating pressure from the United States to further enhance China's IP framework, particularly during the negotiation of the Phase One Trade Deal. The negotiations will be examined later in this chapter.

Table 2 - Timeline of Major Reforms in China's Pharmaceutical IP Regime

Date	Law/Policy Instrument	Summary/Significance
1984	Patent Law (1st version)	Excluded pharmaceutical products; weak IP enforcement
1992	First Amendment to China's Patent Law	Added 20-year protection for pharmaceutical products under U.S. pressure
2000	Second Amendment to China's Patent Law	TRIPS-aligned changes for WTO entry; strengthened enforcement.
2001	WTO Accession	China commits to TRIPS compliance
2008	Third Amendment to China's Patent Law	Introduced compulsory licensing, public interest safeguards, and stricter enforcement.
2015	Made in China 2025	Industrial strategy to shift toward innovation-driven growth
2016	Healthy China 2030 Vision	Long-term health policy integrating innovation, public health, and industrial goals
2019	Phase One U.S.-China Trade Negotiations Begin	U.S. pushes for stronger pharmaceutical IP protections
15 January, 2020	Phase One Trade Deal Signed	Formal U.S.-China trade deal, and China agrees to implement stricter IP enforcement
17 October, 2020	Fourth Amendment to China's Patent Law Passed	Introduces patent linkage, patent term extension, and data exclusivity.

1 June, 2021	Implementation of the Fourth Amendment to China's Patent Law	CNIPA and NMPA begin enforcement of new IP protections
2021	Patent Linkage Implementation (Part of Fourth Amendment)	CNIPA and NMPA create a pre-approval dispute system
5 August, 2022	Supreme People's Court Decision in *Chugai v. Haihe* Case	Landmark case favouring a domestic generic firm
2022	NHSA & CNIPA Opinions on Centralized Drug Procurement	Policy guidance shaping procurement and pricing; it intersects with pharmaceutical innovation and IP protection.
July 2024	Full-Chain Support for Innovation Initiative Approved	Comprehensive biopharmaceutical strategy, including pricing reform, clinical trial acceleration, and IP incentives

4.1 Key Actors in China's Pharmaceutical IP Landscape

Pro-Stringent IP Actors: Proponents of Stronger Patent Rights

This section examines the key actors shaping pharmaceutical intellectual property policy in China, focusing on both international and domestic proponents of stronger patent protections. It highlights the influence of multinational corporations, global governance pressure, and locally driven innovation firms to illustrate China's evolving IP regime within a globalized pharmaceutical landscape.

International Actors

This subsection examines how multinational pharmaceutical firms, such as Pfizer and BeiGene, in conjunction with international pressure from the United States Trade Representative, have prompted China to adopt stricter IP enforcement. It highlights how legal disputes, anti-counterfeiting efforts, and trade negotiations have influenced the strengthening of IP norms and institutional protections.

Global pharmaceutical companies in China, such as Pfizer of the U.S., AstraZeneca of the UK and Roche of Switzerland, support stronger IP regulations and protect their innovative investments. Pfizer, for instance, has been actively advocating for the government to uphold the principles of IP. China has taken swift action since 1980 to advance IP protections by joining WIPO, signing treaties, amending its IP laws, and joining international organizations (Bronshtein, 2008, p. 440). Despite these efforts, China remains a prominent actor in the counterfeiting of drugs on the market, and reversing this trend can be achieved by taking effective measures against IP infringement (Bronshtein, 2008, pp. 440-441). Counterfeit products generate profits but are often detrimental to the health of individuals and contribute to thousands of deaths worldwide (Bronshtein, 2008, p. 440). Pfizer is a key actor in China's pharmaceutical sector. In 2005, Pfizer prevailed in a fight against counterfeit sales of Lipitor, a treatment for high cholesterol, which led to criminal indictments and a massive U.S. recall, largely due to the efforts of the U.S. Food and Drug Administration (Bronshtein, 2008, p. 445). Pfizer responded by collaborating with the Chinese government, setting up a testing laboratory in Dalian, China, and working closely with regulatory agencies to combat counterfeiting. Through these efforts, the government confiscated large quantities of counterfeit medicines and shut down unlicensed manufacturers. Hence, these events portray Pfizer as a multinational pharmaceutical and biotechnology company; Pfizer's legal

battles and anti-counterfeiting efforts helped strengthen China's pharmaceutical IP implementation and patent protections.

Another international pharmaceutical company, BeiGene, initially from China, outlines the importance of protecting IP in the pharmaceutical sector. Intellectual property protection is essential for BeiGene's research and development of novel drugs. Given that drug development takes 10–15 years and involves high costs and risks, BieGene believes that patents stimulate private investment. Without IP protection, the company expressed that it would be challenging to continue R&D. BeiGene emphasizes the responsible use of intellectual property to promote innovation and expand access to treatments and medicines (BeiGene, 2022a, para. 1). BeiGene recognizes that affordability, particularly of life-saving oncology medicines, is a critical concern. This awareness shapes the company's mission and directly informs its approach to drug discovery, pricing strategies, and patient access programs (BeiGene, 2022a, para. 2). BeiGene, a founding member of the International Cancer Control's Access to Oncology Medicines (ATOM) coalition, displays a leadership role in advancing global oncology equity (BeiGene, 2022a, para. 3). Apart from its coalition involvement, BeiGene independently champions access to cancer treatments in low- and middle-income countries (LMICs) through direct partnerships with governments and organizations (BeiGene, 2022a, para. 3). Its use of voluntary licensing and strategic collaborations enables the provision of affordable, high-quality oncology medicines (BeiGene, 2022a, para. 3). Therefore, BeiGene manages strong IP protection with access by using voluntary licensing, allowing trusted partners especially in emerging countries to produce its medicines affordably. This strategy avoids the need for direct donations or subsidies to other companies, while the company can focus on expanding access to medicines. The model keeps profits from protected markets and uses licensing to make treatments more accessible globally. This proactive stance

underscores BeiGene as a contributor to ATOM, while also being a driving force, demonstrating how Chinese multinational corporations can harmonize intellectual property protection with global health goals (BeiGene, 2022a, para. 3). BeiGene reflects how MNCs from emerging markets shape international health access narratives through ethical innovation (BeiGene, 2022a, para. 3).

MNCs such as Jiangsu Hengrui Medicine are pivotal actors that invest in R&D to develop novel drugs. Their business model is designed to provide strict IP protection. Jiangsu Hengrui Pharmaceuticals Co., Ltd., a leading pharmaceutical company in China, excels in innovative healthcare solutions for oncology, surgery, and chronic diseases. Jiangsu Hengrui Pharmaceuticals Co., Ltd. has been listed for six consecutive years on *Pharma Exec*'s annual Top 50 global pharmaceutical companies and was ranked 8th in Citeline's 2024 list of "Top 25 Global Pharma Companies by Pipeline Size," reflecting the strength of its drug development portfolio (Jiangsu Hengrui Pharmaceuticals Co., Ltd., n.d., para. 1). Jiangsu Hengrui centers its growth strategy on innovation, investing over US$6.35 billion in R&D and built a global team of 5,500+ researchers across 14 R&D centers. With operations in the U.S., Europe, Australia, and Japan, the company has launched twenty-three new molecular entities and four additional innovative drugs. By the end of 2024, Jiangsu Hengrui was managing around 400 clinical trials for 90+ drug candidates and held over 1,800 granted patents globally, including 1,084 in Greater China (Jiangsu Hengrui Pharmaceuticals Co., Ltd., n.d., para. 2). The company has patented medical products in antibodies and biologics, small molecule drugs, pharmaceutical compositions/formulations and combination therapies (Patents Assigned to Jiangsu Hengrui Medicine Co., Ltd, n.d.).

BeiGene and Jiangsu Hengrui exemplify China's shift toward pharmaceutical innovation and stronger IP protection. Both companies are R&D-driven but also proponents of more stringent IP rights, viewing them as essential to recoup R&D investments and compete globally. Jiangsu

Hengrui, a specialist in cancer and pain management, has emphasized the importance of patent protection, focusing on innovation. BeiGene, headquartered in China, has internationalized through global partnerships and voluntary licensing, striking a balance between strong IP protection and access strategies. These companies reflect China's evolving pharmaceutical sector as anchored in innovation backed by stringent IP enforcement.

The United States Trade Representative (USTR) is a prominent international actor that aims to influence IP policy in China. The United States has faulted China for not meeting its enforcement obligations in vast areas, including copyright, patent, and trademark infringement (Brander et al., 2017, p. 909). The U.S. has designated China as a Priority Watch List country in its Special 301 Report (Office of the United States Trade Representative, 2024a, p. 44). The United States-China Economic and Trade Agreement (Phase One Agreement), signed in January 2020, contains several provisions on trade to address long-standing issues in China. Some of these are expanding civil liability to cover areas like electronic intrusions as misappropriation of trade secrets, imposing the burden of proof on the accused party, permitting preliminary injunctions to prevent abuse of stolen trade secrets, criminalizing willful misappropriation, and prohibiting unauthorized government or third-party expert disclosure of trade secrets and confidential business information (Office of the United States Trade Representative, 2024a, p. 24). Together, the Phase One Agreement and the recurring critiques in the Special 301 Report illustrate a multifaceted U.S. strategy: using both diplomacy and reputational tools to pressure China into aligning its IP regime with U.S. standards and expectations.

Domestic Pharmaceutical Firms

This subsection analyzes how Chinese pharmaceutical companies have emerged as central actors in the domestic IP system and explores their divergent strategies. While some domestic

firms align with innovation-driven, pro-stringent IP models comparable to international firms, others emphasize generics, access, and affordability, revealing internal tensions between IP protection and public health goals.

Zhang Lianshan, Deputy General Manager of Jiangsu Hengrui Pharmaceuticals and President of Global R&D mentioned that "intellectual property is the lifeline of Hengrui Pharmaceuticals" and highlighted the company's firm IP commitment ever since its inception (Intellectual Property Office of Jiangsu Province, 2023, para. 3). This commitment is institutionalized through internal structures, such as a company-level Patent Decision-Making Committee led by the Chairman of the Board, and an in-house IP department staffed by over thirty full-time specialists (Intellectual Property Office of Jiangsu Province, 2023, para. 3). Moreover, Jiangsu Hengrui Pharmaceuticals has achieved enormous success with its IP campaigns by filing over 1,000 domestic patents and more than 600 patents through the Patent Cooperation Treaty (PCT), where most of them have received well-respected and excellence awards at the China Patent Awards. The Patent Cooperation Treaty allows inventors to apply for patent protection in multiple countries at once through a single "international" application. Individuals who are nationals or residents of a PCT member country can submit this application either through their national patent office or directly to the International Bureau of WIPO in Geneva (World Intellectual Property Organization, n.d.). The company's IP practice reflects its efforts to establish robust patent protections, driving innovation and enhancing its competitiveness in the pharmaceutical sector. Jiangsu Hengrui Pharmaceuticals is a prominent pro-stringent IP advocate in China, pushing intellectual property forward in the pharmaceutical industry as innovative medicines are sought after and developed.

Pro-Lax IP Actors: Advocating for Flexible Patent Protections

Domestic Advocacy Actors

Various civil society organizations in China advocate for access to affordable medicines, seeking more flexibility in the IP landscape, given that life-saving drug access is a crucial consideration.

The first NGO is the Chi Heng Foundation. This foundation was established in 1998 by Chung To, and it works towards educating, aiding, and caring for children in Mainland China and Hong Kong who are HIV/AIDS-positive (Tatler Asia, n.d., para. 1). The NGO battles social stigma by conducting public awareness and education outreach. With an estimated 36.7 million people worldwide infected with HIV/AIDS, of whom 2.1 million are minors, Chi Heng focuses on education and partial support for the living expenses of children affected, emphasizing resettling them within society (Tatler Asia, n.d., para. 2). Chi Heng is widely recognized as a pioneer organization in innovative schooling, including distance-learning websites which enable rural kids to join companionship learning programs. "Chi Heng," or "wisdom in action," best describes the organization's philosophy. With five regional branches and having helped over 23,000 adults and children, the foundation has a lasting impact on how society views HIV/AIDS (Tatler Asia, n.d., para. 3).

The Aizhixing Institute is another NGO advocacy group to ensure affordable HIV/AIDS treatment of drugs. Aizhixing, which connotes love, knowledge, and action, was initiated in 1994 to assist vulnerable communities with access to healthcare within China (Bristow, 2010, para. 8). These actors play a limited role in advocacy efforts in China due to the restrictions they encounter. Aizhixing's founder and AIDS activist, Wan Yanhai, has expressed the bureaucratic barriers civil society groups face in China. NGO advocacy by actors in China has been allowed. Still, these

groups sometimes face suspicion by the Communist Party of China, which has the utmost control in the region (Bristow, 2010, para. 11).

Domestic Pharmaceutical Companies

While Jiangsu Hengrui and BeiGene represent China's innovation-driven, pro-stringent IP strategy, Haihe is focused on generics, pricing, and local coverage. Its business model prioritizes affordability and accessibility, using price control and voluntary licensing to meet local health needs. It diverges from innovation-focused, patent-reliant models employed by Chinese innovators and foreign MNCs. Haihe's strategy emphasizes the domestic trade-offs in the Chinese pharmaceutical industry between access and innovation, global integration, and public health priorities in China. The *Chugai v. Haihe* case study will further explore this divergence to illustrate how legal frameworks and IP implementation can differ across lax and stringent IP contexts.

Haihe Biopharma is a domestic pro-lax IP pharmaceutical company. They believe in generic versions of patented drugs, as will be seen in the *Chugai v. Haihe* case, where innovation and access are vital for Haihe, demonstrating that generics are created due to cheaper access to medicines. Their R&D strategies, outlined on the Haihe Biopharma website, mention their global reach of IP in the biopharmaceutical sector, being research-driven and a global leader in the pharmaceutical field. Established in 2011 and headquartered in Pudong, Shanghai, China, they specialize in discovering, developing, and producing oncology medicine (Haihe Biopharma, n.d.).

Limitations of Civil Society

Civil society in China is restricted due to the country's political regime. In the *Made in China Journal*, since 1989, it is described that civil society has been severely limited (Deane, 2021, para. 1). In April 2013, under Xi Jinping, what was called Document Nine, the CCP in China circulated an internal document, constituting civil society groups as an ideological threat to China

(Deane, 2021, para. 3). The Charity Law in place in China accredited charitable organizations. Unlike prior social service organizations that contained various actors, the new accredited charitable organizations were limited in scope (Deane, 2021, para. 9). There were no definitive provisions against violating “social morality” which made HIV/AIDS activists fret that their concerns could violate this provision due to ambiguities (Deane, 2021, para. 10). This highlights the concerns realized by advocacy groups that limited their influence vis-à-vis intellectual property rights in their advocacy for access to medicines. Civil society actors can use framing, nonetheless. With the ideology of suzhi, which means "all-round human cultivation," the state deems this consequential to maintain its legitimacy. Civil society can use this ideology to frame the need for better healthcare management or other issues, such as environmental conservation and child nutrition. Social media can be used to frame the issues. As the internet faces censorship, articles can be written before being removed. People can raise awareness through oral communication (Deane, 2021, para. 24). The China Philanthropy Law Report indicates that "China's one-party state has continued to adopt a skeptical view of China's young civil society sector, viewing it as a potential threat to the party-state's control and legitimacy" (International Center for Not-for-Profit Law, 2023, p. 3). This indicates the difficulties NGOs have faced in China. Ideas regarding China’s civil society relate to the theoretical underpinnings of Dellmuth & Bloodgood (2023), as advocacy groups may either hinder or facilitate global political opportunity structures (p. 325). This resonates with China's legal and political environment, as the one-party state can restrict the influence of advocacy groups, as there are more restrictions under Xi Jinping's leadership. Dellmuth & Bloodgood (2023) suggest that autocratization leads to more significant limitations for civil society (p. 15). The China Philanthropy Law Report portrays China's restrictive legal environment, demonstrating the impediments faced by civil society groups in authoritarian

regimes, where the state is less likely to tolerate NGO advocacy, thereby reducing their ability to participate in global governance and advocacy efforts.

