THE COMPARATIVE POLITICAL ECONOMY OF PHARMACEUTICAL INTELLECTUAL PROPERTY RIGHTS IN MEXICO AND TURKEY

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BOĞAZİÇİ UNIVERSITY

2022

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Thesis submitted to the

Institute for Graduate Studies in Social Sciences

in partial fulfillment of the requirements for the degree of

Master of Arts

in

Political Science and International Relations

by

İpek Tuğba Bayraktar

Boğaziçi University

2022

DECLARATION OF ORIGINALITY

I, İpek Tuğba Bayraktar, certify that

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ABSTRACT

The Comparative Political Economy of Pharmaceutical Intellectual Property Rights in Mexico and Turkey

Since the late twentieth century, the protection of intellectual property has become integral to a free and fair international economic order. The ensuing global harmonization process in intellectual property that aimed to ensure the continuity of international economic activity has turned knowledge and information into globally protected private property. However, despite this overarching process of global convergence, countries differently navigated the course to this new global order in which intellectual property turned into private property. This thesis seeks to answer why and how countries respond differently to commonly experienced global changes by examining the experiences of Mexico and Turkey in the area of pharmaceutical patents. Asking why Mexico and Turkey's similar behaviors regarding pharmaceutical patents in the 1990s gradually diverged during the 2000s, this study examines these experiences in their historical unfolding. By relying on the existing literature in the case of Mexico and examining parliamentary minutes, newspaper articles, and reports published by various other domestic actors in the case of Turkey, this thesis explains the policymaking processes in pharmaceutical intellectual property as an outcome of shifting coalitional alignments in each country. This thesis contributes to many critical analytical themes in the literature on political economy by demonstrating how, despite intense pressures for global convergence, global rules are still negotiated domestically to produce domestic policy change.

ÖZET

Meksika ve Türkiye'de İlaca İlişkin Fikri Mülkiyet Haklarının Karşılaştırmalı Politik Ekonomisi

Yirminci yüzyılın sonlarından bu yana fikri mülkiyetin korunumu serbest ve adil bir uluslararası ticaret düzeninin ayrılmaz bir parçası haline geldi. Uluslararası ekonomik aktivitenin devamlılığını sağlamayı amaçlayan fikri mülkiyete ilişkin küresel harmonizasyon süreci, bilgi ve enformasyonu küresel ölçekte korunan özel birer mülkiyet haline getirdi. Ancak, bu kapsayıcı küresel yakınsama sürecine rağmen, ülkeler fikri mülkiyetin özel mülkiyete dönüştüğü dünyaya uyum sağlarken birbirlerinden farklı yollar izledi. Bu tez, ortak olarak tecrübe edilen bu küresel değişiklere ülkelerin neden ve nasıl farklı cevaplar verdiklerini Meksika ve Türkiye'nin ilaç patentlerine ilişkin tecrübelerini inceleyerek cevap bulmayı amaçlıyor. Meksika ve Türkiye'nin ilaç fikri mülkiyetine dair 1990'lı yıllarda benzeşen davranışlarının 2000'li yıllar boyunca neden giderek farklılaştığını araştıran bu çalışma, iki ülkenin tecrübelerini tarihsel bağlamlarında karşılaştırarak inceliyor. Meksika örneğinde mevcut literatüre, Türkiye örneğinde ise meclis tutanakları, gazete haberleri ve çeşitli yerel aktörlerin yayımladığı raporlara dayanan bu tez, iki ülkenin ilaç patentlerine ilişkin politika yapım süreçlerini değişen yerel güç ilişkilerinin birer sonucu olarak açıklıyor. Bu tez, küresel yakınsamaya yönelik yoğun baskılara rağmen küresel kuralların hala yerel olarak müzakere edilerek politika değişiklikleri ile sonuçlandığını göstererek politik ekonomi literatürünü meşgul eden pek çok önemli analitik temaya katkıda bulunmayı amaçlıyor.

ACKNOWLEDGEMENTS

I feel extremely privileged to spend my time as a graduate student working on a topic that I find not only intellectually fascinating but also personally important. However, writing this thesis would not have been possible without the people who granted me this privilege. My gratitude to my professors, Mine Eder, Huricihan İslamoğlu, Mert Arslanalp, and Yeşim Arat, is beyond words. They have taught me how to think about social reality, encouraged me to discover the questions that truly excite me, and given me the freedom to pursue these questions that profoundly shaped my intellectual identity. I thank them for the guidance, support, and understanding they have given me throughout my academic journey.

I am deeply aware that it is often a privilege for people to freely pursue their dreams. Without the endless love and support of my family, I might have never found the opportunity to pursue my own dreams. I thank them from the bottom of my heart for always encouraging me to seek what makes me happy.

I am also grateful to my friends for their unending love, patience, and encouragement. I thank them for always believing in me and being there for me. I know that life is always better with them.

To Buket

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LIST OF ABBREVIATIONS

ACTN	Advisory Committee for the Trade Negotiations
AİFD	Araştırmacı İlaç Firmaları Derneği (Association of Research-Based Pharmaceutical Companies)
AKP	Adalet ve Kalkınma Partisi (Justice and Development Party)
AMIF	Asociación Mexicana de la Industria Farmacéutica (Mexican Pharmaceutical Industry Association)
AMPPI	Asociación Mexicana para la Protección de la Propiedad Intelectual (Mexican Intellectual Property Association)
ANAFAM	Asociación Nacional de Fabricantes de Medicamentos (National Association of Drug Manufacturers)
ANAP	Anavatan Partisi (Motherland Party)
ANIERM	Asociación Nacional de Importadores y Exportadores de la República Méxicana (National Association of Importers and Exporters)
APIs	Active Pharmaceutical Ingredients
CAFTA	Central America Free Trade Agreement
CANIFARMA	Cámara Nacional de la Industria Farmacéutica (National Chamber of the Pharmaceutical Industry)
CBD	Convention on Biological Diversity
CCE	Consejo Coordinador Empresarial (Business Coordinating Council)
CCPNM	for Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud (Coordinating

	Commission for Negotiating the Price of Medicines and other Health Inputs)
CEMAI	Consejo Empresarial Mexicano para Asuntos Internacionales (Mexican Business Council for Foreign Affairs)
CHP	Cumhuriyet Halk Partisi (Republican People's Party)
COECE	Coordinadora de Organismos Empresariales de Comercio Exterior (Coordinator of Foreign Trade Business Organizations)
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for Protection against Health Risks)
DYP	Doğru Yol Partisi (True Path Party)
EPC	European Patent Convention
FAO	Food and Agriculture Organization of the United Nations
GSP	General System of Preferences
İEİS	İlaç Endüstrisi İşverenleri Sendikası (Turkish Pharmaceutical Manufacturers' Association of Turkey)
IMPI	Instituto Mexicano de la Propiedad Industrial (Mexican Institute of Industrial Property)
PRI	Partido Revolucionario Institucional (Institutional Revolution Party)
IPC	Intellectual Property Committee
LFPPI	Ley de Fomento y Protección de la Propiedad Industrial (Law for the Development and Protection of Industrial Property)
LIM	Ley de Invenciones y Marcas (Law on Inventions and Trademarks)

MÜSİAD	Müstakil Sanayici ve İş Adamları Derneği (Independent Industrialists and Businessmen's Association)
NAFTA	North American Free Trade Agreement
NIEO	New International Economic Order
OECD	Organisation for Economic Co-operation and Development
PAN	Partido Acción Nacional (National Action Party)
PhRMA	Pharmaceutical Research and Manufacturers of America
PRD	Partido de la Revolución Democrática (Party of the Democratic Revolution)
PRI	Institutional Revolution Party (Partido Revolucionario Institucional)
PVEM	Partido Verde Ecologista de México (Ecologist Green Party of Mexico)
R&D	Research and Development
RP	Refah Partisi (Islamist Welfare Party)
SHP	Sosyaldemokrat Halkçı Parti (Social Democratic Populist Party)
SMK	Sınai Mülkiyet Kanunu (Industry Property Law)
SSA	Secretaría de Salubridad y Asistencia (Ministry of Health and Assistance)
TBMM	Türkiye Büyük Millet Meclisi (Turkish Grand National Assembly)
TEB	Türk Eczacıları Birliği (Turkish Pharmacists' Association)
TGSD	Türkiye Giyim Sanayicileri Derneği (Turkish Clothing Manufacturers' Association)

TİSD	Türkiye İlaç Sanayi Derneği (Turkish Pharmaceutical Industry Association)
TOBB	Türkiye Odalar ve Borsalar Birliği (The Union of Chambers and Commodity Exchanges of Turkey)
TPE	Türk Patent Enstitüsü (Turkish Patent Institute)
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
TÜSİAD	Türk Sanayicileri ve İş Adamları Derneği (Turkish Industrialists and Businessmen's Association)
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
YASED	Uluslararası Yatırımcılar Derneği (International Investors Association)

CHAPTER 1

INTRODUCTION

> For social scientists who enjoy comparisons, happiness is finding a force or event that affects a number of societies at the same time. Like test-tube solutions that respond differently to the same reagent, these societies reveal their characters in divergent responses to the same stimulus.
>
> (Gourevitch, 1977, p. 281)

1.1 Diversity amid harmonization: The puzzle

One such sweeping force in the modern global economy was the push for global harmonization in rules over intellectual property. Since the turn of the twenty-first century, the norms, principles, and values guiding global rulemaking processes in intellectual property rights have changed fundamentally, replacing the long-standing principles of sovereignty, territoriality, and diversity with the loss of policy autonomy, universality, and uniformity. The paradigm underpinning this new global framework of rules governing intellectual property was often seen as a natural corollary of the imperative to establish a legal infrastructure for a growingly interconnected, knowledge-based global economy.

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), signed in 1994 as one of the World Trade Organization's (WTO) founding pillars, is at the epicenter of this new global intellectual property rights regime. As a remarkable agreement that made adequate respect for a set of minimum standards in intellectual property a prerequisite to participating in the global economy, the TRIPS Agreement heralded the beginning of a global transition into a world in which knowledge and information turned into a privately protected commodity.

The TRIPS Agreement, however, is only a part of the global story. Since the signing of the TRIPS Agreement, the proliferation of bilateral and regional trade agreements with more demanding requirements in the protection of intellectual property rights has gradually raised the bar for global "minimum" standards, normalizing a further "upward" global harmonization in intellectual property rights. Various other international institutions have also reinforced and facilitated this global harmonization process by disseminating ready-made model laws to achieve global uniformity in national intellectual property laws.