A significant obstacle to NGO advocacy is the ability of foreigners to send funding to Chinese organizations. There are complex requirements to do so, and Chinese NGOs rely on foreign funds to remain sustainable (Bristow, 2010, paras. 14-17). This relates to the Charity Law in China. For the Charity Law, applicants must register with the Civil Affairs department within their locality (International Center for Not-for-Profit Law, 2023, p. 27). Moreover, charitable organizations should be registered as non-profit organizations, social service organizations, or social associations before applying for and obtaining charitable status (International Center for Not-for-Profit Law, 2023, p. 28). These impediments, along with China's restrictive political system, make it difficult for NGOs to receive funding. These restrictions help illustrate that local NGO advocacy is curtailed, which suggests there is greater influence of pro-stringent IP actors in China who promote IP protections, as will be discussed further.

Through the 14th Five Year Plan (FYP) for Social Organizations, which came about in October 2021 to supervise Chinese Organizations more closely for creating professional "high-quality" social organizational sectors, there are limited prospects for forming an independent civil society in China (NGOs in China, 2022b, para. 1). Nonetheless, NGOs in China can partake in specific initiatives to develop the sectors in which they are involved in while aligning with government priorities such as in Section 3.8 which includes innovation-driven development and provisions for professional services and ameliorating science and education (NGOs in China, 2022b, para. 5). Therefore, this policy allows NGOs to align their services and advocacy with these national strategies of China to result in more support from the government. An important innovation can be the expansion of Community Social Organizations (CBOs), where resources

from government procurement and philanthropy can improve communal services within rural and urban regions (NGOs in China, 2022b, para. 8). The 14th Five Year Plan aimed to crack down on social organizations deemed "ineffective" and "illegal" according to Section 3.3 (NGOs in China, 2022a, para. 2). This highlights that state control over civil society in China is pronounced even though NGOs can function through more state-controlled means. Section 3.2 calls for social organizations to be "guided to be thankful for the party, listen to the party, and follow the party" (NGOs in China, 2022a, para. 3). This connotes the importance of following the directives of the Communist Party in China and helps piece together why NGOs can be limited in their influence.

4.2 Coalitions and Political Alliances in China

Pro-Stringent IP Coalitions

Coalition dynamics play a significant role in driving innovative capabilities in China's pharmaceutical sector.

Pro-Stringent IP Pharmaceutical Coalitions (Trade Associations)

Founded in 1988, the China Pharmaceutical Innovation and Research Development Association (PhIRDA) is a national non-profit organization registered with the Ministry of Civil Affairs of China (China Pharmaceutical Innovation and Research Development Association, n.d., para. 1). PhIRDA focuses on innovation, industrialization, and internationalization to advance cooperation between academia, investment, and industry groups. With 181 member organizations, including Jiangsu Hengrui Pharmaceuticals and BeiGene, PhIRDA comprises pharmaceutical R&D enterprises, investment organizations, and research institutions. This facilitates pharmaceutical innovations. Additionally, PhIRDA has several specialized committees in pharmaceutical research, regulation, and development (China Pharmaceutical Innovation and Research Development Association, n.d., para. 2). The key activities of PhIRDA are conducting

policy studies, promoting industry communication, constructing international exchange platforms, supporting investment in pharmaceutical innovation, and providing informational resources to members (China Pharmaceutical Innovation and Research Development Association, n.d., para. 3). PhIRDA aims to expand its services, protect members' rights, and contribute to developing China's pharmaceutical industry and improve public health (China Pharmaceutical Innovation and Research Development Association, n.d., para. 4). PhIRDA is, therefore, a vast entity that espouses IP rights among other pro-stringent IP companies.

Another coalition and trade association is the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), established in May 1989. The coalition operates under the authority of China's Ministry of Commerce and plays a leading role in promoting global trade and cooperation in the healthcare industry. With a membership base exceeding 2,400 organizations, CCCMHPIE includes a wide array of entities such as major research institutions, manufacturers, and trading companies ("Abu Dhabi Investment Office organizes field visit," 2018, para. 16). Its members span multiple sectors, including pharmaceuticals, medical devices, biopharmaceuticals, nutraceuticals, functional cosmetics, and traditional Chinese medicine, making it an influential healthcare trade association in China.

Pro-Lax IP Coalitions

Advocacy Coalitions in China

While there are no formal pro-lax IP coalitions, China has advocacy groups and networks such as the China Alliance of People Living with HIV/AIDS (CAP+) to provide supporting services to individuals and to advocate for better access to treatment. This alliance comprises NGOs, civil society groups, and government organizations that collaborate to exchange information on the prevention of AIDS. The group promotes research and advocacy activities to

enhance the quality of life of people facing such challenges (China Alliance of PLWHA, n.d., para. 1). The organization is committed to various projects such as the 2008 Association Treatment and Medication Advocacy and Networking Project, the 2008 Local Organization Capacity Building Project in Eastern, Southern, and Western China, and the 2010 China AIDS Carriers Association Policy Advocacy Project (China Alliance of PLWHA, n.d., para. 2).

4.3 Mechanisms of Influence in China

Framing Strategies by Pro-Stringent IP Multinational Pharmaceutical Companies

The global pharmaceutical company BeiGene has one of its headquarters located in Beijing. Their strategy outlines three important framing tactics. Firstly, moral framing is utilized as the company champions patent access and global health equity instead of merely being a profit-driven entity. John V. Oyler, Co-Founder, Chairman and CEO, stated that: "All patients with cancer deserve access to high-quality, impactful medicines regardless of their location or socioeconomic status, but many wait years to access, or simply cannot afford innovative treatment options. Our founding belief is that there is a better way to lower these barriers and broaden our reach and impact" (BeiGene, 2025, para. 2). This framing can help garner public support. Secondly, there is an economic framing to ensure medicines are widely accessible to prioritize innovation and affordability. Finally, innovative framing is used to portray how BeiGene is committed to improving healthcare as the company specializes in oncology. As John V. Olyer states, "Our commitment to innovation extends beyond our labs" (BeiGene, 2025, para. 2). Rather than favouring strict IP for mere profit incentives, BeiGene promotes cheaper, accessible medicines to demonstrate their innovative research and drug development. This is the nuanced approach adopted by pharmaceutical companies in China, where they do not lean wholly toward IP but instead promote IP safeguards while ensuring cost-effective medicines.

BeiGene strategically framed pharmaceutical innovation by highlighting the interconnectedness of sustainability, health equity, and intellectual property rights. Through its ESG strategy (Environmental, Social, and Governance) in its press release, BeiGene asserts that "human health and the planet's health are intrinsically linked" (BeiGene, 2023, para. 6), positioning environmental responsibility and equitable access as critical global health concerns. With these issues being at the center of public and policy discourse, BeiGene builds legitimacy for stronger IP protections as essential to advancing such goals. The company's corporate disclosures further reinforce this agenda by stating that its commercial success depends on "the ability to obtain and maintain protection of intellectual property for its medicines and technology" through its partnerships with third-party developers and its ability to secure regulatory approvals and continued funding (BeiGene, 2023, para. 15). With this, BeiGene prioritizes IP protection in its corporate strategy and broader narrative about innovation, global access, and sustainable development, thereby guiding how key stakeholders, including regulators and the public, prioritize issues in the pharmaceutical policy space.

Framing Strategies by Pro-Lax IP Domestic Pharmaceutical Companies

Through the partnership between Haihe Biopharma in China and Taiho Pharmaceutical, a company from Japan, for the drug gumarontinib to treat non-small cell lung cancer, Haihe Biopharma emphasizes the importance of patient care. Haihe discovered gumarontinib (Taiho Pharmaceutical Co., Ltd., & Haihe Biopharma Co., Ltd, 2024, p. 1). In a news release, Ruiping Dong, M.D., Ph.D., Chief Executive Officer of Haihe, declared, "We are pleased to announce that we are entering into a partnership with Taiho, one of the leading oncology companies in Japan. We hope our collaboration shall be able to provide a promising treatment option for the patients with non-small cell lung cancer" (Taiho Pharmaceutical Co., Ltd., & Haihe Biopharma Co., Ltd,

2024, p. 2). Therefore, as mentioned above, Haihe supports lax intellectual property protection while supporting accessible medication. This approach reflects Haihe's broader strategy of navigating the practical need for drug accessibility, as further illustrated by the *Chugai v. Haihe* patent linkage case discussed later. The news release further indicates that "Taiho and Haihe, through its alliance, will make every effort to deliver gumarontinib to patients and healthcare professionals as soon as possible" (Taiho Pharmaceutical Co., Ltd., & Haihe Biopharma Co., Ltd, 2024, p. 2). This partnership, therefore, has resulted in framing strategies to promote medicine access in China.

Venue Shopping

Domestic pharmaceutical actors in China do not rely on broad civil society mobilization or lobbying strategies. Instead, they engage in *venue shopping* by working through state-led policy channels that align with the government's development goals. In an authoritarian context with constrained public advocacy, firms and actors selectively engage with institutional spaces, such as consultative political bodies and strategic policy campaigns, where they are more likely to be heard. These venues offer not just access, but also legitimacy, especially when proposals are framed in terms of contributing to economic modernization and technological advancement. Rather than resisting state policy, these actors position themselves as cooperative partners, shaping reforms from within the system. Two important venues that illustrate this dynamic are the *Healthy China 2030* and *Full-Chain Support for Innovation* initiatives. China's leadership has introduced these two major policy initiatives to shape its healthcare and pharmaceutical sectors: the *Healthy China 2030* vision launched in 2016 (Haynes, 2025, para. 9) and the *Full-Chain Support for Innovation* initiative was implemented in 2024 to strengthen biopharmaceutical innovation across the entire value chain (Deloitte, 2025, para. 1). The implementation of Healthy China 2030 has

involved cross-sector coordination involving input from industry associations, local governments, and private healthcare providers. For example, the China Edition of the Global Health and Healthcare Strategic Outlook highlights how collaboration between the Jinyun County Medical Insurance Bureau and Waterdrop seek to reduce poverty known as the Jin Qing Bang programming 2021 while the partnership between the Beijing Bethune Charitable Foundation and the National Clinical Research Center for Ocular Diseases to treat and diagnose retinal disease, have both assisted in propelling the elements of Healthy China 2030 (Chen, 2023).

Similarly, the Full-Chain Support for Innovation initiative, officially approved in July 2024, was also not developed in isolation. It was shaped by months of deliberation with the leaders of the pharmaceutical industry, including proposals from Fosun International's Co-CEO, Chen Qiyu, and the Chinese People's Political Consultative Conference (CPPCC) members who urged for pricing reforms and innovation incentives (Drug Times, 2024). The emphasis of the policy on faster clinical trials, price elasticity, and insurance reforms reflects input from domestic biopharmaceutical companies to overcome regulatory bottlenecks and funding concerns. In this way, then, both Healthy China 2030 and Full-Chain Support for Innovation are not merely symbolic frameworks. They are sites of continuous negotiation between industry participants and state planners, demonstrating how domestic actors help shape China's evolving healthcare and pharmaceutical innovation environment. These initiatives support the notion that the Chinese government, along with other domestic drivers, are shaping the policy agenda and offering incentives for compliance. These initiatives taking shape in China and the domestically selected venue of firms, in effect, reduce the likelihood of resistance from pharmaceutical firms toward stronger IP protections, which has been influenced by the U.S. The 'Healthy China 2030' plan, which preceded both the Phase One Trade Deal and the Fourth Amendment to the Patent Law,

helped set the agenda, while the subsequent 'Full Chain Support for Innovation' reinforced this direction. With government backing through infrastructure, funding, and regulatory support, pharmaceutical companies benefit from IP reforms instead of resisting them. At the same time, centralized policymaking limits space for advocacy groups to frame alternatives. As IP aligns with national innovation goals, there is a shift in the process from opposition to participation. Henceforth, domestic actors, such as pharmaceutical firms, benefit from government funding, infrastructure, and innovation. This reduces the need for these firms to independently advocate or resist policy changes, as they are situated within a system that meets both domestic goals and international expectations.

The USTR used international leverage to pressure China by invoking the TRIPS Agreement and strategically placing China on its Special 301 Report Priority Watch List (Office of the United States Trade Representative, 2024a, p. 44). By consistently placing China here, the USTR signalled, as they saw, an ongoing non-compliance with global IP standards, framing China as a violator of international norms. The USTR thus functioned as a powerful venue in bilateral trade, using international rules and domestic trade law in tandem to encourage China toward stronger IP implementation.

While foreign actors such as the U.S. continue to exert pressure through mechanisms like TRIPS and the USTR, domestic stakeholders in China often find it more effective to pursue influence through internal venues that prioritize industrial policy goals and innovation capacity over strict IP enforcement.

Pharmaceutical IP Law Trajectory

This section will explore the influence of the United States on China's adoption of more stringent IP based on the Phase One Trade Deal, along with the evolution of IP law in China and

domestic actors involved. Shortly after the deal was brokered between the U.S. and China in early 2020, China amended its IP laws through the Fourth Amendment to China's Patent Law. The patent linkage system ensured IP holders did not conflict with generic drug manufacturers during the agreement and the patent amendment. Following these enactments, domestic IP companies in China started to express the importance of IP protection. As will be outlined, the influence of the U.S. is prominent in China, which resulted in domestic actors following the legal safeguards of IP that the U.S. wanted China to maintain. Interestingly, in 2022, following IP pressures (Phase One Trade Deal) and adoptions (Fourth Patent Amendment), despite the existence of a system to protect patent holders from delaying generic market entry during patent disputes, the court ruled in favour of the generic manufacturer in the *Chugai v. Haihe* case, as will be explored in the final section. While international pressure, particularly through the United States–China Phase One Trade Deal, served as a catalyst for strengthening pharmaceutical intellectual property protections in China, this chapter shows that domestic pro-stringent IP actors played a great role in reinforcing, legitimizing, and institutionalizing these reforms. Although they did not initiate the original legislative changes, organizations such as the Hong Kong University of Science and Technology and the China Pharmaceutical Innovation and Research Development Association have since engaged in sustained agenda-setting and policy harmonization efforts that embed stronger intellectual property norms into China's regulatory and innovation infrastructure. This dynamic reveals how domestic actors can extend the scope and impact of externally driven legal reforms by shaping ongoing implementation and discourse.

4.4 Phase One Trade Deal

Despite far-reaching reforms from 1984 until the 2000s, China's enforcement of intellectual property rights remained a cause of concern, particularly in the pharmaceutical sector, with gaps

in its implementation according to the U.S. There were also China-U.S. tensions that escalated leading up to the 2020 Phase One Trade Agreement, driven by concerns like trade deficits, market access, and protection of IP. U.S. trade officials and drug companies complained, and they felt that China had weak IP protections, a lack of regulatory transparency, and inadequate data exclusivity provisions. Under the more assertive trade strategy of the Trump administration, these complaints were exacerbated, leading to the tariff increase and bilateral negotiations that ranked stronger IP protections as a core requirement. On 15 January 2020, the United States and China executed the Phase One Trade Agreement, a potential turning point in their prolonged trade war (Greenberg Traurig, 2020, para. 1). The agreement, which was signed by U.S. President Donald J. Trump and Vice Premier Liu He of China, aimed to strengthen economic and trade cooperation through holding on to international norms for secure global trade. Rather than offering new laws or regulations, it outlined the mutual obligations that are likely to yield economic benefits if implemented in their entirety. China pledged to increase imports of U.S. agriculture and energy products by $200 billion and to remove some agricultural health measures that previously disrupted trade (Greenberg Traurig, 2020, para. 1). China also pledged to enhance IP protection by addressing trade secrets, trademarks, piracy, and counterfeiting. The deal also prompted judicial reforms and aligned China's legal processes with those of the U.S.

The Phase One Trade Deal 96-page report discusses various issues related to trade between the United States and China. An important section of the deal is on intellectual property in the pharmaceutical sector. In the opening paragraph of *Section C: Pharmaceutical-Related Intellectual Property,* it states: "Pharmaceuticals are a matter concerning people's lives and health, and there continues to be a need for finding new treatments and cures, such as for cancer, diabetes, hypertension, and stroke, among others. To promote innovation and cooperation in the

pharmaceutical sector and to better meet the needs of patients, the Parties shall provide for adequate protection and enforcement of pharmaceutical-related intellectual property rights, including patents and undisclosed test or other data submitted as a condition of marketing approval" (U.S.-China Economic & Trade Agreement, 2020, p. 5). This is significant as it reflects the U.S. goals and ambitions for intellectual property, which will be reflected in China's Patent Law, as will be delved into. The U.S. operates within a policy landscape where IP can be fortified to promote innovation in the pharmaceutical sector. The trade deal outlines the views and legal safeguards that the U.S. wants China to implement, and it provides mechanisms for resolving patent disputes that may arise. Article 1.11 1. (a) states that China ought to have a system to "provide notice to a patent holder, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use" (U.S.-China Economic & Trade Agreement, 2020, p. 6). The goal is to ensure that patent holders can challenge the approval of the new product if they believe it infringes on their patent. Through U.S. pressure, the goal was for China to align their IP policies accordingly. The intellectual property section encompasses many aspects, and the entire section is primarily about pharmaceutical IP protection, which also extends to counterfeit medicines (U.S.-China Economic & Trade Agreement, 2020, p. 11). Specific provisions also relate to having effective patent term extensions (U.S.-China Economic & Trade Agreement, 2020, p. 7). IP is a vital aspect of the Phase One Trade Deal overall, particularly in the pharmaceutical sector. As will be seen, the Fourth Amendment to China's Patent Law demonstrates that China implemented IP into their domestic law not merely to appease Trump during the Phase One Trade Deal negotiations but instead adopted it for domestic incentives. China does not have to comply

with the US, as China can implement IP as it views is suitable to its domestic priorities, so long as it complies with international agreements it is part of, such as TRIPS.

China has been subject to sustained trade pressure from the USTR, including the Section 301 Report and the Phase One Trade Agreement. Meanwhile, India has also been repeatedly targeted in the USTR's Special 301 Reports for its pharmaceutical IP regime. Thus, understanding how pharmaceutical interests in the U.S. provide insight into how those same interests may shape external trade pressures, this section shows how these mechanisms operate in a health-specific policy area, with implications for how IP norms are adopted, contested, or resisted in emerging countries. Corporate actors and advocacy groups shape the IP landscape in the pharmaceutical sector, but the dynamics can differ significantly between the U.S. and emerging economies. Regarding the corporate actors, the Trade Association PhRMA (Pharmaceutical Research and Manufacturers of America) in the United States believes that patent protections allow for the amelioration of medicines so that companies can reformulate medicines to enhance efficacy while diminishing the side effects or discover additional diseases a particular medicine can treat (Pharmaceutical Research and Manufacturers of America, n.d., para. 5). Intellectual property in the United States facilitates an environment conducive to collaboration among biopharmaceutical companies, the government, and academia, and allows for technology transfer. This can enhance innovation and continue to drive the delivery of medicines patients require (Pharmaceutical Research and Manufacturers of America, n.d., para. 6). Consequently, PhRMA has a general concern for the overall long-term benefit of innovation, which is to focus on its research and development for the formulation or reformulation of medicines through intellectual property protection. Monetary benefits can be gained through intellectual property, as an MNC can have more exclusivity over their medicines. With the 21st Century Cures Act, enacted in 2016, this U.S.

federal law sought to streamline the drug approval process and ameliorate medical research funding through, for instance, investing in the National Institute of Health (Lupkin, 2016, para. 3). MNCs lobbied for their objectives. As a leading trade group for brand-name drugmakers, PhRMA was a prominent lobbying force, spending $24.7 million on lobbying efforts in support of the Cures Act before Congress. They supported the focus on enhancing biomedical innovation and declared that the bill would enable new treatments for patients (Lupkin, 2016, para. 10). This signifies the sentiments and actual actions taken by an MNC towards the U.S. government. The advocacy work undertaken by PhRMA illustrates the central role of intellectual property protections in the pharmaceutical industry's approach to innovation. In pushing for provisions in the 21st Century Cures Act to move along with developing new treatments, PhRMA wants policies that strengthen IP rights, enabling pharmaceutical companies to maintain exclusive control over their products. PhRMA spent $8.7 million on lobbying during the first three months of 2021 (Lupkin, 2016, para. 9). PhRMA used lobbying tactics during the COVID-19 pandemic to pressure the Biden administration to oppose waiving IP rights for the COVID vaccines, as this could jeopardize the earnings of private pharmaceutical companies that hold ownership of the vaccine formulations and possess the expertise for production (Ludwig, 2021, para. 9). This depicts how IP lobbying intersects directly with public health policy—especially during crises—an issue also central in the Indian and Chinese contexts, where governments have similarly faced pressure to accommodate innovation incentives with public access to medicines.

Pro-lax IP actors, to the contrary, such as nonprofit advocacy groups, opposed the Cures Act by expressing their concerns that an expedited drug approach could pose safety issues to patients by reducing the standards for the drug approval process (Ludwig, 2021, para. 12). Advocacy organizations such as the Center for American Progress, AFL-CIO and Public Citizens

urged individuals who were part of the decision-making of the act to not hurry the passage of the bill before amending it so that there could be an inclusion for caps on drug prices (Ludwig, 2021, para. 24). This opposition reflects a more profound struggle over how to reconcile intellectual property protections which spur innovation, with policies and regulations that make innovations accessible and safe for everyone. Their call for drug price controls highlights the need for a more equitable distribution of resources in drug development.

4.5 Fourth Amendment to China's Patent Law

China's fourth amended Patent Law, issued on October 17, 2020, and came into effect on June 1, 2021, by the Standing Committee of the National People's Congress in China, introduced significant changes, particularly for pharmaceutical patents (Jones Day, 2020, p. 1). A consequential update includes a patent linkage system, similar to the U.S. Hatch-Waxman Act, which allows for an early resolution of patent disputes over generic drug applications. Under this system, patentees can institute litigation or administrative measures, and drug approval is withheld in case of infringement (Jones Day, 2020, p. 2). The China National Intellectual Property Administration and the China Food and Drug Administration collaborate to link the marketing approval process for new drugs with the patent disputes of new medicines (Che & Wang, 2020, para. 7). Through this process, marketing approval is withheld until any patent issues are resolved. Patent holders whose rights are listed in China's drug patent information registration platform will be able to file lawsuits against applicants seeking approval for potentially infringing drugs. At the same time, manufacturers of generic drugs may request an administrative ruling on the validity of an existing patent (Che & Wang, 2020, para. 7). Since marketing approval is withheld temporarily, meaning that disputes are resolved before the generic drug can enter the market, the system accelerates resolution by handling patent conflicts during the regulatory phase, rather than after

market entry, preventing future issues in legal matters. The amendment further enhances patent protection, extends patent duration, and includes provisions for patent term extension adjustments in the event of new drug delays (Jones Day, 2020, p. 1). This system benefits pro-stringent pharmaceutical companies by delaying generic drug approval until patent disputes are resolved, strengthening market exclusivity. Resolving conflicts during the regulatory phase reduces legal uncertainty, while extended patent protections and term adjustments further enhance exclusivity. Overall, these measures support stronger IP enforcement and protect the interests of innovators. In addition, Article 71 of the Fourth Amendment increases statutory damages (from RMB 10,000-1 million to RMB 30,000-5 million), introduces punitive damages (maximum five times the amount assessed), transfers the burden of proof on damages to the defendant party, and may strengthen enforcement of patents (Jones Day, 2020, p. 3). Furthermore, Article 70 authorizes the China National Intellectual Property Administration to oversee significant nationwide patent controversies, strengthening administrative enforcement (Jones Day, 2020, p. 3).

The U.S. sought to be influential in the Fourth Amendment, which includes provisions aligned with the U.S.-China Phase One Trade Deal. This portrays the impact of pro-stringent IP actors and how the U.S. contributed to IP law adoption. As the Phase One Trade Deal focused on pharmaceutical patents, patent linkages, and extending the terms of patents, as well as more stringent implementation, these issue areas were important in the Fourth Amendment to China's Patent Law. According to Lee (2021), Article 76 of the Fourth Amendment was implemented in line with Article 1.11 of the Economic and Trade Agreement between the U.S. government and of the People's Republic of China (para. 1). With the requirements for pre-market dispute mechanisms, Article 1.11 (1): of the Phase One Trade Deal, mentions: "China shall provide... procedures for judicial or administrative proceedings and expeditious remedies, such as

preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use" (U.S.-China Economic & Trade Agreement, 2020, p. 6). In the Fourth Amendment for China's Patent Law, Article 76 declares: "The party concerned may file a lawsuit before the People's Court and request a judgment on whether the technical solution related to the pharmaceutical product that is applied for registration falls within the protection scope of any pharmaceutical product patent right owned by others" (World Intellectual Property Organization, 2020, p. 6). Both provisions establish legal pathways to resolve patent disputes before drug marketing approval, allowing patent holders to seek judicial determination before product launch. This reflects the creation of a patent linkage system, which did not previously exist in China in this form. Therefore, the U.S. concerns for IP in China during the 2020 negotiations did shape China's IP landscape due to the similarities between the Fourth Amendment and the U.S.-China Phase One Trade Deal. As the Phase One Deal and Fourth Amendment took place at similar times, while also covering similar IP areas to be strengthened, the U.S. influence on the Phase One Trade Deal contributed to reinforcing IP adoption in China.

Domestic Pro-Stringent IP Agenda-Setting Strategies

Agenda-setting is used to raise awareness of IP protection and pharmaceutical innovation in government and industry discussion forums by creating a direct link between research and policy. This awareness was made in 2023 following the Phase One Trade Deal and the Fourth Amendment to China's Patent Law. A PhIRDA coalition participating in IP initiatives demonstrates a continued commitment to advancing progress in the pharmaceutical sector in China, thereby securing stronger intellectual property protections. The Hong Kong University of Science and Technology (HKUST) and the China Pharmaceutical Innovation and Research

Development Association (PhIRDA) solidified their partnership by signing a Memorandum of Understanding (MoU) to form two innovation and research centers. The partnership was meant to help boost Hong Kong's commercialization and innovation capabilities in the pharmaceutical sector and contribute more extensively to pharmaceutical research and development (The Hong Kong University of Science and Technology, 2023, para. 1). The establishment of the Greater Bay Area Center for Policy Research on BioMed Development provides an official platform for drug and medical device regulations. This center facilitates dialogue with mainland and Hong Kong authorities on regulatory matters related to IP protection, a significant topic in future policymaking. One of the main objectives of the center is to "promote the establishment of a review and approval mechanism for drugs and medical equipment in Hong Kong, as well as the alignment of the regulatory mechanisms between Hong Kong and the Mainland" (The Hong Kong University of Science and Technology, 2023, para. 5). This indicates that harmonizing Hong Kong's IP and regulatory framework with China's overall pharmaceutical policies is a priority. The initiative will ease patent enforcement, regulatory approval, and commercialization processes, making it easier for pharmaceutical companies in both associations to access and enforce patents. Further, government support for pro-stringent IP R&D funding reinforces this agenda-setting initiative. HKUST President Prof. Nancy IP reported that the Hong Kong government invested HK$6 billion in supporting life sciences research, showing firm policy support for pro-stringent IP initiatives (The Hong Kong University of Science and Technology, 2023, para. 6). Therefore, by linking public investment to more substantial pharmaceutical IP rights, the initiative can contribute to subsequent policy decisions favouring patent-holding drug firms. Following the implementation of IP provisions in the Fourth Amendment to China's Patent Law and the Phase One Trade Deal, this MoU initiative laid the groundwork for further IP implementation in China, further solidifying

the foundation established through U.S. international pressure. Domestic initiatives were undertaken to implement more stringent IP policies. The U.S. pressured China to implement IP policies and laws, resulting in the Fourth Amendment to China's Patent Law. Moreover, there were agenda-setting initiatives as domestic pro-stringent IP actors came following U.S. pressures, as delineated through the HKUST. Therefore, while U.S. pressure, especially the Phase One Trade Deal, directly catalyzed the inclusion of patent linkage mechanisms in the Fourth Amendment, domestic pro-stringent IP organizations, like HKUST and PhIRDA, later reinforced and institutionalized these reforms. These actors did not appear to initiate the original legislative changes but have since played a key role in agenda-setting and policy harmonization efforts. This pattern suggests that while international influence drove the legal reform, domestic actors have legitimized and extended its implementation within China's pharmaceutical sector.

Agenda Setting Linkages

Agenda-setting in China's pharmaceutical sector enables domestic actors to shape the trajectory of legal implementation and regulatory reform. Farrand (2015) defines agenda-setting as the process of influencing early-stage policymaking by establishing political significance around specific issues (p. 487). In the Chinese context, this mechanism is evident in how organizations like HKUST and PhIRDA have framed pharmaceutical IP as a national priority, linking it to innovation policy, international credibility, and regulatory modernization. These actors helped institutionalize reform by embedding pro-stringency IP objectives into ongoing policy discourse, public investments, and cross-border regulatory harmonization. Their engagement exemplifies how domestic actors extend and deepen externally driven reforms by linking them to long-term industrial and scientific goals. The collaboration has witnessed the creation of innovation and research centers to facilitate pharmaceutical commercialization and

innovation in the Greater Bay Area and strengthen IP protections (The Hong Kong University of Science and Technology, 2023). The Guangdong-Hong Kong-Macao Greater Bay Area Center for Policy Research on BioMed Development is a designated forum for ongoing debate regarding drug regulations, and one of the leading issues here is the harmonization of the IP framework between Hong Kong and Mainland China. This program is aligned with China's broader IP reform agenda in response to the Fourth Amendment to China's Patent Law and the Phase One Trade Deal, pointing to the role of agenda-setting by domestic and international players in shaping policy orientation. Focusing on financing for research and development, which receives government backing, further deepens this pro-stringent IP agenda by inducing investment in drug innovation. The policy decisions that follow, such as China's NMPA approval of tislelizumab facilitated by both domestic and international actors, further solidify the role of IP protection with the pharmaceutical innovation base in China. Agenda-setting is essential in shaping the debate over the strictness of IP law in China's pharmaceutical industry.