This global harmonization process that spanned nearly four decades has largely attained its goal of achieving global similarity. As country after country came under international disciplines by virtue of their membership in WTO, the global expansion in the temporal length and the conceptual breadth of intellectual property rights has created a world in which national laws grew more alike at higher levels of protection they afforded to intellectual property rights (Cardwell & Ghazalian, 2011; Morin & Gold, 2014; Park, 2008; Shadlen, Schrank, & Kurtz 2005).

However, even within this broader process of global harmonization, diversity remains in how countries respond to these commonly experienced global transformations. Indeed, while all countries faced a new world that conditioned respect for privately owned intellectual property to partake in the global economy, how they individually navigated the course to this new global order was marked by striking diversity. Specifically, in implementing their international commitments, countries differed in their choices as to what intellectual property to privately protect, how to protect, when to protect, and to what extent to protect. Consequently, the resulting global landscape turned out to be one of profound diversity in national patterns of compliance with the new international standards in intellectual property.

This thesis attempts to account for this puzzling diversity in the case of pharmaceutical intellectual property. The making of pharmaceuticals as a globally protected private property constitutes an interesting area of study for several reasons. Firstly, the global privatization of pharmaceutical innovation was a profound transformation that radically altered the previous principles and practices that long governed ownership in pharmaceuticals. Prior to the advent of TRIPS, exempting pharmaceutical products and processes from private legal protection was the norm, rather than the deviation, that characterized the global historical landscape. Reflecting the public health value of pharmaceuticals to human welfare, sovereign governments have long regarded pharmaceuticals as non-patentable subject matter to ensure the affordability and availability of medicines to their populations. Indeed, except for a few wealthier countries with technologically advanced pharmaceutical industries, the absence of pharmaceutical patents has persisted well into the 1990s. However, the TRIPS Agreement's mandate to expand patent protection to all areas of technology, increase the duration of patent term to twenty years, and limit the exceptions to the private rights of patent holders served to eliminate these prior arrangements that permitted weak protection and enforcement of intellectual property rights.

Secondly, the making of the new standards in pharmaceutical intellectual property rights constituted the single most contentious change brought about by the global transformations in the politics of intellectual property. The unprecedented expansion of the scope and duration of private rights of property owners that came with TRIPS sparked heated debates among various actors both at the international and national levels. Since intellectual property rights are legal claims of ownership over knowledge and information that permit the owner of intellectual property to

exclude third parties from unauthorized production, sale, use, and dissemination of their property, the question of ensuring public access to medicines under situations of monopoly rights formed the central axis of debate in the making and implementation of the TRIPS Agreement.

Thirdly, pharmaceutical intellectual property rights constitute an area where national responses to global changes are one of the widest in variation. As many developing countries that previously lacked pharmaceutical patents were now required to do so strongly and rapidly, the contention between those who sought to privatize pharmaceutical innovation and those who wished to facilitate its dissemination turned the domestic law-making processes over pharmaceutical intellectual property into a question of how to comply with the new international standards without compromising the public health value of pharmaceuticals. Depending on the outcomes of these conflictual political processes, countries introduced private rights of ownership in pharmaceutical intellectual property at different times, defined patentability criteria in different ways, set exceptions and limitations for the scope of private protection in different manners, and chose to protect and enforce these private rights with different procedures.

Fourthly, variation in national patterns of compliance with pharmaceutical intellectual property standards is further complicated by the fact that diversity often does not result from decisions made in a single moment. Depending on how these newly-established rules operate in practice, countries often gradually adjust their pharmaceutical intellectual property laws and politics to reflect their changing domestic realities and objectives. Therefore, with this temporal dimension that turns intellectual property policymaking into a highly layered political process, the end

result of this global harmonization process is one of profound cross-national and longitudinal variation in national pharmaceutical intellectual property laws.

This thesis examines Mexico and Turkey's responses to the global changes in the politics of pharmaceutical intellectual property as two crucial cases that can shed light on many of the complex political processes that face developing countries in implementing and modifying their externally-derived intellectual property obligations. By showing how and to what extent global changes can alter long-standing domestic practices in pharmaceutical intellectual property and leave lasting legacies for subsequent efforts to adjust these rules to changing domestic needs and objectives, the unique experiences of Mexico and Turkey constitute two analytically valuable cases that illustrate the multidimensional politics of intellectual property policymaking.

Mexico and Turkey's story is one of a similar beginnings but subsequently diverging trajectories of change in pharmaceutical intellectual property policymaking. Similar to many other developing countries, both Mexico and Turkey treated pharmaceuticals as non-patentable subject matter prior to the 1990s. Moreover, like many other developing countries, Mexico and Turkey faced the obligation to relinquish their long-held opposition to pharmaceutical patents in the 1990s to participate in the new global economy. However, what makes Mexico and Turkey unique cases among developing countries is not that they finally acceded to pharmaceutical patents but the extreme manner in which they did so. Mexico and Turkey's patterns of compliance with the new global rules in the 1990s are characterized by an enthusiastic over-compliance, a glaring mismatch between the strength of exclusive rights granted to the patent holders and the countries' economic and technological development levels. Simply put, Mexico and Turkey's new

pharmaceutical intellectual property laws granted highly exclusionary private rights of ownership in pharmaceutical products and processes, with little or no use of public-regarding options allowed under international standards.

Despite this similarity in their initial actions, however, Mexico and Turkey's subsequent efforts to modify their pharmaceutical intellectual property laws in the 2000s diverged significantly from one another. In a series of reforms spanning the 2000s, Mexico's intellectual property regime for pharmaceuticals evolved in a way that further increased the owners' exclusionary rights over their pharmaceutical intellectual property. In contrast to this consolidation trend in Mexico, Turkey gradually reversed its previous extremist stance and weakened the extent of exclusionary rights of property owners.

What explains Mexico and Turkey’s similar beginnings but diverging pathways in pharmaceutical intellectual property policymaking? More specifically, why did both Mexico and Turkey, despite their long-standing opposition to pharmaceutical patentability, exceed global minimum standards in pharmaceutical intellectual property in the 1990s, and why did their policy choices diverge substantially in their subsequent attempts to modify these rules in the 2000s?

Until recently, our understanding as to what accounts for diversity was rather hazy. The long-standing explanations based on socioeconomic factors that predict economically and technologically more developed countries to offer stronger intellectual property rights cannot adequately account for the rapidity and complexity in which countries from all parts of the globe transitioned into this new global order of privately protected intellectual property. As the global changes in the politics of intellectual property compelled countries to abide by the new minimum standards prompted action globally and swiftly, socioeconomic explanations that focus on

domestic factors that often change very slowly cannot capture why, how, and to what extent countries respond to this new external environment.

However, explanations based solely on international obligations also do not provide convincing answers as to why national responses to the new global rules in intellectual property vary significantly across nations and over time. Admittedly, one explanation for cross-national diversity advanced by existing scholarship is the "constructive ambiguity" in the language of the TRIPS treaty, whereby countries are permitted to implement these global requirements in line with their own legal systems within established transition periods. Despite this room for maneuver allowed by the TRIPS Agreement, however, the question of why countries make the choices they do still largely remains unanswered. For instance, why is it that some countries, like Mexico, Turkey, or African less developed countries, choose to go well beyond the minimum global requirements, whereas some others, like Argentina and India, choose to satisfy only the bare minimums (Deere, 2008; Shadlen, 2017)?

Nor explanations based on external pressures are entirely persuasive in accounting for the timing and substance of final policy outcomes. Without a doubt, the economic and political pressures from the US and the EU on developing countries to offer strong pharmaceutical intellectual property rights might eventually compel some countries, like Brazil or South Korea, to acquiesce to their demands (Shadlen, 2017). However, as I will illustrate in the succeeding chapters, not all developing countries that received pressures capitulated nor those that chose to exceed their international obligations were subjected to threats. Unlike what the extant literature often asserts, no automatic causal relationship exists between external pressures and the strength of national pharmaceutical patent systems. Instead, it needs to be explained whether and under what circumstances pressures

from the US and the EU prompt satisfactory a response from the country that received external pressure.

A growingly popular explanation for cross-national variation in pharmaceutical intellectual property rights is the existence of bilateral and regional trade agreements signed with the US or the EU. Numerous scholars argue that these trade agreements are regarded as valuable tools by these countries to raise the global minimum standards beyond TRIPS requirements via the extension of greater market access in exchange for greater regulatory convergence.

However, the mere existence of trade agreements with higher standards for pharmaceutical patents may not be sufficient to predict ultimate policy outcomes. Even within a much-restricted policy discretion allowed under these agreements, some countries, like Mexico and Turkey, may still choose to go beyond their obligations. Moreover, the explanatory power of trade agreements alone in accounting for strong patent regimes is also blurry as it is unclear whether countries over-comply because of these trade agreements or enter into these agreements knowing that they must over-comply (Shadlen, 2017). Rather, it is necessary to explain what these trade agreements signify for individual countries that motivate them to enter into these arrangements that obligate more complex and costly pharmaceutical intellectual property reforms.

While these explanations based on external pressures and trade agreements contribute much to our knowledge about how global-level dynamics continuously shape the parameters of permissible policy action available to developing countries, we still know relatively little about how individual countries make policy decisions within these defined parameters. Put differently, while the global lens of the existing literature persuasively explains the making and changing of the global rules in

intellectual property, we still have little understanding as to how these rules are implemented domestically through what kind of political bargains. As this thesis shows, the question of implementation is a complex political process whereby international rules are almost always negotiated domestically to translate into actual policy change.

In recent years, the greater involvement of political scientists in debates over intellectual property policymaking has brought a new and more nuanced perspective to understanding how individual countries implement their international obligations in intellectual property. Largely correcting the existing scholarship's overemphasis on the global conflicts to the detriment of what occurs on the ground, this new generation of research contributes significantly to our understanding of pharmaceutical intellectual property policymaking by elucidating the complexities of the preference formation processes of domestic actors and their strategies for political mobilization and alliance-building to realize their preferred policy choices. This thesis builds upon and seeks to contribute to this new generation of scholarship by developing a coalition-based framework to explain Mexico and Turkey's experiences in pharmaceutical intellectual property policymaking in two periods of change.

1.2 Coalitional politics in two periods of change: The argument

To explain Mexico and Turkey's pharmaceutical intellectual property policymaking in two periods of change, this thesis advances a three-fold argument that remains attentive to the complex interplay between the broader global economic dynamics and the domestic political negotiations in making pharmaceutical intellectual property laws.