International Pro-Stringent IP Framing Strategies

The international pharmaceutical company BeiGene outlined its appreciation for innovation in the pharmaceutical sector through its policy statement. BeiGene supports intellectual property as it values medicines being commercially available, where innovation can be created and profits can be generated in the pharmaceutical industry (BeiGene, 2022b, para. 19). The National Medical Products Administration, China's regulatory authority, has approved tislelizumab as a second- or third-line treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), which is significant because patients at this stage often have limited treatment options, making the availability of new therapies critical. This approval illustrates how IP protections facilitate the development and commercialization of innovative medicines that address

serious medical needs. The BeiGene statement has a framing strategy for access to medicines and public health. Caicun Zhou, M.D., Ph.D., the director of the Department of Oncology at Shanghai Pulmonary Hospital, director of Cancer Institute of Tongji University, and the principal investigator of the trial, explained, "In the global Phase 3 trial, tislelizumab demonstrated a significant improvement in overall survival and was well-tolerated in patients with previously treated NSCLC. The NMPA's approval of tislelizumab is welcoming news to the lung cancer community in China, and we hope this immunotherapy will help address the unmet needs in second- or third-line treatment of NSCLC" (BeiGene, 2022b, para. 5). This clinical evidence and regulatory approval reinforce BeiGene's framing of pharmaceutical innovation as essential for advancing patient care and justifies the importance of strong IP rights to incentivize such innovation. Framing is present as tislelizumab was regarded as having a positive impact and overall significance, as the "unmet need" fills a lacuna in patient care. This reasoning parallels the U.S. Phase One Trade Deal's vision of China's intellectual property environment, which explicitly links strong pharmaceutical IP protections to meet critical health needs through innovation. For instance, Section C of the Trade Deal, as previously indicated, states: "Pharmaceuticals are a matter concerning people's lives and health, and there continues to be a need for finding new treatments and cures, such as for cancer, diabetes, hypertension, and stroke, among others" (U.S.-China Economic & Trade Agreement, 2020, p. 5). The agreement underscores the importance of "adequate protection and enforcement of pharmaceutical-related intellectual property rights" as a means to "promote innovation and cooperation in the pharmaceutical sector and to better meet the needs of patients" (U.S.-China Economic & Trade Agreement, 2020, p. 5). This mirrors BeiGene's framing by emphasizing that adequate IP protections are essential for the development of innovative medicines that address medical needs, such as those treated with tislelizumab in later-

stage NSCLC patients. Thus, both BeiGene and the U.S. government's trade strategy employ a shared argument that robust IP rights can lead to better accessibility of critical medicines, linking innovation policy directly to public health outcomes.

Membership in the WTO provides the legal and normative framework by which the U.S. can impose tighter pharmaceutical IP reforms in China. The Phase One Trade Deal is an extension of U.S. efforts to get China to align its domestic law with its TRIPS obligations in the pharmaceutical sector. The U.S. has pushed China to fulfill its IP obligations, particularly as a member of the WTO. The 2000 Second Amendment to China's Patent Law was enacted to align with TRIPS and prepare China for WTO membership (Cao et al., 2021, p. 3719; Huang et al., 2023, p. 213). The U.S. utilized China's TRIPS commitments as leverage, including through bilateral pressure of the Phase One Trade Deal, to apply pressure for increased pharmaceutical IP enforcement. The U.S. effectively framed China's accession to the WTO not only as a trade agreement but as a commitment to global legal norms, which includes upholding IP safeguards as a market access requirement (Council on Foreign Relations, 2025, para. 6). As domestic firms are essential in China and voice their concerns while there is also U.S. influence, we can see these pro-stringent IP actors' vast sway in China, taking precedence over the pro-lax IP actors, who are not present as in India.

Framing Linkages

In China's pharmaceutical industry, framing also matters in aligning with the interests of either pro-stringent or pro-lax IP actors. Framing theory suggests that actors (such as multinational companies and nongovernmental organizations) use strategic communication to set the policy discourse of IP by how issues are defined and framed. MNCs and global advocacy networks apply tactics to place IP law on their agendas. For example, the domestic pharmaceutical company

BeiGene prioritizes innovation in terms of the public interest and commercial value of IP protection, advocating that patents facilitate the development of new drugs and a fair market structure (BeiGene, 2022b).

4.6 *Chugai v. Haihe*

The *Chugai v. Haihe* case is a landmark legal precedent in China's shifting pharmaceutical intellectual property landscape. It was a case in which Japanese innovator Chugai Pharmaceutical sued local generic producer Haihe Biopharma for patent infringement involving medicines. This case is significant because it assessed China's commitment to enforcing its strengthened patent laws following the Fourth Amendment, and it highlighted the reluctance of Chinese courts to uphold pharmaceutical patent rights. The ruling reflects broader trends in China's IP regime, under which both national and foreign IP promoters influence judicial practice and regulatory enforcement in the pharmaceutical sector.

In March 2023, the Intellectual Property Court of the Supreme People's Court (SPCIPC) released its Exemplary Cases of 2022, naming *Chugai v. Haihe* as China's first drug patent linkage case. The case is noteworthy as it concerns the drug patent linkage system integrated into China's Patent Law in 2020, which aims to resolve drug patent disputes at an early stage. However, this mechanism is still in its early stages of use in China. The SPCIPC selected this case due to its landmark application of the law (Xiaohiu, 2023, p. 27). Eldecalcitol Soft Capsule, a treatment for osteoporosis developed by Chugai Pharmaceutical, has been patented in China as Patent No. ZL200580009877.6 (Yang, 2022, para. 2). Wenzhou Haihe Pharmaceutical requested the approval of the National Medical Products Administration for the sale of a generic version without any alleged infringement. Chugai sought action in the Beijing Intellectual Property Court (BIPC). On

April 15, 2022, the court declared that the generic product made by Haihe did not infringe on Chugai's patent. This was upheld on August 5, 2022, by the SPCIPC (Xiaohiu, 2023, p. 27).

One of the key issues was the antioxidant excipient in Haihe's generic product. Chugai argued that the excipient infringed on its patent (Xiaohui, 2023, p. 27). Chugai claimed that the medicinal excipient included in the generic drug's formulation, as outlined in the technical solution of the application, constitutes patent infringement (Xiaohui, 2023, p. 27). The SPCIPC clarified that in drug patent linkage cases, the court's role is not to determine whether the actual technical solution utilized by the generic is the same as the patent, but to ascertain whether the application material constitutes infringement. The court dismissed Chugai's evidence requests, confirming that the application material was sufficient to determine the type of antioxidant used in the generic. As a result, the court ruled in favour of Haihe, stating that Chugai's patent did not cover the generic (Xiaohui, 2023, p. 28).

This ruling was significant because it meant that the Chinese court would not automatically favour patent holders' arguments just because there was a legal framework of the patent linkage system in place. Instead, the court analyzed whether the generic drug was indeed within the scope of the patent and hence ruled in favour of generics, much against the interests of patent holders and the general expectation that patent linkage would keep generics off the market prematurely. The *Chugai v. Haihe* case illustrates how the implementation of the Fourth Amendment to China's Patent Law, such as the introduced patent linkage system, relies on case-by-case judicial interpretation. Even though the amendment was intended to strengthen pharmaceutical patent enforcement by allowing pre-market resolution of disputes (Jones Day, 2020, p. 2; Che & Wang, 2020, para. 7), the court ruled in favour of Haihe, permitting the production of its generic cancer drug. As such, *Chugai v. Haihe* highlights the evolving application of China's reformed IP

framework and suggests that enforcement remains sensitive to judicial discretion, even with stronger legal protections (Lee, 2021, para. 1).

Although China has enacted significant IP reforms since 2020—such as patent linkage rules and increased damages for infringement—the *Chugai v. Haihe* judgment highlights the gap between reforms in law and practice. Despite more robust formal protection, the court decision in Haihe's favour suggests that enforcement remains adaptable, particularly in the pharmaceutical sector. This implies that, while China has tightened its legal system, judicial outcomes still reflect domestic priorities, like access to affordable drugs and promoting domestic industry. Rather than measuring IP stringency based solely on the application of legislative actions, this case highlights the importance of considering the enforcement of laws in practice. The law, in theory, appears stricter with IP, while in practice, China's IP regime can be adaptable, with enforcement decided by sector-based considerations and overarching policy goals.

Conclusion

As shown in Table 2, this timeline outlines key milestones in the evolution of China's pharmaceutical IP regime from 1984 to 2024. The takeaway message is that while U.S. trade pressure played a major role in driving China's adoption of formal IP protections, especially in the Phase One Trade Deal, subsequent reforms reflect a growing emphasis on domestic policy goals such as industrial upgrading, health system reform, and innovation-driven growth. The table illustrates the interaction between these international and domestic forces.

In my analysis of how China responded to foreign pressures and domestic constituencies in intellectual property law, I cite the works of several scholars, such as Deere (2009), who points out how foreign pressures, such as MNCs, influence IP policies within a country. Deere (2009) explains how multinationals exert economic coercion on the developing world to re-examine their

IP legislation in the face of sanctions or threats of withdrawal of foreign investment to push them onto the global pro-stringent IP agenda (p. 162). This coercion is central to addressing how China, as a rising power, fulfills global expectations of the U.S. and defends its domestic agenda. The United States' involvement in this process, mainly through the Special 301 report and bilateral investment treaties (BITs), grants economic rewards to countries in exchange for adopting stronger IP law (Shadlen et al., 2005, p. 65). These agreements link IP legal reform to more extensive trade and investment interests, encouraging countries like China to embrace international IP norms in exchange for better trade terms.

As my work focuses on international influence, as Deere (2009) highlights, in my research, it is also notable that incorporating domestic stakeholders in China's pharmaceutical IP system helps to comprehend the nuances. The U.S. pressure on Chinese IP legislation, as evident in the Phase One Trade Deal and the Fourth Amendment to China's Patent Law, demonstrates how external pressure shapes the domestic legal system. Local pharmaceutical companies have spearheaded the pro-stringent IP camp by creating a policy landscape aligned with global standards, including the construction of new R&D centers and ambitious IP protection and investment. Apart from U.S. pressure, local pharmaceutical companies have shaped their pro-stringent sentiment due to their own self-interests as well.

China's IP landscape was influenced by U.S. pressure in the pharmaceutical sector. China amended the 1984 Patent Law in 1992 due to pressure from the U.S. (Cao et al., 2021, p. 3719). Globalization and U.S. economic dominance have influenced countries like China to align their patent laws with U.S. practices. As a key U.S. trade partner, China faces ongoing pressure to alter its IP landscape. China has incorporated nearly all key U.S. patent law principles, including the doctrine of equivalents and the prosecution history of estoppel (Sun, 2005, p. 11). Chugai had

originally claimed a broad range of antioxidants in its patent for eldecalcitol. During a separate invalidation challenge, Chugai amended its claims, narrowing the antioxidant to dl-α-tocopherol only (Yang, 2022, para. 5). The court, therefore, concluded that the plaintiff abandoned the antioxidant that was used by the generic of Haihe and thus, the generic medicine was not within the scope of the plaintiff's patent protection and so the court rejected the appeal. The infringement case was dismissed (Yang, 2022, para. 5). The concept of estoppel refers to “a legal rule that prevents someone from changing their mind about something they have previously said is true in court” (Cambridge University Press, n.d.). In the *Chugai v. Haihe* case, the court applied the principle of estoppel, which prevents a party from contradicting positions it previously held. Since Chugai had narrowed its patent claims during an earlier invalidation proceeding, explicitly limiting the antioxidant to dl-α-tocopherol, it was barred from later asserting that broader antioxidant coverage applied. This meant Chugai could not claim infringement against Haihe’s generic drug, which used a different antioxidant, ultimately leading the court to dismiss the case. Estoppel thus protected Haihe by ensuring that Chugai could not expand the scope of its patent after having narrowed it to maintain its validity.

Since China was included on the Special 301 report to comply with IP regulations, this demonstrates U.S. influence in China. China was seeking to fulfil the WTO requirements for IP. The U.S. and China negotiated, and China was under "intense stress" from combating infringement and counterfeits (The Supreme People's Court of the People's Republic of China, 2025). China had to comply with international regulations in IP based on WTO obligations, while U.S. pressure also put China in a bind by trying to make China implement and alter its IP legislation, especially following the Phase One Trade Deal.

China was surprisingly willing to make concessions in the pharmaceutical sector compared to other industries, such as technology, with its IP protections, which will be explained further in the next and final chapter. It is typically not assumed that the U.S. will dictate domestic policies, so accommodating pharmaceuticals is interesting. China does not have a large domestic drug industry akin to India, so it can give the U.S. what it desires, which is more IP protection. In India, advocacy groups and civil society are prominent, enabling them to push against IP protections. In contrast, China has fewer pro-flexibility actors like those in India, and more pro-stringent actors domestically and internationally.

Apart from foreign pressures, there are also the interests of domestic actors. National strategies, including the *Healthy China 2030* and *Full-Chain Support for Innovation,* exemplify how pharmaceutical IP reform in China is embedded in broader state-led efforts to promote innovation, reduce regulatory barriers, and align industrial development with public health priorities.

Deere's (2009) study examined how international pressure from outside a country influences the making of IP law within a country. The Chinese case, however, illustrates how domestic actors, such as drug companies, courts, and government institutions, shape policy to serve both domestic and foreign interests. While foreign pressure from the United States has driven reforms like the Fourth Amendment, China has also proactively pursued pharmaceutical IP development through state-led innovation strategies. For example, government programs such as *Healthy China 2030* explicitly link public health and industrial strategies to stronger IP protections, encouraging domestic drug innovation and enforcement of patent rights. Regulatory reforms under the National Medical Products Administration, including accelerated approval pathways, further demonstrate China's attempt to align IP policy with domestic public health and economic goals.

These state-led efforts reflect a domestic orientation that goes beyond reactive compliance, showing how China is actively managing foreign pressure while advancing its strategic interests in the pharmaceutical sector. While it has been under immense pressure from the U.S. to align with TRIPS, it has also faced increasing demands from domestic pharmaceutical firms for less aggressive IP policies. As the U.S. has pressured China to adopt IP laws, the actual enforcement has not entirely aligned with these pressures. The *Chugai v. Haihe* court case illustrates a divergence from expectations, as the patent linkage system was not strictly enforced, and the ruling ultimately favoured Haihe, allowing it to produce generic drugs despite the existing patent. Moreover, examining the national level in China, where IP is prevalent in pharmaceutical firms, reveals a nuanced approach. Certain pro-stringent IP actors also seek to ensure access to medicines, a stance that aligns with pro-lax IP actors in India. From an international perspective, China's IP policies are partly explained by the theory of authors like Deere (2009), who argue that China implements strict IP laws in response to U.S. pressure and international norms, which is indeed the case. Still, in practice, enforcement reveals nuances. In the Haihe case, the Supreme People's Court ruled in favour of generics rather than strengthening patent-linkage protections with a pro-stringent IP result. Furthermore, domestic pharmaceutical companies also shape and support IP while ensuring access to medicines. For instance, BeiGene publicly frames IP rights as essential to encouraging pharmaceutical innovation while emphasizing the need to address unmet medical needs, particularly for cancer treatment (BeiGene, 2022b). Therefore, I argue that the influence of domestic and international actors helps provide a comprehensive account of the role of IP in China. The international influence of the U.S. plays a considerable role in implementing IP law. However, actual IP enforcement worked differently in the Haihe case, as courts ruled in favour of generic drugs, which Haihe had wanted.

My chapter builds on Deere (2009), Shadlen et al. (2005), and Dellmuth & Bloodgood (2023) to show how both foreign and domestic pressures shape China's IP law. While Deere (2009) highlights pro-stringent actors and TRIPS compliance in developing countries, I add nuance by examining how China, as a rising power, manages U.S. pressure and domestic interests within its state-led IP system. The Phase One trade deal accelerated reforms like the Fourth Amendment, which aligns with U.S. demands through patent linkage and term extensions. However, China mediated external obligations with domestic goals by selectively enforcing these rules, as seen in the Haihe case and from domestic initiatives such as the collaboration between the PhIRDA and HKUST,

4.7 **Comparisons Against Alternative Explanations for China**

Market Orientation Argument

It follows from classical economic theory about the strictness of IP that more open economies will have more robust IP protections. In open economies, foreign competition and the willingness to attract international investment prompt governments to strengthen IP regulations, as they are seen to be essential to advance innovation and technological development (Maskus, 2001, p. 471). This model assumes that open economies rely more on foreign collaboration and technology transfer, where strong IP protection exists to ensure the benefits of such investments.