First, this study contends that, since the primary impetus for intellectual property reforms in Mexico and Turkey was a regional rather than multilateral trade agreement, both countries were subject to more intense bargain in the 1990s than those that only complied with their TRIPS obligations. More specifically, because regional trade agreements require greater regulatory convergence in exchange for greater market access, Mexico and Turkey faced stricter legal and political requirements for pharmaceutical intellectual property rights in the 1990s to finalize their regional integration projects. Therefore, for both Mexico and Turkey, the issue of pharmaceutical intellectual property policymaking was an inseparable dimension of their regional economic integrations with their largest trade partners, whereby the goal of smoothly finalizing NAFTA and the Customs Union was the most critical concern that guided policy decisions.

The fact that Mexico and Turkey's patterns of compliance with the new global standards in pharmaceutical intellectual property essentially was a question of regional economic integration with more demanding requirements means that their universe of available options was more constrained than other developing countries. However, while this explains why Mexico and Turkey had to adopt stronger pharmaceutical patent laws in the 1990s, the existence of a regional trade agreement still provides little insight into Mexico and Turkey's perplexing policy decisions as neither fully exploited the public-regarding policy options permitted even under these trade agreements. Therefore, while it is essential to understand the broader parameters of policy space set out by NAFTA and the Customs Union, there is still a need to understand why these policy decisions, despite the allowed policy leeway under NAFTA and the Customs Union.

Therefore, the second argument of this thesis is that the similar behaviors of Mexico and Turkey in passing strong pharmaceutical patent laws in the 1990s were an outcome of the similar domestic coalitional alignments whereby the prospects offered by NAFTA and the Customs Union asymmetrically empowered the actors in the pro-patent coalitions at the expense of those in the anti-patent coalitions. Specifically, the broader global economic dynamics that precipitated these regional arrangements in the 1990s reshaped domestic actors' preferences and capabilities in such profound ways that, by weakening the actors opposing pharmaceutical patents, they strengthened the power of the actors defending pharmaceutical patents.

In Mexico and Turkey, the key members of the pro-patent coalitions were the Executives. As central actors that undertook trade negotiations and the implementation of global commitments, the new context created by the regional trade agreements radically transformed Mexican and Turkish Executives' preferences for the appropriate pharmaceutical patent policy in the 1990s and turned them into avid proponents of patent protection in pharmaceuticals.

It might be argued that seeing the Executive branch as one of the many participants in domestic coalitions for policy change may be redundant since they are, by default, critical players in policymaking processes due to their power positions. However, my intention in conceptualizing the Executives as autonomous players in domestic coalitions is to highlight the fact that the Mexican and Turkish Executives had their own preferences for pharmaceutical intellectual property, based on their own calculations due to their very power positions, which sometimes overlapped and conflicted with those of other societal actors. In other words, the Executives in Mexico and Turkey had policy preferences regarding pharmaceutical intellectual property that were intertwined with the foreign economic policy

objectives they established for their respective nations. However, they were dependent on the support from the actors in the state and society to realize their desired policy changes.

The main societal actors that fought over pharmaceutical patents in Mexico and Turkey were the transnational and domestic pharmaceutical companies. Whereas transnational pharmaceutical companies vigorously advocated for new patent laws with strong exclusionary rights as quickly as possible, domestic pharmaceutical companies staunchly resisted their aspirations. Whose preferences ultimately prevailed were contingent upon the economic and political resources each group possessed at the time of policy change. The relative power of domestic pharmaceutical companies vis-à-vis transnational pharmaceutical companies was historically rooted in the sense that the degree to which domestic manufacturers achieved self-sufficiency in the production and marketing of pharmaceuticals determined their ability to deal with the disruptions caused by economic liberalization policies and the challenges presented by the regional trade agreements in the 1990s.

The global changes in the 1990s also prompted actors with no immediate stake in pharmaceutical patents to participate in policymaking debates. Since Mexico and Turkey's regional trade agreements were conditioned on the satisfactory provision of pharmaceutical patents, or at least the credible promise to do so, exporters and the business community, as the leading beneficiaries of these arrangements, mobilized in support of pharmaceutical patents. In both countries, these actors were essential players in the pro-patent coalitions, who exerted pressure on their respective governments to make the necessary adjustments not to jeopardize the conclusion of these regional agreements.

Therefore, in both Mexico and Turkey, the outcome in the 1990s was a formidable pro-patent coalition comprised of Executives, transnational pharmaceutical companies, exporters, and the business community prevailing over the anti-patent coalitions led by domestic manufacturers, whose historical dependencies rendered them vulnerable to the changes of the decade.

In the 2000s, both Mexico and Turkey underwent a new wave of pharmaceutical intellectual property reforms. During this period, the overarching objective of reform efforts was to address the increasing burden that rising drug prices put on public health finances, which precipitated greater awareness and assertiveness from health authorities regarding the adverse effects of the previously enacted pharmaceutical intellectual property rules. Nonetheless, despite the expansion of issues that influenced the Executive's preferences on the appropriate pharmaceutical intellectual property policies for the country, their ability to pursue their policy objectives was again contingent on amassing the support of various state and society actors.

The third argument of this thesis, therefore, is that the divergent pathways of Mexico and Turkey's pharmaceutical intellectual property policies were an outcome of the differing strength of the competing coalitions mobilized for and against the Executive's preferred pharmaceutical intellectual property policy changes.

In this second period of change, the policy processes illustrate how "effect becomes the cause" in pharmaceutical intellectual property politics (Farrell & Newman, 2014; Pierson, 1993; Shadlen, 2017; Thelen, 1999, 2003). The previous policy decisions in pharmaceutical patents created a "politics" in the sense that, by differentially empowering competing groups, they generated feedback effects that reverberated in the subsequent periods by altering the preferences of domestic actors

and their abilities for political mobilization (Pierson, 1993, 2000, 2005). Accordingly, actors facing positive (self-reinforcing) feedback effects emerge as the winners of the past policy choices, wish to maintain the status quo, and reinforce the direction being followed (Mahoney, Mohamedali, & Nguyen, 2016; Pierson, 2000). Indeed, in both Mexico and Turkey, transnational pharmaceutical companies emerged as the primary beneficiaries of pharmaceutical patents that allowed for single supplier status and pushed for the continuation and consolidation of pharmaceutical intellectual property systems.

In contrast, domestic pharmaceutical companies confronting negative feedback effects had to adapt to the status quo, whereby their strategies of adjustment were largely determined by the impact and timing of past policy choices (Fioretos, Falleti, & Sheingate, 2016; Mahoney, Mohamedali, & Nguyen, 2016; Shadlen, 2017). Specifically, in Mexico and Turkey, the adjustment patterns of domestic pharmaceutical companies to the new status quo depended on i) the extent of the exclusionary rights conferred to the patent owners in the 1990s that determined the magnitude of the initial shock they faced and ii) the temporal proximity between the introduction and modification efforts that determined the extent to which these shocks affected them. As Mexico and Turkey differed in these two crucial aspects, so did local manufacturers' political mobilization and alliance-building capabilities.

Mexico's decision to introduce pharmaceutical patents instantly and with a strong form of retroactive protection caused the adverse effects of pharmaceutical patents to be felt sooner and more acutely than in Turkey, which began processing pharmaceutical patents later and offered a weaker form of retroactive protection. Furthermore, the temporal proximity between the introduction and modification efforts in Mexico is significantly greater than in Turkey, resulting in a variation in

the degree to which the initial shock transformed domestic actors' capacity for political mobilization. Consequently, compared to Turkey, the longer time lag between the start date of patent protection and reform efforts in Mexico resulted in a significantly reconfigured domestic pharmaceutical industry that rendered domestic manufacturers significantly powerless vis-à-vis transnationals. In turn, the diminished capabilities of domestic manufacturers hindered the Executives' ability to garner support from the societal base and resist transnational companies' extremist demands. In contrast to Mexico, the relatively later introduction of pharmaceutical patents and the comparatively less time between the introduction and modification efforts in Turkey enabled coalition-building possibilities that could support the Executive's health-oriented policy changes.

To summarize, although Mexico and Turkey exhibited similar behaviors in the 1990s, the magnitude of the disruptions caused by their decisions was not. While pharmaceutical patents increased the presence of transnational pharmaceutical companies in the domestic markets in both countries, variations in the extent of the exclusionary nature of the initial policy choices and the temporal proximity between policy decisions led to a variation in coalition-building opportunities in the subsequent period of modification, which, in turn, led to different policy trajectories (Pierson, 2003, 2004; Shadlen, 2017).

1.3 Globalization, regionalization, and consequences of past policy choices: Objectives and contributions

Why is the question of ownership in intellectual property so profoundly important to understand the legal infrastructure of our current global economy? Why the rulemaking processes in intellectual property has been and continue to be so

conflictual at both the global and domestic levels? And what implications do the current rules that we have in intellectual property mean for economic prosperity and the welfare of humanity in an immensely interconnected and growingly knowledge-based global economy?

These broader and rather deeper questions that inevitably arise throughout this analysis are not only analytically valuable issues that contribute to major lines of debates in political science. They are also crucial because they carry critical implications for human welfare by fundamentally shaping the extent of public access to knowledge and information in a world marked by immense technological advancement. By focusing on pharmaceutical intellectual property rights, the very subset of intellectual property where the clash between private interests and public benefits is the most intense, this thesis seeks to show how rulemaking in intellectual property has been an integral part of the changing dynamics of the modern global economy and how the implementation of these rules generate important implications for public health.

By emphasizing how and to what extent global rules are still negotiated domestically to produce policy change, one of the main objectives of this thesis is to situate the question of intellectual property policymaking into the broader political economy literature. Indeed, compared to social scientists in other fields, political scientists have been relatively late to take an interest in the question of intellectual property rights. This is striking given that the study of intellectual property provides ample opportunities to add insights to many of the long-standing debates in comparative and international political economy.

At a deeper level, for instance, this thesis seeks to depict developing countries' intellectual property reforms as part of their encounter with economic

globalization. Situating intellectual property rights as part of the broader economic globalization process is important essentially because it is dubious to expect national intellectual property systems to undergo substantial change absent the impetus of international obligations, as many developing countries long regarded lax intellectual property as a critical tool for development (Shadlen, 2017, p. 23).

Therefore, by conceptualizing intellectual property reforms as second-stage economic policy reform, the very "rules of globalization" that aim to facilitate and coordinate intensifying cross-border economic activity, this thesis reveals a relatively understudied aspect of the trade-offs that developing countries have faced since the late twentieth century (Braithwaite & Drahos, 2000, p. 3; Wilcox, 2005). Indeed, whether to obtain greater market access by succumbing to regulatory convergence or to attract foreign direct investment by signaling their business-friendliness, the global harmonization process in intellectual property rights is part of the new world in which developing countries are now compelled to make choices they do not have to be enthusiastic about (Gill & Law, 1989; Ohmae, 1995; Strange, 1996).

Exposing this intimate connection between economic globalization and the push for intellectual property harmonization is crucial to grasping why, how, and to what extent the global pressures can lead to changes in domestic policy choices. Therefore, by tracing the domestic-level projections of global transformations, this thesis shows how valuable a theme the study of intellectual property policymaking is to understand the "second image reversed" effects on policy outcomes, that is, how global changes can reconfigure domestic politics (Gourevitch, 1978).

However, this thesis also cautions against disregarding the uniqueness of countries' individual experiences. Indeed, the main analytical concern of this study is to understand the nuances of variation in national patterns of compliance with the

new global rules despite an overarching process of global convergence. Therefore, by focusing on the persistence of variation amid harmonization, this thesis questions economic globalization's ability to homogenize national disparity in laws and policies. In that sense, this thesis argues for how essential it is to appreciate globalization as a process of "degrees," whereby a multitude of actors participate in complex policymaking processes that necessitate deep empirical work to unravel why and how commonly experienced global changes lead to divergent outcomes across contexts (Braithwaite & Drahos, 2000, p. 8).

In explaining diversity, this thesis reveals insights into the role of political institutions in adapting global changes to the domestic level. By undertaking deep empirical research on the relationship between the Executive and Legislative branches and the dynamics of interest representation in the Legislative branches in Mexico and Turkey, this thesis shows how external pressures and obligations for stronger intellectual property rights differentially empower actors in the state and society and how different political institutions mediate competing interests in distinct ways (Blyth, 2002; Etchemendy, 2011; Mosley, 2003; Murillo, 2009; Steinmo, Thelen, & Longstreth, 1992). The different political systems of Mexico and Turkey provides a useful test to assess the impact of different political institutions on policy outcomes.

Relatedly, this thesis demonstrates that examining intellectual property policymaking processes can significantly improve our understanding of how temporality affects policy trajectories (Pierson, 2005). Because patents, as private property rights over inventions, create clear winners and losers, the substance and timing of earlier policy decisions can significantly alter the preferences and capabilities of domestic actors and leave an imprint on later policymaking stages.

Consequently, this study shows how the politics of intellectual property policymaking could constitute a valuable theme in the historical institutionalist analysis as an area that could reveal the role played by political institutions in causing policy change and how these policy changes can influence subsequent institutional transformation modalities.

A more specific contribution of this thesis is to the debates on the differences between multilateralism and regionalism. Indeed, Mexico and Turkey's responses to the new global rules in intellectual property rights provide a valuable terrain for assessing the more transformative impact of the "deep integration" of the 1990s on intellectual property policymaking as they are essentially reform efforts undertaken as part of these two countries' regional integration projects (Lawrence, 1996). In that sense, Mexico and Turkey's experiences could help us better grasp the different impacts of multilateralism and regionalism on the dynamics of intellectual property policymaking by underlining the more extensive regulatory requirements that regional trade agreements require in return for greater market access. This is a significant contribution that connects with the broader debates on the multilateralism vs. regionalism debate that consume much attention in the political economy literature.

Moreover, Mexico and Turkey's unique experiences also illustrate the different impacts of different regionalisms. In that sense, Mexico and Turkey's introduction of pharmaceutical patents that mainly revolved around their regional integration projects under NAFTA and the Customs Union, respectively, also reveals the differing roles of the US and the EU in inducing change in national policies.

By revealing the normative implications that characterize the policymaking in intellectual property, another main objective of this thesis is to show why and how

the gap between economic “imperatives” and public health concerns is uniquely the widest in the politics of pharmaceutical intellectual property. Unlike many other areas of economic policy, debates over pharmaceutical patents frequently necessitate the resolution of an important question with a substantial normative component: how to simultaneously encourage inventive activity by pharmaceutical companies and not restrict access to medicines due to higher prices. Therefore, studying pharmaceutical intellectual property rights can show us how concerns over public health may also create unconventional politics whereby the question of access to medicines that may even extend to life-or-death situations can generate distinct political concerns that might be more difficult for policymakers to balance.

1.4 Research design, methodology, and data sources

This thesis is a qualitative comparative study that examines Mexico and Turkey's responses to the new global rules in pharmaceutical intellectual property in the 1990s and 2000s. But why are Mexico and Turkey ideal settings to study pharmaceutical intellectual property? The case selection rationale is based on four major reasons. Firstly, Mexico and Turkey share important commonalities related to pharmaceuticals that act as control variables in understanding their patterns of compliance with the new intellectual property rules in the 1990s. For one, Mexico and Turkey's pharmaceutical intellectual property rules before the 1990s were broadly similar. Both countries exempted pharmaceuticals from patent protection and staunchly opposed pharmaceutical patentability on similar grounds. More specifically, for both Mexico and Turkey, the lack of patent protection in pharmaceuticals was an intentional choice to increase domestic manufacturers' production capabilities and safeguard against high drug prices (Baca, 1994; Bacalski,

2006, p. 725; Eren-Vural, 2007a, 2007b; Sezgin Huysal, 2009; Shadlen, 2010, p. 826)

Relatedly, the evolution of domestic pharmaceutical industries in both countries exhibited broadly similar evolutionary dynamics, marked by high dependencies. In that sense, despite their long-standing preference for non-patentability in pharmaceuticals, domestic pharmaceutical companies largely failed to achieve high levels of self-sufficiency in innovation, production, or sale of pharmaceuticals. Domestic manufacturers' high levels of dependence on other actors that put their market dominance on fragile grounds serve as an explanatory variable in understanding Mexico and Turkey's policy choices in the 1990s.

Secondly, Mexico and Turkey also show striking similarities in their broader economic development processes that also act as valuable control variables in understanding their initial patterns of compliance. As developing countries located at the frontiers of the US and Europe, Mexico and Turkey's experiments with neoliberal economic policies have largely been similar in terms of their substance and timing (Eder, 2001; Özel, 2018). Moreover, although both were initially regarded as pioneers in market-oriented economic transition, the troubles they subsequently faced growingly put them in a similarly disadvantaged position in the global economy and increased their vulnerability to the "deep integration" of the 1990s (Eder, 2001). This, in turn, made their experiences in regional economic integrations with their regional blocs witness similarly deteriorating bargaining terms (Eder, 2001).

Thirdly, in both Mexico and Turkey, the pharmaceutical intellectual property policymaking processes in the 1990s were essentially a part of their regional integration projects with their largest trade partners. The centrality of regional trade

agreements in pharmaceutical intellectual property policymaking processes distinguishes Mexico and Turkey from other developing countries, the majority of which mainly strived to satisfy their TRIPS obligations. Therefore, the common variable of regional trade agreements serves as an explanatory variable in understanding Mexico and Turkey's policy choices in the 1990s.

Fourthly, the similar behaviors of Mexico and Turkey in the 1990s that act as control variables in modification efforts in the 2000s help assess the role of temporality in explaining the subsequently diverging policy trajectories of Mexico and Turkey. While Mexico and Turkey's policy choices in the 1990s were not exactly the same, understanding how the similar coalitional alignments that produced these initial behaviors subsequently changed requires attention to the role of time in accounting for their divergent policy choices in the 2000s.

The coalition-based framework I develop to explain the strength of Mexico and Turkey's pharmaceutical intellectual property rights takes into account the complex interplay between global economic dynamics and domestic political negotiations that determine the changing terms of relationships between domestic actors. In that sense, I conceptualize coalitions as relatively informal and malleable arrangements among various groups in the state and society that come together to engage in collective political action based on their shared interests or goals (Doner & Schneider, 2016; Shadlen, 2017).

To understand the making and changing of coalitional alignments in each domestic setting, I rely heavily on the case-based and temporally-oriented tools of comparative historical analysis (Mahoney & Thelen, 2015). In each country case, I observe the temporal unfolding of processes connecting events to outcomes in order to develop a mechanism-based causal explanation (Bennett, 2008; Mahoney, 2012;

Mahoney & Thelen, 2015). Within-case analysis and process tracing allow us to understand how the temporal ordering of events affects processes of preference formation, political mobilization, and coalition-building that constitute parts of the mechanism-based explanation for final policy outcomes (Mahoney & Thelen, 2015; Pierson, 2004). Therefore, comparative historical analysis permits a thorough examination of the complex policymaking processes that transpire in the making of pharmaceutical intellectual property laws.

The data sources for this thesis vary depending on the cases. For Mexico, I rely heavily on secondary resources, most importantly the existing literature. To ensure the accuracy of the evidence I present in this study, I gathered empirical evidence from a large body of literature and found consistency across texts. For Turkey, I amassed evidence from parliamentary records, official government reports, newspaper articles, and documents published by industry associations. In order to ensure the validity of my findings, I also compared them to the existing literature.

1.5 Overview of chapters

This thesis is organized into six chapters. Chapter 2 explores the literature on the global political economy of intellectual property rights. The first two sections of this chapter present the emergence and subsequent evolution of the global intellectual property rights regime and review the major debates in these two periods. The third section of this chapter builds on the first two sections to provide a critical evaluation of the existing literature. By focusing specifically on the question of variation in national patterns of compliance with the new global rules in intellectual property, this chapter addresses why the existing literature fails to provide a persuasive explanation for cross-national and longitudinal diversity.

Chapter 3 turns to the experiences of Mexico and Turkey and presents the explanatory framework of this study. In doing so, the first section provides an overview of conflicts surrounding pharmaceutical intellectual property rights. The second section critically evaluates the existing scholarship on intellectual property policymaking in Mexico and Turkey and assesses the explanatory power of these existing accounts. The third section presents an analytical framework to explain Mexico and Turkey's patterns of compliance with the new rules on pharmaceutical intellectual property.

Chapter 4 presents the policy processes when Mexico and Turkey introduced pharmaceutical patent protection in the 1990s. The first section of this chapter describes the shift in Mexican and Turkish Executives' preferences and the legislative processes that led to the enactment of new patent laws in the 1990s. The second section examines the conflicts between transnational and domestic pharmaceutical companies and their involvement in debates over pharmaceutical patents. The third section examines the expansion of pro-patent coalitions in Mexico and Turkey as a result of the mobilization of exporters and the business community.

Chapter 5 presents a detailed analysis of the policy processes when Mexico and Turkey attempted to modify their pharmaceutical patent systems in the 2000s. The first section of this chapter provides the available evidence on the impact of pharmaceutical patents in Mexico and Turkey. The second section analyzes the modification efforts in Mexico and describes how health-oriented policy initiatives failed to achieve their intended objectives. The third section examines the modification efforts in Turkey and explains how health-friendly policy initiatives succeeded in achieving their intended objectives.