However, as a more closed economy, China makes such an argument untenable. Although classical economic theory links IP stringency to market openness, China complicates this model. It has increasingly adopted stronger IP protections despite remaining a state-led and semi-closed economy. These changes took place across multiple reforms. The Third Amendment to the Patent Law, enacted in 2008, aimed to enhance IP implementation by strengthening patentability requirements, encouraging patent usage, and clarifying rules for compulsory licensing and the

protection of genetic resources (Yang & Yen, 2010, p. 4). This was followed by the Fourth Amendment in 2020, a pivotal reform that introduced patent linkage, patent term extensions, and increased damages for infringement (Yao, 2024, p. 2).

China has also strengthened its judicial institutions to govern IP rights better. The introduction of specialized intellectual property courts in 2014 marked a pivotal effort to institutionalize the rule of law within China's IP regime (Lee & Zhang, 2017, p. 901). These courts were created to operate more independently than existing IP tribunals within the People's Courts, and their role is central to enforcing private rights and reviewing administrative decisions. Since IP systems rely on coordination between lawmakers, regulators, and neutral adjudicators, the establishment of dedicated courts improved the overall credibility of China's pharmaceutical IP regime (Lee & Zhang, 2017, p. 901). The *Chugai v. Haihe* case exemplifies how these courts are becoming increasingly adept at handling complex pharmaceutical patent disputes.

The internationalization of IP norms aligns with the growing acceptance of intellectual property protection as a part of China's global competitiveness policy. However, these reforms were prompted more by the strategic behaviour of the government authorities than by market forces. Policy reform is supported by industrial policies that demand more stringent IP policies. The *Healthy China 2030* vision, launched in 2016, represents the most significant health governance reform in decades, channeling public investment into biopharmaceutical R&D (Haynes, 2025, para. 9). The *Full-Chain Support for Innovation* initiative of 2024 introduced targeted support mechanisms for domestic drug development, further driving demand for reliable IP protection (Deloitte, 2025, para. 1). These developments demonstrate a gradual increase in IP protection, driven by international pressure and by China's innovation and industrial policy agendas. China's Fourth Amendment to its Patent Law, including its patent linkage system,

represents significant steps taken by government authorities to meet international expectations, particularly those of the U.S., as outlined in the Phase One Trade Agreement. Hence, China's evolution of IP law represents state-led reform influenced by domestic and international actors rather than the open economy model that would otherwise lead to more robust protections for IP.

Regime Type Argument

The regime-type hypothesis suggests that democratic regimes will have more robust intellectual property rights protection since they are accountable to entrepreneurs, civil society, and international norms. Laplume et al. (2014) express that the stronger a country's democratic regime, the more positive the impact of IPR on the probability of entrepreneurs adopting the latest technologies (p. 815). That reasoning indicates that democracies, due to openness, legal checks, and competitive pressure, should uphold robust IP laws, while autocracies may lack such drivers. China, however, does not conform to this model. Although an autocratic regime, China has significantly fortified its pharmaceutical IP system in recent years, not because it has yielded to democratic pressures but because it has been strategic in response to WTO/TRIPS pressures, U.S. trade pressure, and domestic industrial policy goals. The implementation of patent linkage, data exclusivity, and specialized IP courts indicates that state-led planning of innovation and international influence, rather than regime type, explains China's legal reforms. To this extent, China demonstrates how authoritarian leadership can create strong IPR protections, not through democratic accountability, but through centralized policymaking to propel economic modernization and obtain international legitimacy.

Even as China officially strengthened its IP regime for medicines through legislative reforms, such as the Fourth Amendment, and established a patent linkage system, the actual implementation of the law remains interpretive and discretionary, especially in matters of public

health and the accessibility of generic drugs. The *Chugai v. Haihe* case is a notable example; despite patent protection, the courts ruled in favour of generic manufacturer Haihe, permitting the manufacture of eldecalcitol and signalling that judicial discretion still governs pharmaceutical IP enforcement. This implies that China's commitment to pharmaceutical IP reform is driven by external pressure and domestic priorities as well. While U.S. pressure through the Phase One Trade Deal and WTO/TRIPS obligations triggered reform in the pharmaceutical sector, China enforces IP differently in the technology sector, where policy goals are matched by innovation capabilities, as will be explored in the final chapter. With China being influenced by the U.S. regarding IP stringency, and as generics are valued more highly than strict IP in the *Chugai v. Haihe* case, China's strategy thus combines firm formal IP commitments with selective enforcement.

Chapter 5: Conclusion

This thesis has examined the following research question: What factors explain the variation in the stringency of intellectual property (IP) law implementation in emerging countries? Why do certain countries end up with stricter domestic IP laws than others? The study illustrates that although other explanations, such as market openness and regime type, may be used as explanations for these questions, the most insightful explanation is found in the relationship between international and domestic actor influence.

India serves as a test of my hypothesis. It supports the hypothesis that countries where pro-lax actors, such as public health NGOs and access-to-medicine advocates, hold greater influence relative to pro-stringent actors are more likely to adopt flexible pharmaceutical IP regimes that prioritize affordability and access. Although both coalition types are present, pro-lax actors have been more effective in shaping legal and policy outcomes. Public health organizations, such as MSF, CPAA, and Oxfam, have influenced legal discourse through campaigns like the "Drop the

Case," which, although not directly cited in court rulings as shaping influence, aligned with key judicial decisions. The 2005 Patents (Amendment) Act, the rejection of Novartis's patent under Section 3(d), and the granting of a compulsory license in *Bayer v. Natco* all reflect India's alignment with access-oriented IP policies over global patent standards and illustrate the impact of pro-lax actors' dominance.

The case of China supports my hypothesis that countries where pro-stringent IP coalitions are more influential than pro-lax actors are more likely to adopt stricter pharmaceutical IP protections. While both coalition types exist, pro-stringent actors such as PhIRDA, MNCs, and key state agencies have dominated policy venues. U.S. trade pressure, particularly through the Phase One Deal, pushed for specific reforms, including the patent linkage system and the Fourth Amendment to the Patent Law. However, the continuation and deepening of these pro-stringent reforms have been driven by domestic priorities, with state-led initiatives such as Healthy China 2030 and the Full-Chain Support for Innovation of 2024, framing pharmaceutical innovation as central to national development. These developments reflect the sustained dominance of pro-stringent actors and support the hypothesis.

This thesis sought to account for why two large emerging economies, China and India, have followed divergent trajectories in pharmaceutical IP law stringency, despite their shared WTO/TRIPS commitments. The analysis began by following the international framework, established by the TRIPS Agreement, which sets minimum patent standards (Su, 2000; Yu, 2009). The Doha Declaration reaffirms the imperative to protect public health through flexibilities, such as compulsory licensing (Abbott, 2002; Harris, 2010). Nonetheless, implementation has diverged, driven by the domestic and international political and economic arrangements of each country, as well as the multitude of actors shaping the political landscape within them.

In India, pro-lax IP stakeholders, including generic pharmaceutical manufacturers, health NGOs, and the judiciary, have utilized TRIPS flexibilities to prioritize access to affordable medicines. Starting with the process-only patent regime of the 1970 Patents Act, India developed a thriving generics industry (Papaioannou et al., 2016; Grover, 2018). Even when the TRIPS-compliant amendment of 2005 restored product patents, provisions like Section 3(d) against evergreening and compulsory licensing remained as usable flexibilities (Liu, 2015). Landmark rulings such as *Novartis v. Union* enforced stringent efficacy requirements under Section 3(d) (Gabble & Kohler, 2014), and *Bayer v. Natco*, India's first compulsory license for Nexavar (Onderkova, 2021; Mueller, 2007), demonstrate how domestic stakeholders have successfully fought against patent monopolies despite U.S. pressure through the U.S. Special 301 report.

China's trajectory is in sharp contrast. Through consecutive Patent Law amendments in 2000 and 2008, China progressively aligned with international standards, such as TRIPS, and faced pressure from the United States Trade Representative (Deng, 2010; Cao et al., 2021). The Fourth Amendment of China's Patent Law was created following the U.S.-China Phase One Trade Deal, which introduced a patent linkage system, patent term extensions, and punitive damages (Jones Day, 2020; U.S.-China Economic & Trade Agreement, 2020). Subsequently, domestic pro-stringent IP advocates, such as PhIRDA and HKUST, deepened these reforms through innovation programs, through the creation of research centers via a Memorandum of Understanding (The Hong Kong University of Science and Technology, 2023). The Healthy China 2030 Policy (Haynes, 2025) and the Full-Chain Support for Innovation program (Deloitte, 2025) were domestic strategies to uphold national priorities in China. As *Chugai v. Haihe* showed, however, Chinese courts continue to exercise discretion to favour generics when public health or industrial interests dictate (Xiaohui, 2023; Yang, 2022; Lee, 2021).

Timing was an important factor in likely shaping actor influence in both India and China. In India, pro-lax groups like MSF and the CPAA mobilized after the 2005 Patents (Amendment) Act, using new legal tools such as Section 3(d) to influence outcomes, as seen in the Novartis case. Their continued involvement reflects sustained impact on IP interpretation. In China, U.S. pressure following the 2020 Phase One Trade Deal led to the 2021 Fourth Amendment, followed by the 2024 Full-Chain Innovation Initiative. Earlier efforts, such as the 2016 *Healthy China 2030* policy, laid the groundwork for stronger IP implementation. This sequence shows how both international and domestic actors may have shaped reform at critical junctures.

The two alternative explanations — regime type and market openness — do not account for these patterns. Classical theory suggests that open economies tend to have more robust IP protection (Maskus, 2000a). In contrast, semi-closed, state-led China has enacted more stringent laws than the more open economy of India. Similarly, democratic regimes are commonly viewed to enforce IP more stringently (Laplume et al., 2014), yet the democratic authoritarian regime of India has a more lenient IP regime than authoritarian China. These discrepancies highlight the inadequacies of market orientation or regime-type models alone.

Alternatively, this thesis argues that the variation in IP stringency is best explained by the contest between pro-stringent and pro-lax actors in both international and domestic spheres. On the pro-stringent side, U.S. trade and diplomatic levers, multinational pharmaceutical companies, and domestic pharmaceutical companies push for stronger IP protections. In contrast, pro-lax actors, including international non-governmental organizations, public health advocacy groups, and certain domestic pharmaceutical companies, advocate for more flexible IP regimes to promote access to medicines and broader public welfare. The dynamic interaction between these opposing coalitions shapes the trajectory of IP policy outcomes. In India, robust pro-lax IP networks used

TRIPS flexibilities to protect generics and public health. In China, state-led pro-stringent IP actors institutionalized stricter IP implementation. While domestic pharmaceutical companies and the U.S. sought to advance their IP ideals, courts adopted a flexible and pragmatic stance in their judicial decisions.

By incorporating levels of influence, this study informs a more sophisticated and nuanced understanding of global IP governance. It shows that the influence of power between domestic and international actors ultimately determines how IP norms are implemented. For policymakers, it is essential to be aware of these dynamics, as successful IP regimes must reconcile international commitments with domestic public health, innovation, and industrial priorities, all of which are mediated through stakeholder input and judicial oversight.

In both India and China, intellectual property advocacy has followed distinct trajectories, shaped by the types of actors involved and the prevailing political context. In India, civil society pressure enables INGOs, such as MSF, and NGOs, like the CPAA, to employ all four strategies: lobbying, framing, venue shopping and agenda-setting, effectively positioning access to medicines as a public right. These strategies are particularly effective in legal venues, as seen in the Novartis and Bayer cases. Conversely, MNCs operating in India rely on lobbying, such as the OPPI and opinions expressed by the Pharmaceutical Research and Manufacturers of America. However, there were lax results by the country's independent judiciary and robust advocacy groups. In China, where public activism is limited, domestic firms and MNCs like BeiGene and Haihe framed their arguments in ways that aligned with government priorities, emphasizing themes like innovation and sustainability. While U.S. pressure, including the TRIPS framework and Special 301 reports, prompted China to adopt reforms like the Fourth Patent Law Amendment, domestic

actors also contributed to facilitating IP reforms. For instance, the MoU between HKUST and PhIRDA institutionalized IP policy coordination.

Given their scale and regional influence, India and China's pharmaceutical IP policies reflect domestic priorities, global pressure, and strategic innovation goals. India's strong generic industry and active civil society suggest ongoing resistance to the stringent IP standards of TRIPS, especially in the pharmaceutical sector. Its rising biotechnology sector may support IP strengthening in high-value areas, such as biosimilars (Jayakumar, 2025, para. 8). China is expanding exclusivity protections and aligning IP with state-led innovation, aiming to become a global leader in biopharmaceuticals by 2030. Both regions are modernizing regulations, investing in supply chains, and pursuing international partnerships, signalling that industrial strategy and actor influence, rather than regime type, will drive future IP policy. As regional leaders, countries are likely to shape the IP norms of neighbouring countries through trade and regulatory alignment. The future of pharmaceutical IP in my case studies will thus hinge on how innovation, access, and geopolitical strategy are made and managed.

Limitations and Future Research Avenues

This thesis draws on qualitative case studies of China and India based on legislative texts, court decisions, and secondary research on advocacy campaigns, trade associations and pharmaceutical companies. Its conclusions may not fully generalize to other emerging markets or formal enforcement dynamics. Future research analysis could develop a quantitative IP stringency index by combining statutory provision metrics, prosecution backlogs, patent linkage utilization, and compulsory licensing to compare legislative and enforcement outcomes in a larger set of countries, such as Brazil and South Africa. Expanding sectoral coverage to sectors such as digital data privacy or information technology would test whether the same interplay of international

pressures and domestic actors holds beyond pharmaceuticals. Methodologically, incorporating primary fieldwork, such as interviews with industry lobbyists, pharmaceutical representatives, judges, and public health activists, would illuminate informal channels of influence and real-time decision-making that are not captured in public documents. Longitudinal studies on the post-COVID-19 landscape, especially regarding vaccine IP waivers, would illuminate how acute public health crises reshape the concerns between IP protection and public health access.

5.1 Future Avenues for the Technology Sector

In the technology sector, China has pro-lax attitudes towards taking advantage of less stringent IP protections for technology transfer and industrial development, particularly in areas with weak IP protections (Schiappacasse, 2003, p. 165). The difference in approach to IP protection between the technological and pharmaceutical sectors reflects differing priorities. In the technology sector, China maintains a less robust IP implementation to encourage technology transfer from foreign firms, thereby enabling rapid innovation and growth by domestic firms. The benefits will be that it boosts their industrial development, which has raised concerns over IP theft and forced technology transfers. In 2017, following a seven-month investigation into China's intellectual property system, the Trump administration accused China of engaging in forced technology transfer (Huang et al., 2023, p. 211). Forced technology transfer typically means that the U.S. and other foreign companies are expected to share their technology with China by partnering with local firms through joint ventures, allowing China to access the country's large and appealing market (Huang et al., 2023, p. 211). The sector-specific differences in China can allow for nuanced explorations.

China is a behemoth in the technology sector, as it envisions its industrial policy to thrive by utilizing innovation from other regions. China’s "Made in China 2025" policy, introduced in

2015 by Premier Li Keqiang, is a long-term strategy to shift manufacturing from a quantity-driven to an innovation-based approach, seeking weaker IP protection to boost global competitiveness and build a world-class technology industry. To realize this vision, the government launched a planning structure called “1+X” where “1” refers to the overarching plan, and "X" represents sector-specific guidelines developed jointly by over 20 government ministries and agencies, including the Ministry of Industry and Information Technology (The State Council of the People's Republic of China, 2017). These efforts targeted industries like smart manufacturing, high-end equipment, and green technology, encouraging local governments, enterprises, universities, and financial institutions to boost China’s manufacturing industry and competitiveness. The plan relied on public-private engagement, positioning innovation, craftsmanship, and entrepreneurship as key drivers of a new industrial era. Premier Li emphasized the plan's emphasis on quality and modernization, which demonstrates the role of domestic institutions in driving China's technological advancements. The strategy outlines a three-phase vision: to become a manufacturing powerhouse by 2025, promote manufacturing advances by 2035, and achieve top-level manufacturing and innovation by 2049 (Nair, 2022). It emphasizes a market-oriented approach backed by the government. It outlines nine key priorities for developing China’s manufacturing sector, including enhancing innovation, connecting IT with industry, creating domestic brands, and adopting green manufacturing, while advancing 10 key high-tech sectors like aerospace, robotics, biotechnology, and medical devices (Nair, 2022). Given the higher strategic value China places on its technology sector, the government has been willing to offer concessions in the pharmaceutical domain, such as strengthening the patent linkage system and expanding data exclusivity to bolster its reputation as a compliant WTO member and integrate more deeply into the global trade system. Therefore, this would allow China to gain from foreign innovation and

imports. I expect that in the technology sector, China would want more lax IP laws so that it can utilize the knowledge from other firms for innovation and economic benefits.

Although China has made progress in early-stage drug discovery, it remains reliant on foreign companies to bring innovative therapies to market (Groenewegen-Lau, 2025, para. 1). This is mainly because domestic demand for high-cost treatments and the supporting commercial infrastructure are still underdeveloped. As a result, Chinese pharmaceutical firms often rely on global partnerships and licensing agreements to conduct late-stage development and ensure market access. Furthermore, several pharmaceutical breakthroughs in China have been introduced in international markets, including fruquintinib for metastatic colorectal cancer, tislelizumab from BeiGene, and toripalimab by Junshi Biosciences (The State Council of the People's Republic of China, 2024). These launches often occurred through partnerships with American and European companies. This reveals China's dependence on foreign regulatory approval processes, distribution networks, and access to global markets for commercializing its high-end pharmaceutical innovations. In contrast, China enforces weaker IP protections in the technology sector to accelerate domestic innovation and support industrial policy goals. Although the Phase One Trade Deal included U.S. demands for stronger IP protections across multiple sectors, such as technology, China chose to address these demands through reforms in the pharmaceutical sector via the Fourth Amendment to the Patent Law. This choice reflects the strategic importance of the technology sector to China's national agenda. It helps explain the smoother implementation of pharmaceutical IP reforms, given the lack of strong pro-lax IP coalitions in that sector. The Made in China 2025 policy portrays the influence of domestic government agencies on shaping the sector, which aligns with my theoretical framework, which states that domestic actors influence IP implementation.

As the U.S. influenced IP in the pharmaceutical sector, the technology sector's lack of IP implementation was due to domestic government policies, such as "Made in China 2025", which went against IP since they prioritized their own goals. China selectively implemented U.S.-influenced IP reforms in the pharmaceutical sector, where compliance not only aligned with domestic health and innovation goals but also served to ease U.S. trade pressure. The alignment of these reforms with national policy priorities such as *Healthy China 2030* and the *Full-Chain Support for Innovation* initiative, the interests of domestic pharmaceutical firms and the low political cost of implementation made China's compliance strategically beneficial. In contrast, China resists similar reforms in the technology sector, where strong IP protections conflict with national initiatives like the “Made in China” initiative *2025*. This sectoral divergence illustrates that U.S. pressure shapes China’s IP law only when it complements, rather than impedes, China’s core domestic priorities. A further examination of the tech sector is an avenue for future research. Overall, by examining how diverse actors engage with intellectual property in the pharmaceutical sector, this thesis demonstrates that competing interests actively seek to shape both the course of innovation and the governance of global health.

References

Abbas, M. Z. (2021). An evaluation of the Indian legislative framework for patent opposition Mechanism: Merits and demerits of the procedural safeguard. *Journal of Intellectual Property Studies*, *5(2)*, 62-86.

Abbott, F. M. (2002). The Doha Declaration on the TRIPS Agreement and public health: Lighting a dark corner at the WTO. *Journal of International Economic Law*, *5(2)*, 469-506.

Abbott, F. M. (2013). The judgment in Novartis v. India: What the Supreme Court of India said. *Intellectual Property Watch*, 1-4.

Abu Dhabi Investment Office organizes field visit for delegation from China Chamber of Commerce for Import & Export of Medicines & Health Products. (2018, September 9). *Albawaba.* Retrieved from LexisNexis.

Adams, S. (2010). Intellectual property rights, investment climate and FDI in developing countries. *International Business Research*, *3*(3), 201-209.

Ahmad, K. (2005). India's new patent bill threatens generic industry. *The Lancet. Infectious Diseases*, *5*(5), 265.

Baker, B. K. (2012, April 1). Why global health activists are fired up about Novartis. *HIV i-Base*. https://i-base.info/htb/16267

Basheer, S. (2005). India's tryst with TRIPS: The Patents (Amendment) Act. *Indian Journal of*

Law and Technology, *1*(1), 15-46. https://doi.org/10.55496/EPGU2741

Basheer, S, & Reddy, P. (2008a). Ducking TRIPS in India: Saga involving Novartis and the legality of section 3(d). *National Law School of India Review*, 20(2), 131-155.

Basheer, S., & Reddy, T. P. (2008b). The efficacy of Indian patent law: Ironing out the creases in section 3(d). *SCRIPTed,* 5(2), 232-266.

Batok, N. (2024, November 15). The role of multinational corporations in global economy: How MNCs influence economic development, trade, and technological progress across borders. *Meer.* https://www.meer.com/en/82735-the-role-of-multinational-corporations-in-global-economy

Batra, N. (2022). Lessons from India's implementation of Doha Declaration on TRIPS and Public Health (No. 166). *South Centre*, 1-28.

Bauza, P. (2019, May 9). Medicines shouldn't be a luxury: It's time to stop big pharma's profiteering. *Médecins Sans Frontières Access Campaign*. https://www.msfaccess.org/medicines-shouldnt-be-luxury-its-time-stop-big-pharmas-profiteering

Bazzle, Timothy. (2011). Pharmacy of the developing world: Reconciling intellectual property rights in India with the right to health: TRIPS, India's patent system and essential medicines. *Georgetown Journal of International Law*, 42(3), 785-816.

BeiGene. (2022a). *Our global statement on patents & intellectual property*.

https://www.beigene.com/wp-content/uploads/2022/12/Patent-Statement-Draft-11.1.22-FINAL.pdf

BeiGene. (2022b, January 6). *China NMPA approves tislelizumab as second- or third-line treatment for patients with locally advanced or metastatic non-small cell lung cancer*. https://ir.beigene.com/news/china-nmpa-approves-tislelizumab-as-second-or-third-line-treatment-for-patients-with-locally-advanced-or/3e337eaa-a5f6-4368-95e0-3e0d35a71254/

BeiGene. (2023, April 25). *BeiGene announces goals focused on sustainable growth and workforce diversity in a new ESG report*. https://ir.beigene.com/news/beigene-announces-goals-focused-on-sustainable-growth-and-workforce-diversity-in-new-esg-report/fa1710c5-d665-4f09-95b2-d58a45a0137d/

BeiGene. (2025). *Our strategy*. https://beigene.com/responsibility/our-strategy/

Bennett, W. J. (2014). Indian pharmaceutical patent law and the effects of Novartis AG v. Union of India. *Washington University Global Studies Law Review,* 13(3), 535-558.

Bhattacharya, R. (2008). Are developing countries going too far on TRIPS? A closer look at the new laws in India. *American Journal of Law and Medicine,* 34(2), 395-421.

Bill & Melinda Gates Foundation. (n.d.). *India: Health*. https://www.gatesfoundation.org/our-work/places/india/health

Binderkrantz, A. (2005). Interest group strategies: Navigating between privileged access and

strategies of pressure. *Political Studies*, *53*(4), 694-715.

Biotechnology Innovation Organization. (2024, January 30). *BIO comments to USTR as part of the 2024 Special 301 review highlighting global IP concerns*. https://www.bio.org/letters-testimony-comments/bio-comments-ustr-part-2024-special-301-review-highlighting-global-ip

Borah, R. (2024). Growing India–U.S. ties and what it means for India–Russia ties. *Australian Journal of International Affairs*, *78*(3), 379-386.

Brander, J. A., Cui, V., & Vertinsky, I. (2017). China and intellectual property rights: A challenge to the rule of law. *Journal of International Business Studies*, *48*(7), 908-921.

Bristow, M. (2010, June 7). Chinese AIDS group feels government pressure. *BBC News.* http://news.bbc.co.uk/1/hi/world/asia-pacific/8717429.stm

Bronshtein, D. M. (2008). Counterfeit pharmaceuticals in China: Could changes bring stronger protection for intellectual property rights and human health? *Pacific Rim Law & Policy Journal,* 17(2), 439-466.

Budget 2025: Pharma sector calls for tax breaks, R&D support, and patent box overhaul. (2025, January 7). *The Economic Times.* https://pharma.economictimes.indiatimes.com/news/pharma-industry/budget-2025-pharma-sector-calls-for-tax-breaks-rd-support-and-patent-box-overhaul/117013210

Cambridge University Press. (n.d.). Estoppel. In the *Cambridge Dictionary*.

https://dictionary.cambridge.org/dictionary/english/estoppel

Cancer Patients Aid Association. (n.d.). *Cancer Patients Aid Association*. https://cancer.org.in/

Cancer Patients Aid Association. (2013, April 2). *Novartis loses landmark India patent case on Glivec*. https://cancer.org.in/advocacys/novartis-loses-landmark-india-patent-case-on-glivec-reuters-mumbai-new-delhi/

Cao, Z., Chen, Y., Jiang, W., & Li, W. (2021). The legislative approach and system improvement of China's compulsory licensing for drug patents. *Drug Design, Development and Therapy*, 3717-3731.

Cardwell, R., & Ghazalian, P. L. (2012). The effects of the TRIPS Agreement on international protection of intellectual property rights. *The International Trade Journal*, *26*(1), 19-36.

Cardwell, R., & Ghazalian, P. L. (2015). The TRIPS Agreement as a coercive threat: Estimating the effects of trade ties on IPR protection regimes. *Global Economy Journal*, *15*(2), 257-275.

Chalmers, A. W. (2013). Trading information for access: Informational lobbying strategies and interest group access to the European Union. *Journal of European Public Policy*, *20*(1), 39-58.

Chaudhry, S. (2011). Product v. process patent in India. *SSRN,* 1-21.

Che, J., & Wang, Y. (2020, October 19). Breaking news: China passes fourth amendment to the

Chinese patent law. *China Patent Strategy.* https://chinapatentstrategy.com/breaking-news-china-passes-fourth-amendment-to-the-chinese-patent-law/

Chen, H. (2023, June 28). How can we achieve a healthy China by 2030? *World Economic Forum.* https://www.weforum.org/stories/2023/06/how-can-we-achieve-a-healthy-china-by-2030/

China Alliance of PLWHA. (n.d.). *China Development Brief*. https://chinadevelopmentbrief.org/ngos/china-alliance-of-plwhacap/

China National Intellectual Property Administration. (2021). *Comprehensive reinforcement of IP protectio*n. https://english.cnipa.gov.cn/module/download/down.jsp?i_ID=176472&colID=2936

China Pharmaceutical Innovation and Research Development Association. *PhIRDA*. (n.d.). http://en.phirda.com/about.html

Choudhry, S., & Stacey, R. (2013). International standards for the independence of the judiciary. *The Center for Constitutional Transitions at NYU Law & Democracy Reporting International Briefing Papers*, 1-14.

Cipla. (n.d.). *HIV/AIDS*. https://www.cipla.com/our-offerings/our-therapies/hiv-aids

Cipla breached patent rights by slashing cancer drug price: Bayer Pharma. (2012, May 10). *The Economic Times* https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla-

breached-patent-rights-by-slashing-cancer-drug-price-bayer-pharma/articleshow/13078231.cms

Council on Foreign Relations. (2025, February 6). *What happened when China joined the WTO?* https://education.cfr.org/learn/reading/what-happened-when-china-joined-wto

Deane, L. (2021, July 15). Will there be a civil society in the Xi Jinping era? Advocacy and non-profit organising in the new regime. *Made in China Journal.* https://madeinchinajournal.com/2021/07/15/will-there-be-a-civil-society-in-the-xi-jinping-era-advocacy-and-non-profit-organising-in-the-new-regime/

Deere, C. (2009). *The implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries*. New York: Oxford University Press.

Dellmuth, L., & Bloodgood, E. A. (2023). *Advocacy group effects in global governance: Populations, strategies, and political opportunity structures*. Palgrave Macmillan. https://doi.org/10.1007/978-3-031-27864-8

Deloitte. (2025, February 21). *Full-chain support for innovation: Chinese government continues its supporting to the biopharma industries, and implications to the industry companies.* https://www2.deloitte.com/cn/en/pages/life-sciences-and-healthcare/articles/full-chain-support-for-innovation.html

Deng, M. M. (2010). China patent law and implications for international pharmaceutical

companies. *Expert Review of Clinical Pharmacology*, *3*(6), 713-716.

Department for Promotion of Industry and Internal Trade. (2023, September 15). *Office of the Controller General of Patents, Designs and Trade Marks* https://dpiit.gov.in/about-us/attached-subordinate-offices/office-controller-general-patents-designs-trade-marks

Department of Pharmaceuticals. (2024, March 12). *National policy on research & development and innovation in the pharma-med tech sector in India.* https://pharma-dept.gov.in/policy/national-policy-research-development-and-innovation-pharma-med-tech-sector-india

Department of Science & Technology. (2018, July 10). *Drugs & pharmaceutical research*. https://dst.gov.in/drugs-pharmaceutical-research

Differding, E. (2017). The drug discovery and development industry in India—Two decades of proprietary small- molecule R&D. *ChemMedChem*, *12*(11), 786-818.

Dolcerocca, A. (2016). Intellectual property monopolies: Towards a new mercantilism? *Marmara University Journal of Political Science, 4*(1), 217–235. https://doi.org/10.14782/sbd.2016117954

Dr. Reddy's Laboratories. (n.d.). *Innovation in R&D top focus*. https://www.drreddys.com/media/1062197/innovation-in-rd-top-focus.pdf

Drug Times. (2024, July 6). *The "comprehensive chain support plan for the development of*

innovative medicines" has been reviewed and approved, and the industry has responded enthusiastically!

https://www.drugtimes.cn/2024/07/06/thecomprehensivechainsupportplanforthedevelopmentofinnovativ/

Du, D. (2014). Novartis AG v. Union of India: "Evergreening," TRIPS, and "enhanced efficacy" under section 3(d). *Journal of Intellectual Property Law,* 21(2), 223–263.

Dür, A., & Mateo, G. (2013). Gaining access or going public? Interest group strategies in five European countries. *European Journal of Political Research*, *52*(5), 660-686.

ESCR-Net. (2020, September 3). *Novartis AG v. Union of India (2007)*.

https://www.escr-net.org/caselaw/2020/novartis-ag-v-union-india-2007

European CEO. (n.d.). *Daniel Vasella*.

https://www.europeanceo.com/profiles/daniel-vasella-novartis/

European Patent Office. (n.d.). *How long is the term of protection of Indian patents?*

https://www.epo.org/en/service-support/faq/searching-patents/asian-patent-information/india/general-information-about-2

European Union Chamber of Commerce in China. (2023, June 25). Protecting pharmaceutical IP in China's drug procurement: Coordinated governance. E*UROBiz.*

https://www.eurobiz.com.cn/protecting-pharmace utical-ip-in-chinas-drug-procurement-coordinated-governance

Evangelista, M. (1995). Transnational relations, domestic structures, and security policy in the USSR and Russia. In T. Risse-Kappen (Ed.), *Bringing transnational relations back in: Non-state actors, domestic structures and international institutions* (pp. 146–188) (No. 42). Cambridge University Press.