Chapter 6 provides a broad summary of this thesis. The first section of this chapter summarizes the thesis's main findings and reiterates this study's contributions to the broader comparative and international political economy literature. The second section evaluates the limitations of this thesis and suggests research questions that await investigation. The third section points to the options available to developing countries to balance private rights and public benefits in pharmaceutical intellectual property rights.

CHAPTER 2

THE GLOBAL POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS: A LITERATURE REVIEW

The global intellectual property rights regime that governs the ownership, control, and use of knowledge and information is a complex artifact. Surpassing more than twenty-five years since its first emergence, the global rulemaking processes over the intangible property witnessed an exceptionally dynamic, rarely consensual, and deeply conflictual evolving landscape. While the quest for minimum universality over geographical diversity has succeeded in the global harmonization of private rights in intellectual property in the late twentieth century, continuous efforts to ease and expand public access to knowledge and information characterized much of the twenty-first century. With its focus on the contentious political processes of the making and changing of the global rules over intangible property, there exists a vast literature on the intellectual property's global political economy.

This chapter explores this vast literature with two objectives in mind. Firstly, this chapter aims to present the emergence and evolution of the global intellectual property rights regime. By probing deep into the nature of conflicts and examining the preferences and strategies of the key actors involved, my aim is to elucidate how such profound changes in the global governance of intellectual property took place, by whom, and for what purposes. Understanding these changes is crucial to make sense not only of the unique dynamics of intellectual property regulation that enabled it to escape the broader deregulatory trend (Arup, 1998, p. 367) but also to grasp the nature of contestations over economic prosperity and human welfare that the changing parameters of the permissible policy space in intellectual property set.

Secondly, this chapter aims to critically evaluate the existing literature on the global political economy of pharmaceutical intellectual property rights. While the existing scholarship provides explanations as to how the new global rules in pharmaceutical intellectual property have led to commonly experienced hardships in addressing problems in public health, as well as how these hardships continuously fueled conflicts at the global level, it fails to provide a persuasive and systematic explanation as to how, in fact, the nature and intensity of these experiences varied as a result of the countries' differing patterns of compliance with the new international standards in pharmaceutical intellectual property rights. This gap in the extant literature serves as the primary motivation for this study.

Importantly, while the late twentieth century saw the emergence of a new form of global governance in knowledge and information that set new minimum international standards in intellectual property, the ways in which individual countries complied with these minimum requirements varied significantly. Put differently, while facing similar global constraints set by the minimum standards in intellectual property, countries still differ in their decisions as to what knowledge to protect, how to protect, when to protect, as well as to what extent to protect private rights over intellectual property. Consequently, depending on how they chose to move to a world in which pharmaceutical innovation became private property, the degree, and types of challenges they faced also varied accordingly.

Therefore, the key argument of this chapter is that while different generations of research on the global political economy of pharmaceutical intellectual property rights have provided convincing explanations as to why and how changes at the global level transpired that ultimately defined the parameters within which countries are allowed to act, the existing scholarly work is remarkably less successful in

providing a systematic framework that could causally explain the diversity of national responses to commonly experienced global changes. As I argue in the fourth section of this chapter, the literature's scant attention to the question of variation in pharmaceutical intellectual property mainly stems from its proclivity to focus on the conflicts and contestations at the global level, often to the detriment of what happens on the domestic level. While the last decade has witnessed a proliferation of studies that growingly turned attention to pharmaceutical intellectual property policymaking on the ground, much of these studies still fail to present a coherent explanatory framework that could account for how the domestic and international variables interact.

This chapter unfolds in four parts. The following two sections present an overview of how the global intellectual property rights regime evolved and what implications this evolution produced for the permissible policy space for developing countries in terms of pharmaceutical intellectual property. To do so, the first section focuses on the initial debates in the literature, when the new global regime of intellectual property rights emerged. By focusing on the broader dynamics of the global political economy, this section narrates how and why intellectual property rights became a vital issue of international trade. The second section focuses on the subsequent debates in the literature, when the new international rules on pharmaceutical intellectual property were backlashed. By placing the relationship between intellectual property rights and access to medicines into the broader context of problems set out by the TRIPS Agreement, this section shows that the intense clash between private rights and public benefits in the area of pharmaceutical intellectual property is why access to medicines constitutes the most contested and publicized debate in the post-TRIPS era. The third section synthesizes these previous

debates to problematize why there exists no persuasive explanation in the existing literature to account for the profound cross-national and longitudinal diversity in national patterns of compliance.

2.1 Intellectual property rights and international trade: The initial debates

How and by whom the rules governing the ownership, control, and use of knowledge and information are made? What norms, principles, and values guide these rulemaking processes that ultimately define the boundary between public and private in rights over the intellectual property, between monopoly and competition in economic activity? These questions that lie at the heart of the intellectual property rulemaking characterize the perennial dilemma in the legal construction of rights over intellectual property at all levels of inquiry: how to define and distribute property rights in knowledge and information that could best resolve the tension between the private rights of owners in their intellectual efforts and the benefit that would accrue to the society from the free flow of the products that result from these individual endeavors.

As Sell and May (2001) argue, throughout the long history of intellectual property, the "pendulum swung both ways" across time and space: while some "moments in law" clearly favored private interests seeking to restrict access, others favored public benefits wishing to expand access. The powerful insight that emerges from their argument is that the rules defining and justifying intellectual property relations always reflect the power relationships within each economy and society, attesting to the inherently political nature of intellectual property rulemaking processes (Deere, 2008, p. 7).

When one examines this historically contested landscape, the "pendulum" appears to linger more on the public side of the debate. As numerous scholars demonstrate, all across the globe and for centuries, the triumph of private interests over public concerns appears to be a fleeting "moment" that quickly turns to laxity, at least well until the turn of the twenty-first century.[1] Reflecting the fact that public worth of intangible property has often been the enduring priority of each economy and society, the making of laws and policies defining what types of intellectual assets are to be protected, to what extent, for how long, and through what legal, administrative and judicial mechanisms have largely been within the scope of sovereign governments, formulated in conformity with the countries' level of economic development, technological capabilities, industrial structures, and specific socioeconomic needs and goals (Chang, 2001; Dutfield & Suthersanen, 2005; May, 2007; Mercurio, 2010; Sell & May, 2001). As a result of this prevailing public-regarding concern, therefore, this long history of intellectual property has been marked by an enormous cross-national rule heterogeneity in terms of the scope, subject matter, and length of private rights in intellectual property (Braithwaite & Drahos, 2000; Deere, 2008; Dutfield & Suthersanen, 2005; Sell & May, 2001).

Importantly, this profound rule diversity underpinned by public-oriented laxity has largely been allowed under the loose global framework of rules in intellectual property. Indeed, many of the international conventions that embodied the then-existing global intellectual property rules were just instances whereby states

[1] For a detailed analysis of the three broad phases of global intellectual property regulation, see: Braithwaite and Drahos (2000, p. 57-63) and Sell and May (2001, p. 479-494).

extended the principles of national treatment[2], non-discrimination[3], and the right of priority[4] through the "contractual device of treaty-making" (Drahos, 1997, p. 202): they created neither globally enforceable international law in strong intellectual property rights, nor attained enough membership to mandate global uniformity in strong intellectual property rights (Braithwaite & Drahos, 2000; Deere, 2008; Matthews, 2002; Sell & May, 2001).[5] To the contrary, this system of global rulemaking in intellectual property has largely respected the sovereign's wide policy autonomy, the principle of territoriality, and the ensuing profound multiplicity in the rules over intangible property (Braithwaite & Drahos, 2000; Dutfield & Suthersanen, 2005; Deere, 2008, p. 37-41; Sell & May, 2001).[6]

However, since the late twentieth century, the pendulum started to swing to the other extreme. Decades of efforts at the national, regional, and multilateral levels that sought to globally harmonize a stronger and stricter set of rights in intellectual property have largely succeeded in replacing the long-standing principles of sovereignty, territoriality, and diversity with the loss of policy autonomy, universality, and uniformity. The new paradigm underpinning the global rulemaking processes often justified the goal of minimum uniformity in rights over intellectual property as a natural corollary of a growingly interconnected, knowledge-based global economy. Consequently, what we witness since the late 1970s is the

[2] The principle of national treatment requires the signatory countries to treat the foreigners and nationals equally by extending to foreigners the same ownership rights and legal remedies the country's own nationals enjoy (Deere 2008, 36).
[3] The principle of non-discrimination requires that the foreign owners of intellectual property should encounter no impediment in their entry into the national market (Sell & May 2001, 484).
[4] The principle of the right of priority requires the state to protect the rights of the owner from unauthorized use of intellectual property (Chang, 2001, p. 292; Sell & May 2001, 484).
[5] The Paris Convention for the Protection of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Works of 1886 were the first two attempts to create an international framework for intellectual property rights. For an analysis of why and how these first international conventions emerged, see: Braithwaite and Drahos (2000, p. 58-61) and Deere (2008, p. 36-7).
[6] The principle of territoriality denotes that the legal protection conferred to intellectual property in one country only applies within the confines of that country (Braithwaite & Drahos, 2000, p. 58).

beginnings of efforts to construct a new global legal infrastructure for the incipient knowledge economy, the establishment of globally secure private rights in intellectual property.

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) sits at the center of this new global regime of intellectual property rights. As a culmination of hard-fought battles during the GATT Uruguay Round (1986-1994), the TRIPS Agreement was signed in 1994 as one of the constitutive multilateral trade agreements that established the World Trade Organization (WTO). In effect, three distinct features of the TRIPS Agreement make it a remarkable arrangement.

Firstly, by building on and going beyond the patchwork of conventions administered by the World Intellectual Property Organization (WIPO), the TRIPS Agreement specifies an unprecedentedly high set of substantive minimum standards regarding the scope, subject matter, duration, and enforcement of private rights over a diverse range of intellectual property.[7] In this new world defined by the TRIPS Agreement, therefore, knowledge and information turn into a globally exchangeable commodity with temporally longer and geographically broader private monopoly rights in intellectual property.

Secondly, to amend the previous arrangements' lack of enforcement capability, the TRIPS Agreement creates a powerful institutional design to ensure adequate compliance. With its TRIPS Council that seeks to secure proper and timely compliance and its powerful dispute settlement machinery that serves to ensure adequate enforcement, the TRIPS Agreement endows the WTO with significant

[7] The TRIPS Agreement includes provisions over patents, trademarks, copyrights, trade secrets, geographical indications, industrial designs, and undisclosed information. For a detailed legal analysis of the TRIPS Agreement, see: Reichman (1995) and Yu (2009).

policing power in the global protection and enforcement in intellectual property rights (Braithwaite & Drahos, 2000, p. 64).