Farrand, B. (2015). Lobbying and lawmaking in the European Union: The development of copyright law and the rejection of the anti-counterfeiting trade agreement. *Oxford Journal of Legal Studies*, *35*(3), 487-514.

Feng, L., & Yu, X. (2023). The fourth amendment of Chinese patent law and discussion on its practical effects. *European Review*, *31*(2), 196-211.

Freedom House. (2025). *Freedom in the world 2025: India*. https://freedomhouse.org/country/india/freedom-world/2025

Fyan, S. (2010). Pharmaceutical patent protection and section 3(d): Comparative look at India and the U.S. *Virginia Journal of Law & Technology*, 15(2), 198-226.

Gabble, R., & Kohler, J. C. (2014). To patent or not to patent? The case of Novartis' cancer drug Glivec in India. *Globalization and Health*, *10*, 1-6.

Gao, X., & Teets, J. (2021). Civil society organizations in China: Navigating the local government for more inclusive environmental governance. *China Information*, *35*(1), 46-66.

Gilead Sciences, Inc. (2014, October). *Intellectual property and patient access: Gilead Sciences*

policy position. https://www.gilead.com/~/media/Files/pdfs/other/Intellectual%20Property%20and%20Patient%20Access101014.pdf

Goans, J. W. (2003). Intellectual property and developing countries: An overview. *Briefing Paper*, 1-16.

Goldenberg, M. M. (2012). Multiple sclerosis review. *Pharmacy and therapeutics*, *37*(3), 175-184.

Golikeri, P. (2018, March 17). Cipla takes a risk, rolls out Bayer's cancer drug. *DNA India.* https://www.dnaindia.com/business/report-cipla-takes-a-risk-rolls-out-bayer-s-cancer-drug-1369109

Gopakumar, K. M. (2010). Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime. *The Law and Development Review*, *3*(2), 326–368. https://doi.org/10.2202/1943-3867.1061

Gould, D. M., & Gruben, W. C. (1996). The role of intellectual property rights in economic growth. *Journal of Development Economics*, *48*(2), 323-350.

Greenberg Traurig. (2020, January 21). *Impact of the China-U.S. trade deal on intellectual property protection*. https://www.gtlaw.com/en/insights/2020/1/impact-of-the-china-us-trade-deal-on-intellectual-property-protection

GreyB Insights. (n.d.). *Novartis Pharmaceuticals patents – Insights & stats*. https://insights.greyb.com/novartis-pharmaceuticals-patents/

Groenewegen-Lau, J. (2025, March 20). China is advancing in drug discovery but needs foreign firms to get drugs to market. *MERICS*. https://merics.org/en/comment/china-advancing-drug-discovery-needs-foreign-firms-get-drugs-market

Grover, A. (2018). Politics of access to medicines and human rights. In R. Parker & J. García (Eds.), *Handbook on the Politics of Global Health* (pp. 307-320). Routledge.

Hafner-Burton, E. M. (2008). Sticks and stones: Naming and shaming the human rights enforcement problem. *International organization,* 62(4), 689-716.

Haihe Biopharma. (n.d.). *Haihe Biopharma*: *Home*. https://www.haihepharma.com/en

Hájek, P. (2024). Patent box-A measure for sustainable development. *Interaction of Law and Economics: Sustainable Development,* 69-75.

Harris, D. (2010). TRIPS after fifteen years: Success or failure, as measured by compulsory licensing. *Journal of Intellectual Property Law*, 367-400.

Hassoun, N. (2014). Globalization, global justice, and global health impact. *Public Affairs Quarterly*, *28*(3), 231-258.

Haynes, L. (2025, February 7). China: The big re-alignment. *PharmaBoardroom.* https://pharmaboardroom.com/articles/china-the-big-re-alignment/

Healthcare campaigners hail Novartis patent rejection by Indian court. (2013, April 2). *Asian News International*. Retrieved from LexisNexis.

Heiss, A., & Johnson, T. (2016). Internal, interactive, and institutional factors: A unified framework for understanding international non-governmental organizations. *International Studies Review*, *18*(3), 528–541.

Huang, C., Cao, C., & Coreynen, W. (2023). Stronger and more just? Recent reforms of China's intellectual property rights system and their implications. *Asia Pacific Journal of Innovation and Entrepreneurship*, *18*(3), 210-223.

India orders first compulsory license for Bayer's Nexavar cancer drug to Natco. (2012, March 13). *Genetic Engineering and Biotechnology New*s. https://www.genengnews.com/news/india-orders-first-compulsory-license-for-bayers-nexavar-cancer-drug-to-natco/

Indian Pharmaceutical Alliance. (n.d.). *Introduction to IPA*. https://www.ipa-india.org/about-ipa/introduction/

Industry fears drugs law reversal: India's pledge to make its pharmaceutical patent regime innovator-friendly may be under threat following the results of May's general election. Emma Barraclough assesses what is at stake for drugs companies as the new government finalizes its product patent rules (2004). *Managing Intellectual Property*. Retrieved from LexisNexis.

Intellectual Property Office of Jiangsu Province. (2023, July 4). *Jiangsu Province's*

"Intellectual property helps strengthen the industrial chain" "Industry-talent engagement • entering enterprises" onsite exchange and engagement event successfully held. https://jsip.jiangsu.gov.cn/art/2023/7/4/art_77589_10940929.html

International Center for Not-for-Profit Law. (2023, May). *China: Philanthropy law report.* https://www.icnl.org/wp-content/uploads/China-PLR-June-2023.pdf

International Intellectual Property Alliance. (2014). *Appendix C: Chart of countries' Special 301 placement (1989-2013) and IIPA 2014 Special 301 recommendations.* https://web.archive.org/web/20150724025940/http://www.iipa.com/pdf/2014SPEC301HISTORICALCHART.pdf

Jamil, A. (2017, March 2). Biocon: Creating value through incisive IP strategy. *Bio Conversations*. https://bioconblog.com/2017/03/02/biocon-creating-value-through-incisive-ip-strategy/

Jayakumar, P. B. (2025, March 2). India's pharmaceutical industry poised for global leadership: McKinsey report. *Fortune India*. https://www.fortuneindia.com/business-news/indias-pharmaceutical-industry-poised-for-global-leadership-mckinsey-report/120894

Jiangsu Hengrui Pharmaceuticals Co., Ltd. (n.d.). *About Us.* https://www.hengrui.com/en/about.html

Jones Day. (2020, November 6). *China promulgates fourth amendment to patent law,* 1-5.

https://www.jonesday.com/en/insights/2020/11/china-promulgates-fourth-amendment-to-patent-law

Kamiike, A. (2020). The TRIPS Agreement and the pharmaceutical industry in India. *Journal of Interdisciplinary Economics*, *32*(1), 95-113.

Katragkou, A., Tsikopoulou, F., Roilides, E., & Zaoutis, T. E. (2012). Posaconazole: When and how? The clinician's view. *Mycoses*, *55*(2), 110-122.

Keck, M. E., & Sikkink, K. A. (2014). *Activists beyond borders: Advocacy networks in international politics*. Cornell University Press.

Klüver, H., Braun, C., & Beyers, J. (2015). Legislative lobbying in context: Towards a conceptual framework of interest group lobbying in the European Union. *Journal of European Public Policy*, *22*(4), 447-461.

Kobori, S. (2003). Post-Doha challenges for the WTO. *Asia Pacific Review*, *10*(1), 72-81.

Laplume, A. O., Pathak, S., & Xavier-Oliveira, E. (2014). The politics of intellectual property rights regimes: An empirical study of new technology use in entrepreneurship. *Technovation,* 34(12), 807-816.

Lee, A. (2021, March 18). China's Hatch-Waxman Act: Patent linkage system implemented in the 4th amendment to the Chinese patent law. *Rothwell Figg's Biosimilars Law Bulletin*. https://www.biosimilarsip.com/2021/03/18/chinas-hatch-waxman-act-patent-linkage-system-implemented-in-the-4th-amendment-to-the-chinese-patent-law/

Lee, L. L. (2008). Trials and TRIPS-ulations: Indian patent law and Novartis AG v. Union of India. *Berkeley Technology Law Journal*, 23(1), 281-314.

Lee, N., & Zhang, L. (2017). Specialized IP courts in China–judicial governance of intellectual property rights. *IIC-International Review of Intellectual Property and Competition Law*, *48*(8), 900-924.

Ley, A. J., & Weber, E. P. (2015). The adaptive venue shopping framework: How emergent groups choose environmental policymaking venues. *Environmental Politics*, *24*(5), 703-722.

Liu, J. (2015). Compulsory licensing and anti-evergreening: Interpreting the TRIPS flexibilities in sections 84 and 3(d) of the Indian Patents Act. *Harvard International Law Journal 56*, 207-227.

Long, H., Yang, Y., Geng, X., Mao, Z., & Mao, Z. (2022). Changing characteristics of pharmaceutical prices in China under centralized procurement policy: A multi-intervention interrupted time series. *Frontiers in Pharmacology*, *13*, 1-16.

Ludwig, M. (2021, May 8). Pharma breaks lobbying record defending high drug prices and vaccine patents. *Truthout.* https://truthout.org/articles/pharma-breaks-lobbying-record-defending-high-drug-prices-and-vaccine-patents/

Lupkin, S. (2016, November 28). A frenzy of lobbying on 21st century cures. *KFF Health*

News. https://kffhealthnews.org/news/a-frenzy-of-lobbying-on-21st-century-cures/

Luthfiah, N. S., & Oppusunggu, Y. U. (2024). Implications of WTO DSB panel ruling on imbalance of power between WTO member states. *Uti Possidetis: Journal of International Law*, *5*(2), 239-279.

Madras High Court. (2007, August 6). *Novartis AG v. Union of India & Others*, (2007) 4 MLJ 1153. Judgment by R. Balasubramanian & P. Sridevan. https://www.globalhealthrights.org/wp-content/uploads/2012/12/HC-2007-Novartis-v.-Union-of-India.pdf

Mahajan, M. (2018). Philanthropy and the nation-state in global health: The Gates Foundation in India. *Global Public Health*, *13*(10), 1357–1368. https://doi.org/10.1080/17441692.2017.1414286

Makoba, J. W. (2002). Nongovernmental organizations (NGOs) and third world development: An alternative approach to development. *Journal of Third World Studies*, *19*(1), 53-63.

Mandal, K. C. (2024). How India became the 5th largest economy? An indepth study. *Socrates Journal of Interdisciplinary Social Studies*, *10*(39), 1-18.

Mani, V. S., Srivastava, D., Chakrapani, M., & Erstling, J. (2017). The India patent system: A decade in review. *Cybaris®*, *8*(1), 1-60.

Mashelkar to head panel on patent law. (2005, April 6). *The Economic Times*.

https://economictimes.indiatimes.com/news/economy/policy/mashelkar-to-head-panel-on-patent-law/articleshow/1070509.cms

Maskus, K. E. (2000a). Intellectual property rights and foreign direct investment. *Centre for International Economic Studies Working Paper*, 1-19.

Maskus, K. E. (2000b). Parallel imports. *The World Economy*, *23*(9), 1269–1284. https://doi.org/10.1111/1467-9701.00329

Maskus, K. E. (2001). Intellectual property challenges for developing countries: An economic perspective. *University of Illinois Law Review*, 2001(1), 457-474.

Matai, A. (2024, January 29). Anil Matai – Director General, OPPI India. *PharmaBoardroom*. https://pharmaboardroom.com/interviews/anil-matai-director-general-oppi-india/

Matthews, D. (2004). WTO decision on implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health: A solution to the access to essential medicines problem*? Journal of International Economic Law*, 7(1), 73-107.

Mavroidis, P. C., & Sapir, A. (2021). All the tea in China: Solving the 'China problem' at the WTO. *Global Policy*, 12, 41-48.

Médecins Sans Frontières. (n.d -a). *India*. https://www.msf.org/india

Médecins Sans Frontières. (n.d -b). The "Drop the Case" campaign in pictures: Novartis and

"Drop the Case": Defending a key source of generic drugs. *MSF Access Campaign*. https://msfaccess.org/drop-case-campaign-pictures

Médecins Sans Frontières. (2012a, February 15). *About the Novartis Drop the Case campaign*. https://www.msf.org/about-novartis-drop-case-campaign

Médecins Sans Frontières. (2012b, February 22). *As Novartis shareholders meet, MSF urges company to drop court case in India*. https://www.msf.org.za/news-and-resources/press-release/norvatis-shareholders-meet-msf-urges-company-drop-court-case-india

Médecins Sans Frontières. (2012c, September 17). MSF statement on India's dismissal of Bayer's request for a stay on compulsory licence [Statement]. *MSF Access Campaign*. https://campaign.msfaccess.org/msf-statement-indias-dismissal-bayers-request-stay-compulsory-licence

Médecins Sans Frontières. (2012d, December 4). Novartis vs. India: Supreme Court hearing ends. *MSF Access Campaign*. https://www.msfaccess.org/novartis-vs-india-supreme-court-hearing-ends

Médecins Sans Frontières. (2021, March 9). *WTO COVID-19 TRIPS Waiver: Doctors Without Borders Canada briefing note*. https://www.doctorswithoutborders.ca/wp-content/uploads/2023/04/msf_canada_briefer_on_trips_waiver.pdf

Médecins Sans Frontières. (2023, September 15). From TRIPS to PPR: Addressing intellectual

property barriers on lifesaving medical products. *MSF Access Campaign.* https://msfaccess.org/trips-ppr-addressing-intellectual-property-barriers-lifesaving-medical-products

Menghaney, L. (2013). 'Drop the Case': Campaigning against Novartis. *Economic and Political Weekly*, 52-54.

Mennis, B. (1978). [Review of the book *U.S. Power and the Multinational Corporation: The Political Economy of Foreign Direct Investment*, by R. Gilpin]. *The American Political Science Review, 72*(2), 789–790.

Merck & Co., Inc. (2024, February). *Intellectual property*. https://www.merck.com/wp-content/uploads/sites/124/2024/03/Intellectual_property_statement_MRK_FEB2024.pdf?form=MG0AV3

Mercurio, B. (2006). TRIPS-plus provisions in FTAs: Recent trends. In L. Bartels & F. Ortino (Eds.), *Regional trade agreements and the WTO legal system* (pp. 215–237). Oxford University Press.

Mitra, S. K., & Enskat, M. (1999). Parties and the people: India's changing party system and the resilience of democracy. In P. J. Burnell & P. Calvert (Eds.), *The resilience of democracy: Persistent practice, durable idea* (pp. 123–154). F. Cass.

Mueller, J.M. (2007). The tiger awakens: The tumultuous transformation of India’s patent

system and the rise of Indian pharmaceutical innovation. *University of Pittsburgh Law Review*, 68(3), 491-576. Retrieved from LexisNexis.

Murthy, D. (2001). The Future of compulsory licensing: Deciphering the Doha Declaration on the TRIPS Agreement and public health. *International Law Review*, 1299-1347.

Nair, S. (2022, August 30). Made in China 2025: China's quest for self-reliance and market dominance. *Organisation for Research on China and Asia.* https://orcasia.org/made-in-china-2025#:~:text=What%20is%20Made%20in%20China,%2Dmedicine%2C%20and%20rail%20infrastructure.