Thirdly, and perhaps most interestingly, the TRIPS Agreement achieves all these dramatic changes in the global governance of intellectual property by making adequate respect to these new minimum standards in intellectual property an essential prerequisite to participate in the global economy. Indeed, in an unprecedented move, the TRIPS Agreement's "single-undertaking" conditions membership in the multilateral trade regime on compliance with the new standards in intellectual property. Thereby, in this new world established by the TRIPS, countries willing to partake in the multilateral trade regime in seek of greater market access must also be equally ready to concede to greater regulatory convergence (Shadlen, 2005). This grand bargain that the TRIPS is predicated upon, in turn, effectively eliminates the long-standing respect for sovereign's national policy autonomy and the ensuing rule diversity, turning what was once strictly within the discretion of sovereign governments now subject to international disciplines that seek to promote global uniformity (Arup, 1998, p. 374; Braithwaite & Drahos, 2000, p. 63).

To account for this transformation from enormous rule diversity to minimum universality, the earliest debates on the new politics of intellectual property sought to understand the causes and consequences of these profound changes. Spawned in the 1990s, a corpus of literature has produced compelling empirical accounts of the complex political economy behind the making of the new rules in intellectual property, asking why, how, and by whom this great transformation took place. Despite their differences in methodologies, approaches, data sources, as well as fields of social sciences, these early works concur in their conclusions: the TRIPS Agreement is a remarkable example of how a group of private actors, entirely

dedicated to the arduous task of globalizing stronger intellectual property rights, effectively made globally binding international public law (Abbott, 1989, 1996; Braithwaite & Drahos, 2000; Doane, 1994; Drahos, 1995, 1997, 2002; Liu, 1994; Matthews, 2002; Pugatch, 2004; Ryan, 1998; Sell, 1995, 2003; Weissman, 1996; Wolfhard, 1991). The three critical "moments" they observe depict the gradual, but steady, transition into a world in which knowledge and information turned into a globally protected private property.

Firstly, these analyses show that the new trade-based approach to intellectual was strategically formulated and promoted by the knowledge-intensive companies in the United States, who had a vested interest in stronger, broader, and globally enforceable private rights in intellectual property (Braithwaite & Drahos, 2000; Sell, 2003). Numerous scholars agree that these companies, tightly organized under industry associations, have been remarkably successful in persuading the US government to link intellectual property protection to bilateral trade action as an initial step toward global protection (Braithwaite & Drahos, 2000; Liu, 1994; Matthews, 2002; Sell, 2003)[8]. Indeed, the amendments in Section 301 of the Trade and Tariff Act of 1984 were often seen as a direct response to the aggressive and intensive lobbying from the knowledge-intensive companies (Braithwaite & Drahos, 2000; Matthews, 2002; Sell, 2003).[9]

Two changes in the 1984 amendments were particularly important. For one thing, the 1984 amendments significantly enhanced the executive's capacity to

[8] Sell (2003) notes that these industry associations consisted of the International Intellectual Property Alliance, the Pharmaceutical Manufacturers Association, the Chemical Manufacturers Association, National Agricultural Chemicals Association, Motor Equipment Manufacturers Association, Auto Exports Council, Intellectual Property Owners, Inc, the International Anti-counterfeiting Coalition, and the Semiconductor Industry Association (p. 76).

[9] Importantly, the 1984 amendments were not the first legal change that included provisions over intellectual property. The 1984 amendments build and extend upon the 1974 and 1979 amendments that also included intellectual property provisions. For a detailed analysis of the 1974 and 1979 amendments, see: Sell (2003, 76-78) and Matthews (2002, p. 14-5).

redress the industry's complaints by transforming the Office of the United States Trade Representative (USTR) into a powerful agency capable of identifying and initiating action on its own against those countries that failed to accord adequate and equitable respect to the US companies' intellectual property rights (Matthews, 2002; Sell, 2003).[10] Equally important, the 1984 amendments conditioned the extension and revision of non-reciprocal trade concessions granted under the Generalized System of Preferences (GSP) on the adequate protection of intellectual property rights (Matthews, 2002; Sell, 2003). Together, Section 301 and the GSP linkage fundamentally altered the US approach to international intellectual property protection.

An important question that these early works sought to answer was why these knowledge-intensive industries grew increasingly uneasy with the absence of international intellectual property protection at this particular period of time. Arguably, this shift in the attitude of these industries was a response to the changing patterns of production and competition in the growingly knowledge-based global economy. Intellectual assets now constituted not only a frequently traded global commodity but also a highly value-added property that promised unprecedented profitability (Primo Braga & Fink, 1998). However, with the absence of global respect for intellectual property rights, the expanding world trade in knowledge- and information-intensive goods only served to expand the possibility of growing competition through copying and imitation (Doane, 1994).

Indeed, increasingly into the late 1970s, the prominent knowledge-intensive industries started to feel the pain. For instance, while the copyright industry

[10] While the USTR had been established in 1962 by the Trade Expansion Act, it was in 1974 that the post became a Cabinet-level agency within the Executive Office of the Presidency. See: Matthews (2002, p. 177).

increasingly began to voice concerns about widespread piracy, the brand-name goods companies saw growing trade in counterfeit goods as a fundamental threat to their commercial viability (Braithwaite & Drahos, 2000; Doane, 1994; Matthews, 2002; Sell, 2003). The pharmaceutical industry has also been harmed by "unfair" competition, as the easily codifiable nature of pharmaceutical innovation was particularly ripe for reverse engineering and imitation (Nogués, 1990; Roemer-Mahler, 2013). Unsurprisingly, when confronted with a significant threat to their profitability, the copyright, brand-name goods, and research-intensive industries called on the US government to help cease weak international protection of intellectual property (Braithwaite & Drahos, 2000; Matthews, 2002; Sell, 2003). While these industries initially lobbied the US government to initiate reform in the WIPO conventions and to incorporate and an anti-counterfeit code into the GATT Tokyo Round negotiations[11], by the early 1980s, they realized that the most effective means of global protection was actually through bilateral trade action (Adede, 2003; Braithwaite & Drahos, 2000; Drahos, 1995; Matthews, 2002; Sell, 2003).[12]

How did these private actors prove to be so politically powerful that they became the critical agents of change in the US trade policy? According to Sell (2003), the answer lies in the late twentieth century's unusual circumstances that led to a sharpening of focus on trade policymaking to treat the "diminished giant

[11] In the late-1970s, the growing trade in counterfeit goods precipitated the mobilization of 100 multinational corporations under the Anti-Counterfeiting Coalition, which sought to make protection against counterfeiting as part of the GATT Tokyo Round agenda. For Matthews (2002, p. 9), the failure of the Anti-Counterfeiting Coalition to reach the GATT level "paradoxically" further galvanized the US business to work hard to put the intellectual property on the next GATT round's agenda. For a detailed analysis of the Anti-counterfeiting Coalition, see: Matthews (2002, p. 8-9).

[12] In the early 1980s, the US corporations reliant on global intellectual property protection persuaded the US government to initiate a series of bilateral consultations with Hungary, Mexico, Singapore, Korea, and Taiwan. The willingness of these countries, except for Mexico, to offer stronger protection for intellectual property convinced both the US government and the US companies that bilateral trade pressure could be an effective venue to realize change. For an analysis of these early bilateral negotiations, see: Sell (2003, p. 70-80).

syndrome" of the US (Bhagwati, 1993). In effect, what transpired was complex: the perceived causal relationship between surging trade deficits, increased foreign competition, and the apparent ebb of American industrial superiority all collectively contributed to the rise of protectionist sentiments and a deepening domestic debate over the decaying US competitive edge (Drahos, 1995; Granstrand, 1999; Sell, 2003; Zysman & Cohen, 1987). In such a context, according to Sell (2003), the search for effective remedies for America's trade problems was what precisely allowed the industry to exert such profound sway over trade bureaucracy.

A cursory examination of the Advisory Committee for the Trade Negotiations (ACTN) suffices to substantiate this claim. As a peerless entity created to institutionalize direct business input into the formulation of US trade policy, the ACTN was instrumental in communicating the aggregated interests of diverse stakeholders to key policymakers (Braithwaite & Drahos, 2000; Drahos, 1995; Matthews, 2002; Sell, 2003). Perhaps more importantly, however, what made the ACTN succeed was its active engagement in the production of new "knowledge" about intellectual property that framed, and in turn, legitimized, the trade-based protection of intellectual property as an undeniable economic necessity for the future of US prosperity.[13] Unsurprisingly, with an unprecedented degree of access to trade policymaking, coupled with their good economic standing, the united political voice of these knowledge-intensive industries succeeded in persuading the US government to take concrete action against weak intellectual property protection, firstly, in the

[13] The critical role played by Edmund Pratt should not be forgotten. With his dual post both as the CEO of Pfizer Pharmaceuticals and the chair of ACTN from 1981 onwards, Pratt not only brought diverse industries together around the common goal of globalizing intellectual property rights but also actively engaged in formulating concrete proposals as to how to achieve that end (Braithwaite & Drahos, 2002, p. 62; Drahos, 1995, p. 8; Matthews, 2002; Sell, 2003).

form of bilateral trade legislation (Drahos, 1995; Matthews, 2002; Sell, 2003; Weissman, 1996).