Natco Pharma Limited. (n.d.). *Mission & Heritage*. https://www.natcopharma.co.in/about/mission-heritage/

Nayyer, K. (2002, January). *Globalization of information: Intellectual property law implications. First Monday*. https://firstmonday.org/ojs/index.php/fm/article/download/925/847

Nedumpara, J. J., & Misra, P. (2012). Natco v. Bayer: Indian patent authority grants its first ever compulsory license on pharmaceutical products. *Global Trade and Customs Journal*, 7(7/8), 326-330.

NGOs in China. (2022a, January 4). *The 14th Five Year Plan for Social Organizations and the future of civil society in China*. https://ngochina.blogspot.com/2022/01/the-14th-five-year-plan-for-social.html

NGOs in China. (2022b, January 6). *The 14th Five Year Plan for Social Organizations: Opportunities for NGOs*. https://ngochina.blogspot.com/2022/01/the-14th-five-year-plan-for-social_6.html

O'Connell, J. P., & Guggenheim, M. (2016). Separating drugs from supplements: In Bayer, court considers the appropriate substantiation standard for dietary supplement non-disease claims. *FDLI Update*, 2016(1), 4-9.

O'Connor, A. (2007, March 7). Activists protest at Novartis's patent law challenge. *The Times (London).* Retrieved from LexisNexis.

O'Dea, C. (2012, February 28). Novartis awaits cancer drug ruling in India. *SWI swissinfo.ch.* https://www.swissinfo.ch/eng/business/novartis-awaits-cancer-drug-ruling-in-india/32197530

Office of the United States Trade Representative. (2007). *2007 Special 301 report*. https://ustr.gov/sites/default/files/2007%20Special%20301%20Report.pdf

Office of the United States Trade Representative. (2024a). *2024 Special 301 report*. https://ustr.gov/sites/default/files/2024%20Special%20301%20Report.pdf

Office of the United States Trade Representative. (2024b, April 25). *USTR releases 2024 Special 301 Report on intellectual property protection and enforcement/* https://ustr.gov/about-us/policy-offices/press-office/press-releases/2024/april/ustr-releases-2024-special-301-report-intellectual-property-protection-and-enforcement

Onderkova H. (2021, October 12). Compulsory licensing in India and changes brought to it by the TRIPS Agreement. *IP Helpdesk European Commission*. https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en

Organisation of Pharmaceutical Producers of India. (n.d.). *All members*. https://www.indiaoppi.com/all-member/

Organisation of Pharmaceutical Producers of India. (2024, September). *OPPI Newsletter: Inaugural Issue*. https://www.indiaoppi.com/wp-content/uploads/2024/09/OPPI_Newsletter_Sep_2024.pdf

Oxfam. (2001, February). *Cutting the cost of global health: The role of UK Government and EU in reforming drug patent rules* [Parliamentary Briefing]. https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114025/pb-cutting-cost-global-health-010201-en.pdf

Oxfam. (2006a, November 14). *Patents versus patients: Five years after the Doha Declaration* [Briefing Paper]. https://policy-practice.oxfam.org/resources/patents-versus-patients-five-years-after-the-Doha-declaration-114562/

Oxfam. (2006b, November 14). *Questions and answers on Novartis and the Glivec patent case in India.* https://www.oxfamamerica.org/explore/stories/questions-and-answers-on-novartis-and-the-glivec-patent-case-in-india/

Page, V. (2024, June 22). The fundamentals of how India makes its money. *Investopedia.* https://www.investopedia.com/articles/investing/043015/fundamentals-how-india-makes-its-money.asp

Papaioannou, T., Watkins, A., Mugwagwa, J., & Kale, D. (2016). To Lobby or to partner? Investigating the shifting political strategies of biopharmaceutical industry associations in innovation systems of South Africa and India. *World Development*, *78*, 66-79.

Patent Bill finally gets Left support. (2005, March 22). *Rediff.com*. https://www.rediff.com/money/2005/mar/22patent2.htm

Patents Assigned to Jiangsu Hengrui Medicine Co., Ltd. (n.d.). *Justia Patents.* https://patents.justia.com/assignee/jiangsu-hengrui-medicine-co-ltd

Paul, S. (2019). Doctors Without Borders – Médecins Sans Frontières. In S. N. Romaniuk, M. Thapa, & P. Marton (Eds.), *The Palgrave encyclopedia of global security studies* (pp. 312-316). Cham, Switzerland: Palgrave Macmillan.

Pharmaceutical Research and Manufacturers of America. (n.d.). *Intellectual property*. https://phrma.org/policy-issues/Intellectual-Property?utm_source

Pharma lobby bats for drug approvals in India to align with global markets. (2023, December 29). *Business Standard.* https://www.business-standard.com/industry/news/pharma-lobby-bats-for-drug-approvals-in-india-to-align-with-global-markets-123122900247_1.html

Plahe, J. K., & McArthur, D. (2021). After TRIPS: Can India remain 'the pharmacy of the developing world'? *South Asia: Journal of South Asian Studies*, *44*(6), 1167–1185. https://doi.org/10.1080/00856401.2021.1980839

Pradhan, J. P. (2017). Indian outward FDI: A review of recent developments. *Transnational Corporations*, *24*(2), 43-70.

Pralle, S. B. (2003). Venue shopping, political strategy, and policy change: The internationalization of Canadian forest advocacy. *Journal of Public Policy*, *23*(3), 233-260.

Puckett, A. L., & Reynolds, W. L. (1996). Rules, sanctions and enforcement under section 301: At odds with the WTO? *The American Journal of International Law*, *90*(4), 675–689. https://doi.org/10.2307/2203997

Radulescu, I. G., Panait, M., & Voica, C. (2014). BRICS countries challenge to the world economy: New Trends. *Procedia Economics and Finance*, 8, 605–613. https://doi.org/10.1016/S2212-5671(14)00135-X

Ramesh, R. (2005, March 23). Cheap aids drugs under threat. *The Guardian.* https://www.theguardian.com/world/2005/mar/23/india.aids1

Rangnekar, D. (2006). No pills for poor people? Understanding the disembowelment of India's patent regime. *Economic and Political Weekly*, 409-417.

Reed Smith. (2001, July 1). *The amended PRC patent law.*

https://www.reedsmith.com/en/perspectives/2001/07/the-amended-prc-patent-law

Report of the Technical Expert Group on Patent Law Issues (March 2009*).*

Government of India. https://www.ipindia.gov.in/writereaddata/images/pdf/report-technical-expert-group-on-patent-law-issues.pdf

Reserve Bank of India. (2022, April 29). *Chapter IV: Harnessing open economy vistas for faster growth* (pp. 89–116). https://www.rbi.org.in/SCRIPTs/PublicationsView.aspx?id=21038

Risse-Kappen, T. (1995). Bringing transnational relations back in: Introduction. In *T. Risse-Kappen (Ed.), Bringing transnational relations back in: Non-state actors, domestic structures and international institutions* (pp. 3–36) (No. 42). Cambridge University Press.

Rodrik, D. (2018). What do trade agreements really do? *Journal of Economic Perspectives*, *32*(2), 73-90.

Rompaey, K.V. (2018). Trading away global health? Unravelling the intellectual property, trade, and investment nexus and the impact on the right to health. In R. Parker & J. García (Eds.), *Handbook on the Politics of Global Health* (pp. 312-320). Routledge.

Sadashiv, K. R. (2023). Foreign direct investment dynamics and economic growth in the case of India*. Journal of Business and Economic Options, 6(*1), 45-52.

Schiappacasse, M. (2003). Intellectual property rights in China: Technology transfers and economic development. *Buffalo Intellectual Property Law Journal*, *2*, 164-185.

Sell, S. K., & Prakash, A. (2004). Using ideas strategically: The contest between business and

NGO networks in intellectual property rights. *International Studies Quarterly*, *48*(1), 143-175.

Shadlen, K. C., Schrank, A., & Kurtz, M. J. (2005). The political economy of intellectual property protection: The case of software. *International Studies Quarterly*, *49*(1), 45-71.

Shi, T. (2008). Democratic values supporting an authoritarian system. In Y.-H. Chu, L. Diamond, A. J. Nathan, & D. C. Shin (Eds.), *How East Asians view democracy* (pp. 209–237). Columbia University Press.

Shift in Novartis strategy. (2013, April 2). *The Telegraph* https://www.telegraphindia.com/business/shift-in-novartis-strategy/cid/1549637

Singh, K. (2012, May 19). Bayer demands withdrawal of Natco Pharma's compulsory licence. *The Economic Times*. Retrieved from LexisNexis.

Sismondo, S., & Greene, J. A. (Eds.). (2015). *The Pharmaceutical Studies Reader.* Wiley

Sohrabji, N., & Maloney, K. (2022). Section 3(d) and pharmaceutical patents in India. *Journal of Intellectual Property Rights (JIPR)*, *25*(3-4), 65-73.

Srinivasan, S. (2004). A network for the rational and ethical use of drugs. *Indian J Med Ethics*, *1*(1), 13-14.

Stevens, F., & Willems, E. (2024). Information, politicization, and reputation: Assessing interest groups' agenda-setting influence in the EU. *European Political Science Review, 16(4),*

578-595.

Stroup, S. S., & Wong, W. H. (2017). *The authority trap: Strategic choices of international NGOs*. Cornell University Press.

Su, E. (2000). The winners and the losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and its effects on developing countries. *Houston Journal of International Law,* 23(1), 169-218.

Sun, H. (2004). The Road to Doha and beyond: Some reflections on the TRIPS Agreement and public health. *European Journal of International Law*, *15*(1), 123-150.

Sun, Y. (2005). A comparative study of the Chinese patent law practice. Part I: Obtaining a Chinese patent. *Perspectives*, 6(4), 9–17.

https://www.morganlewis.com/-/media/files/publication/outside-publication/article/sun_article_comparativestudychinesepatent.pdf

Sundaram, J. (2014). Brazil's implementation of TRIPS flexibilities: Ambitious missions, early implementation, and the plans for reform. *Information & Communications Technology Law*, *23*(2), 81-116.

Supreme Court of India. (2013, April 1). *Novartis AG v. Union of India & Ors. AIR 2013 Supreme Court 1311.* https://indiankanoon.org/doc/165776436/

Taiho Pharmaceutical Co., Ltd., & Haihe Biopharma Co., Ltd. (2024, March 1). *News release.*

https://www.taiho.co.jp/en/release/files/pdf/20240301.pdf

Tatler Asia. (n.d.). *Chi Heng Foundation*.

https://www.tatlerasia.com/profile/chi-heng-foundation?listId=124

Tenni, B., Lexchin, J., Phin, S., Kittitrakul, C., & Gleeson, D. (2023). Lessons from India and Thailand for Cambodia's future implementation of the TRIPS Agreement for pharmaceutical patents. *The Journal of World Intellectual Property*, 26(2), 166-194.

The Hong Kong University of Science and Technology. (2023, February 27). *HKUST and PhIRDA establish innovation and research platforms to propel pharmaceutical innovation and development in Greater Bay Area.*

https://hkust.edu.hk/news/internationalization-and-partnership/hkust-and-phirda-establish-innovation-and-research

The Law Codes. (n.d.-a). *Patent office and its establishment.*

https://thelawcodes.com/article/patent-office-and-its-establishment/

The Law Codes. (n.d.-b). *Powers of controller generally.*

https://thelawcodes.com/article/powers-of-controller-generally/

The State Council of the People's Republic of China. (2017, February 15). *Joint efforts to implement Made in China 2025.*

https://english.www.gov.cn/premier/news/2017/02/15/content_281475568073500.htm

The State Council of the People's Republic of China. (2024, March 18). *China's innovative drugs gain momentum in global expansion efforts.* https://english.www.gov.cn/news/202403/18/content_WS65f80544c6d0868f4e8e5347.html

The Supreme People's Court of the People's Republic of China. (2025, April 30). *Patent law revolution: China's 40-year journey from adaptation to advancement*. https://english.court.gov.cn/2025-04/30/c_1089932_3.htm

Third World Network. (2019, July 3). *TWN info service on intellectual property issues.* https://www.twn.my/title2/intellectual_property/info.service/2019/ip190701.htm

Tudor, M. (2023). Why India's democracy is dying. *Journal of Democracy, 32*(2), 36–50. https://www.journalofdemocracy.org/articles/why-indias-democracy-is-dying/

U.S.-China Economic & Trade Agreement. (2020). *Economic and trade agreement between the government of the United States of America and the government of the People's Republic of China*. https://d3i6fh83elv35t.cloudfront.net/static/2020/01/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf

US steps up lobbying efforts against compulsory licensing. (2012, July 17). *Mint.* Retrieved from LexisNexis.

V-Dem Institute. (2025). *Democracy report 2025: 25 years of autocratization – Democracy*

trumped? https://v-dem.net/documents/61/v-dem-dr__2025_lowres_v2.pdf

Vaughan, S. K., & Arsneault, S. (2021). *Managing nonprofit organizations in a policy world* (2nd ed.). Melvin & Leigh, Publishers.

Weissman, R. (2007). Preserving the pharmacy to the developing world. *Multinational Monitor, 28(2),* 14–15.

Wong, H. (2020). The case for compulsory licensing during COVID-19. *Journal of Global Health*, *10*(1), 1-5.

World Generic Markets Pharmaceuticals. (2005, March 30). *India Passes Patent Amendments*. (2005, March 30). Retrieved from LexisNexis.

World Intellectual Property Organization. (n.d.). *Patent Cooperation Treaty (PCT)*. https://www.wipo.int/treaties/en/registration/pct/

World Intellectual Property Organization. (2010, August 31). *Building on a foundation of IP*. https://www.wipo.int/en/web/ip-advantage/w/stories/building-on-a-foundation-of-ip

World Intellectual Property Organization. (2020). *Decision of the Standing Committee of the National People's Congress on amending the Patent Law of the People's Republic of China*. https://www.wipo.int/wipolex/en/legislation/details/21027

World Intellectual Property Organization. (2021, March 15). Managing intellectual

property rights in innovation: The key to reaching the market. *WIPO Magazine*. https://www.wipo.int/web/wipo-magazine/articles/managing-intellectual-property-rights-in-innovation-the-key-to-reaching-the-market-41957

World Intellectual Property Organization. (2024). Global Innovation Index 2024: India. In *Global Innovation Index Rankings*. https://www.wipo.int/gii-ranking/en/india

World Trade Organization. (1997, December 19). *India—Patent protection for pharmaceutical and agricultural chemical products* (WT/DS50/AB/R). https://www.worldcourts.com/wto/eng/decisions/1997.12.19_India.pdf

Xiaohui, Wu. (2023). Analysing the rules of proof in China's first drug patent linkage suit. *Managing Intellectual Property*, 298, 27-29.

Yang, K. (2022, November 14). China's Supreme People's Court issued its first patent linkage decision. *Jolt Digest*. https://jolt.law.harvard.edu/digest/chinas-supreme-peoples-court-issued-first-patent-linkage-decision

Yang, W., & Yen, Y. (2010). The dragon gets new IP claws: The latest amendments to the Chinese patent law. *IPO Articles and Reports*, 1-23.

Yao, X. F. (2024). Characteristics and outcomes of the drug patent linkage system in China. *Globalization and Health*, *20*(1), 1-9.

Yu, P. K. (2009). The objectives and principles of the TRIPS Agreement. *Houston Law Review,*

46(4), 979–1046.

Yueh, L. (2009). Patent laws and innovation in China. *International Review of Law and Economics*, *29*(4), 304-313.

Zhou, Y., & Xin, T. (2003). An innovative region in China: Interaction between multinationals corporations and local firms in a high-tech cluster in Beijing. *Economic Geography*, *79*(2), 129-152.