Secondly, these early works illustrate that, as an interim step in their quest to confer intellectual property rights global protection, these same private actors in the US- now mobilized under the Intellectual Property Committee (IPC)- shifted the decision-making power in intellectual property away from World Intellectual Property Organization (WIPO) to GATT framework (Braithwaite & Drahos 2000; Drahos 2004; Sell, 2003). As an entity that was established in March 1986, just six months before the Punta del Este Meeting that launched the GATT Uruguay Round negotiations, the IPC's success in this shifting of forums within a surprisingly short period of time is remarkable not only because of its outcome but also for its process.[14]

Why did the IPC seek to shift the intellectual property agenda from WIPO to GATT? According to many, this was primarily due to the US' perception of the WIPO as a platform that clearly favored the developing country interests (Matthews, 2002; Sell, 2003). Indeed, this was not without much truth. By the 1980s, the WIPO became a "battleground" between the developed and developing countries (Drahos, 2002b, p. 166), where the developing country bloc- led by Argentina, Brazil, and India- clearly had the upper hand (Deere, 2008; Matthews, 2002). While the developed countries, prompted by their industries, proposed to revise the existing conventions to strengthen international intellectual property protection, the developing countries' staunch opposition to any revision and counter-attempts to

[14] As Braithwaite and Drahos (2000) argue, throughout the postwar era, the strategy of forum-shifting or forum-blocking has often been employed by powerful states like the US in order to optimize their power and minimize opposition. For a detailed analysis of forum-shifting, see: Braithwaite and Drahos (2000, p. 28-9).

even lower the existing standards of protection rendered these efforts largely futile (Adede, 2003; Braithwaite & Drahos, 2000; Deere, 2008; Drahos, 2002b)

The developing countries' adamant opposition was partly a continuation of their growing assertiveness against stronger and international protection of intangible property since the 1960s, which reached its apex with the calls for a New International Economic Order (NIEO) in the 1970s (Blakeney, 1998; Chang, 2001; Deere, 2008). The prevailing consensus then was to see the rules over intellectual property as a tool to achieve technological capability, which they hoped would result in greater political and economic independence (Blakeney, 1998; Deere, 2008). Therefore, throughout the period and at various United Nations-affiliated fora, many of the developing countries questioned what they perceived to be an imbalance in the international rules over intellectual property, requesting special rights and permissions to address the unique needs of their societies and better provisions to facilitate the acquisition of foreign technology (Deere, 2008, p. 41-45; Drahos, 2002b).[15] Indeed, the perceived significance of the intellectual property rules as a tool for economic development and emancipation played a significant role in the establishment of the WIPO as a specialized agency of the UN in 1974 (Blakeney, 1998; Braithwaite & Drahos, 2000; Deere, 2008, p. 45; Yu, 2007).[16]

Furthermore, many note that for the US corporations, the WIPO was, by its very design, ill-equipped to globalize stronger intellectual property standards

[15] Two prominent examples of these UN-affiliated institutions include UNCTAD and UNESCO. According to Braithwaite and Drahos (2000, p. 68), more than any other international organization, it was the UNCTAD that could have a legitimate claim over the development of a trade-related agreement in intellectual property. This is because the UNCTAD had long been engaged in efforts that closely investigated the relationship between international trade and technology transfer. For a more detailed analysis of these UN-affiliated institutions, see Braithwaite and Drahos (2000, p. 67-9) and Deere (2008, p. 42-5).

[16] Importantly, the WIPO was first established in 1967. The establishment of the WIPO as an UN-affiliated specialized agency in 1974 was a result of the developing country efforts to make the WIPO more-development friendly (Deere, 2008, p. 45).

(Braithwaite & Drahos, 2000; Matthews, 2002). With its disparate treaties that varied in membership, its general rather than specific obligations, its lack of an enforcement mechanism, and one-state-one-vote decision-making, the WIPO was simply too impotent to advance stronger and global intellectual property protection (Braithwaite & Drahos, 2000; Drahos, 1995; Matthews, 2002). For the US, the GATT was the preferred route: a forum that is capable not only of attracting global membership and ensuring an effective enforcement mechanism but also where it could exert its market size as a profound leverage to reap concessions (Adede, 2003, p. 26; Braithwaite & Drahos, 2000; Drahos, 1995; Sell, 2003). Despite the predictably strong resistance from the developing countries over GATT's competence in intellectual property, however, the IPC succeeded in shifting forums from WIPO to GATT in a remarkably short period of time (Braithwaite & Drahos, 2000; Sell, 2003; Weissman, 1996).

A large body of works has examined how the IPC accomplished this spectacular shift (Braithwaite & Drahos, 2000; Matthews, 2002; Sell, 2003). Much of the answer lies in the peculiarity of IPC that enabled it to rewrite the rules on intellectual property and make them acknowledged globally. Importantly, the IPC was tasked with a single mission: to rally the support of European and Japanese businesses to put the intellectual property on the Uruguay Round agenda (Drahos, 1995; Sell, 2003). To do so, the ACTN's member companies decided to form a "club" of CEOs representing a broad array of industries[17], which provided the necessary funding and human resources to muscle the intellectual property battle (Braithwaite & Drahos, 2000; Sell, 2003). In that sense, as a well-managed, well-

[17] The IPC represented a broad array of US industries – chemical, computer, creative arts, electronics, heavy and consumer manufacturing, and pharmaceutical industries. In 1986, the members of the IPC included: Pfizer, IBM, Merck, General Electric, DuPont, Hewlett-Packard, Bristol-Meyers, CBS, General Motors, Johnson and Johnson, Monsanto (Sell, 2003, p. 2).

staffed, and well-funded single-issue business group that prioritized rapid action over broad consensus, the IPC was indeed a peculiar entity that not only succeeded in defining its objectives and strategies in fairly short order but also in convincing the initially reluctant EC and Japan to join (Braithwaite & Drahos, 2000; Drahos, 1995; Sell, 2003).

Indeed, the IPC's prowess in persuading their counterparts in the EC and Japan, the UNICE and Keidanren, respectively, was particularly impressive. For both UNICE and Keidanren, intellectual property was not only too new of a subject to become a part of the GATT regime but also too complicated to survive in an already complex round agenda that included sensitive issues like agriculture (Sell, 2003). However, the IPC's persuasive skills in appealing to their common interests in safeguarding future prosperity and competitiveness, as well as their identification of the WIPO as a forum tangled with special interests of the developing countries, eventually put the UNICE and Keidanren on board to adopt the trade-based approach to intellectual property (Sell, 2003).

The trilateral group achieved its first victory when they persuaded the GATT Preparatory Committee to include intellectual property in the Uruguay Round agenda (Braithwaite & Drahos, 2000; Matthews, 2002; Sell, 2003). While the proposal did not receive wide consent, it nevertheless put intellectual property to be discussed at the Punta del Este Ministerial Declaration in 1986 (Muzaka, 2011, p. 50).

Following this initial victory, the IPC, UNICE, and Keidanren intensified their collective efforts between 1986 and 1988, focusing on developing a consensus-based intellectual property code. Finally, in June 1988, these three industry groups presented the "Basic Framework of GATT Intellectual Property Provisions: Statement of the European, Japanese, and US Business Communities," which

effectively laid the groundwork for the final TRIPS text (Braithwaite & Drahos, 2000; Sell, 2003). Importantly, this transatlantic alliance between the American, European, and Japanese businesses was not only that “for the first time in modern economic history, the industrial countries have come to an agreement on “appropriate” patent protection” globally (Nogués, 1990, p. 2-3), but also "a significant breakthrough in the involvement of the international business community in trade negotiations” (Drahos, 1995, p. 13).

Thirdly, and lastly, these early studies illustrate the immensely contentious nature of the TRIPS negotiations, marked by the aggressive use of “sticks”, as well as “carrots”, to suppress developing country opposition. Indeed, the IPC and its allies in Japan and the EU were well aware that their goal of globalizing intellectual property would be impossible to achieve if the TRIPS Agreement failed to materialize. Therefore, as the TRIPS negotiations stalled between 1986 and 1989, these private actors pushed their home states to intensify pressures on the dissenters to abide.

The so-called "Group of Ten" countries, led by India, Argentina, and Brazil, maintained their opposition to both the GATT's competence and emerging developed country proposals (Adede, 2003, p. 24; Sell, 2003, p. 108). Importantly, the developing countries' reservations were not unwarranted. For one thing, the proposed rules made it abundantly clear that developing countries would need to engage in significant legislative activity in order to establish the necessary administrative and enforcement capacities (Braithwaite & Drahos, 2000; Primo Braga & Fink, 1998). Worse, the proposed rules fueled fears that, if adopted, new intellectual property rules could result in significant welfare losses in developing countries, as new rules would simply result in speeding the transfer of rents from developing to developed

countries (Chang, 2001; Primo Braga & Fink, 1998). Indeed, given the wide North-South technology divide, the new rules in intellectual property carried the risk of impeding industrial development in late-comers not only by limiting opportunities to imitate and adapt foreign technology to domestic standards but also by making the acquisition of foreign technology prohibitively expensive (Drahos 2002b, p. 3; Fink & Maskus, 2005). Additionally, the proposed rules in intellectual property also sparked fears that domestic prices for a variety of essential goods, ranging from medicines to copyrighted materials, would escalate, resulting in constrained public access in a number of areas critical to human welfare (Fink & Maskus, 2005; Primo Braga & Fink, 1998).

However, by the end of 1989, the developing country opposition to the TRIPS Agreement had largely waned (Braithwaite & Drahos, 2000; Drahos, 1995; Sell, 2003, p. 109). Why did the developing countries finally concede, despite the fact that they stood to lose the most from such a move? The scholarship advances three major explanations for why previously recalcitrant developing countries eventually yielded.

Firstly, numerous scholars agree that the primary factor weakening developing country opposition was economic coercion (Braithwaite & Drahos, 2000; Drahos, 1995; Liu, 1994; Sell, 2003; Yu, 2006). For example, Pugatch (2004) notes that, especially in the latter part of the 1980s, the EC intensified bilateral pressure on a number of developing countries, most notably on South Korea in 1987. However, it has been suggested that more than the EC's pressure, it was the fear of being targeted by the USTR that converted dissenters into conformers. Indeed, while South Korea's amendment of its intellectual property rights in 1986 has often been cited as a "success" of the US bilateral pressure, the threat of denying GSP benefits has also

been a frequently used "stick" against a number of Latin American countries (Shadlen, 2017).

The effectiveness of the US pressure may be particularly true following the passage of the 1988 Omnibus Trade and Competitiveness Act. Importantly, the passage of the 1988 Act paralleled the process that produced the 1984 Act. As Sell (2003) notes, the knowledge-intensive industries' dissatisfaction with the US government's reluctance to take retaliatory action against recalcitrant GSP beneficiaries was the primary driver of the post-1984 period's intensifying lobbying activity. The 1988 Trade and Competitiveness Act further strengthened the trade-based approach to intellectual property by, among other measures, requiring the USTR "not only to determine whether foreign government practices are unfair, but also to take action" (Bello & Holmer, 1988, p. 8). Thus, under the new 1988 Act, the USTR was now responsible for annually identifying priority violator countries and determining the appropriate retaliatory measure to be taken within strict time limits (Sell, 2003). Armed with a far more credible threat, the USTR targeted the TRIPS' most vocal critics: India, Argentina, and Brazil. Indeed, Brazil's capitulation to aggressive US pressure is frequently cited as a watershed moment that diminished developing country resistance.[18] Therefore, for many developing countries, it became evident that "if they did not negotiate multilaterally, they would each have to face the US alone" (Drahos, 2002a, p. 774).

[18] Brazil has been under US pressure at least since 1985 due to Pharmaceutical Manufacturers' Associations' (PhRMA) complaints about the lack of pharmaceutical patents in Brazil. In 1988, the PhRMA's persistent complaints finally led to retaliatory action when the US imposed trade sanctions on Brazil that raised tariffs to 100% on US$ 39 million worth of Brazilian exports (Braithwaite & Drahos, 2000, p. 79; Nogués, 1990, p. 7-8; Sell, 2003, p. 108; Shadlen, 2017). The US-Brazil dispute, which also reached the GATT, eventually resolved in 1990, when Brazil acceded to introduce patent protection for pharmaceuticals.

Second, many scholars concur with Sell's (2003) assertion that the "glaring asymmetry" in the North and South's expertise and experience played a significant role in the latter's inability to negotiate effectively during the TRIPS negotiations (Drahos, 1995, 1997; Matthews, 2002, p. 44; Sell, 2003, p. 110; Yu, 2006). Indeed, this argument is not without much truth. In comparison to developed countries, which largely benefited from close ties to their corporate lobbies that provided technical and legal expertise to their negotiators (Braithwaite and Drahos, 2000, p. 69-70; Doane, 1994; Drahos, 1995; Sell, 2003), developing countries exhibited only a "high degree of ignorance... as to the costs of increasing intellectual property protection" (Drahos, 2000, p. 3). Only a few countries, like India, Argentina, and Brazil, had developed specific counter-proposals demonstrating comparable technical deftness, which called for shorter protection terms and increased autonomy in compulsory licensing (Drahos, 1995, 2002; Sell, 2003, p. 110). Nonetheless, these proposals were often rejected by the US negotiators, whose decades of technical and legal expertise enabled them to “pull rank” over their inexperienced counterparts (Drahos, 1995, p. 15).

Finally, some scholars argue that, while the TRIPS was a “grand bargain” that worked to the detriment of developing countries, the prospect of increased market access for textiles and agricultural products was still a sufficient incentive for developing countries to concede on intellectual property standards (Braithwaite & Drahos 2000, 1997; Drahos 1995, 15; Matthews, 2002, p. 45). Indeed, this argument has merit in the sense that the “single-undertaking” of the WTO agreements effectively presented a “package deal” wherein developing countries were required to cede non-trade concessions in order to obtain greater trade concessions (Adede, 2003, p. 26).

What these explanations suggest is that whether through economic coercion, technical persuasion, or a "package deal" obligation, the TRIPS Agreement is a far cry from being a voluntary cooperation. Indeed, what the making of the TRIPS Agreement exemplifies is how the imperatives of intensifying international trade and rapid technological change profoundly altered the stakes, blurred the boundaries between the public and private and led to the emergence of a constructive alliance between the business and government that effectively turned private actors as the key agents of global regulatory change. As these private actors sought to establish the regulatory infrastructure for the global safety of their assets, what fell on the share of developing countries was a shrinking policy space.

In this narrowed policy space, developing countries were granted certain safeguards and public-regarding options that they could use to balance private rights and public benefits when they set out to implement their new intellectual property rules. While the specific options vary according to the type of intellectual property in the treaty, the most important patent-related "TRIPS flexibilities" were: i) transition periods for developing countries, ii) permission to define the national standards of patentability criteria, iii) permission to define areas to be exempted from patentability, iv) permission to define exceptions to patent rights, v) permission to issue compulsory licenses, vi) permission to define the rules of exhaustion in patent rights, vii) permission to address abuse of patent rights through competition policy (Global Development Policy Center, 2019; Musungu & Oh, 2006; 't Hoen, Veraldi, Toebes, & Hogerzeil, 2018).

However, as I will show next, the extent to which developing countries are actually permitted to use these flexibilities inherent in the treaty has always been debatable. Because these policy options were efforts to counterbalance the extremist

demands of the US, the dissatisfaction of the US with TRIPS only sowed the seeds for further disputes.

2.2 Intellectual property rights and access to medicines: Doha Declaration and beyond

Since its emergence, the TRIPS Agreement has proved to be one of the most controversial international agreements. As a "particular contemporary globalized settlement," TRIPS only triggered further contestation and dispute between the winners and losers of this new intellectual property arrangement (Sell & May, 2001, p. 468-9). However, unlike the previous decade that witnessed conflicts mostly over whether intellectual property rightfully belonged to the domain of global commerce, the post-TRIPS era saw intellectual property ceasing to be strictly a matter of international trade and increasingly as a critical factor that determined the extent of public access in various areas of human welfare: farmers' access to seeds, programmers' access to source codes, people's access to literary works, and patients' access to medicines (Muzaka, 2011; Morin, 2014, 276). The resulting landscape, therefore, was not only a dramatic expansion in the range of issues associated with intellectual property but also a deepening complexity and intensity of conflicts over intellectual property.

Importantly, the main reason for this multiplication and complication of contestations was the challenges that emerged as developing countries set out to satisfy their new international commitments. Admittedly, the emergence of a new set of conflicts in the post-ratification phase has been the common fate of many complex international agreements that defer the resolving of remaining tensions to the implementation stage (Muzaka, 2011, p. 64). However, what made conflicts over

TRIPS unusually complex was not only that it fundamentally redefined the permissible policy space in efforts to reconcile the inherently conflictual tension between private rights and public benefits, but it did so by leaving behind a legacy that sowed the seeds for its own questioning. Indeed, the TRIPS' imbalanced nature is evident not only during the contestations over its making but also during the subsequent fights on the implementation scene. In other words, what the post-TRIPS era saw was the emergence of often acrimonious debates over the fairness and legitimacy of TRIPS as the question of "appropriate" implementation, i.e., what interpretations of the "constructive ambiguity" in the language of the treaty constitute consistent behavior to which developing countries must adhere, fueled a yet another episode of conflict over intellectual property rules (Deere, 2008; Muzaka, 2011, p. 64; Sell, 2003; 2004, 365).

For one thing, the post-TRIPS era experienced an intensification of confrontation between the North and South, marked by an ever-widening gap between their objectives. For developed countries, while much of the new rules in TRIPS have been written by them and their companies, TRIPS was nevertheless a consensus document that lost too much to multilateralism. For instance, while the long transition periods, the rather permissive provisions for compulsory licensing and exhaustion of rights, as well as the exceptions for protection in areas like plants, animals, and biotechnology, effectively made TRIPS much weaker than what the US desired, the inadequate protection TRIPS conferred to certain geographical indications was why the EU was dissatisfied (Deere, 2008; Muzaka, 2011; Sell, 2003). Moreover, although the enforcement provisions in TRIPS have been regarded by both as a case of success, the still territorial nature of intellectual property administration has incited concerns about weak domestic enforcement (Sell, 2003).

Thus, what the developed countries, led by the US and the EU, wanted and sought, was quicker implementation, better enforcement, less use of existing flexibilities, and, hopefully, even stronger protection of private rights in an ever-expanding set of intellectual property (Deere, 2008; Dutfield & Suthersanen, 2005; Matthews, 2002; Muzaka, 2011, p. 65; Sell 2003).

For the developing countries, however, the new wave of pressures from the developed countries and their companies to quickly implement TRIPS necessities without using the existing flexibilities only further exacerbated the costs of compliance. Already struggling to execute the costly legal, administrative, and judicial changes as the deadline loomed large (Matthews, 2002; Muzaka, 2011), the complexities of implementation heightened developing countries' awareness of the grave implications of TRIPS' "one-size-fits-all" rules, leading to a greater assertiveness and alliance among the weak (Deere, 2008, p. 113-142; Sell, 2011, p. 449). Therefore, what the developing nations, headed by Brazil and India, wanted and sought was a clarification, and possibly an expansion, of the existing flexibilities that would allow them to preserve and enhance their national policy autonomy to better address their specific goals and needs (Deere, 2008).

Importantly, in the post-TRIPS era, the widening disparity between the developed countries' aspirations and developing countries' expectations were accompanied and aggravated by the greater participation of non-state actors in discussions over intellectual property, profoundly shaping the evolution of global rules over intellectual property. Often at the epicenter of "dialogic webs," or "webs of persuasion," the deepening engagement of non-state actors in these debates, both directly and through constructive relationships with governments, attests to how agency matters in shifting the terms of policy debates (Braithwaite & Drahos, 2000,

p. 552-3). These actors and the competing knowledge networks they constructed often profoundly altered the perceptions and preferences of governments and the public during the implementation stage, by continuously feeding them new knowledge about the nature of problems and by providing new "ideas" as to how to resolve these problems (Braithwaite & Drahos, 2000; Haunss & Kohlmorgen, 2009; Sell, 2004; Sell & Prakash, 2004).

Equally important was the fact that as much as the "strategic use of ideas" mattered, so did the "strategic use of institutions" to amplify the impact of these ideas (Helfer, 2004; Sell, 2004; Sell and Prakash, 2004). Indeed, because "different institutions offer different opportunities for actors to participate, affecting which perspectives on the appropriate balancing are advanced" (Shaffer, 2004, p. 464), strategic selection of institutions, both by the strong and the weak, emerged as a pervasive reality of the post-TRIPS era (Helfer, 2004; Sell 2011, p. 450).

The existing scholarship provides ample evidence as to how the complex interaction between "bloc unity," "strategic use of ideas," and "strategic use of institutions" transpired in the post-TRIPS era. Numerous scholars agree, for instance, that as the historically intimate relationship between the US industries and the USTR further strengthened in the post-TRIPS era, the industry groups, as well as the various expert associations, think-tanks, and lawyers they commanded, forged a formidable "web of surveillance" (Braithwaite & Drahos, 2000, p. 87) at various levels of interaction, seeking to ensure adequate and timely TRIPS or TRIPS-plus implementation (Deere, 2008; Matthews, 2002; Muzaka, 2011; Sell, 2003).

While Sell (2003) notes that the TRIPS Council has been openly acknowledged by US business groups as an effective venue for pressuring and "educating" developing countries on how to implement TRIPS, Muzaka (2011),

Deere (2008), Drahos (2002; 2008; 2010), and Matthews and Munoz-Tellez (2006) caution that it was the technical assistance programs that provided a template, ready-made model for developing countries to follow. Additionally, numerous scholars point out that when these developing countries failed to implement a version of TRIPS the US "preferred," the dispute settlement mechanism and bilateral trade pressure were frequently present to maintain discipline (Drahos, 2003; 2004; Matthews, 2002; Muzaka, 2011; Sell, 2003).

Additionally, scholarship demonstrates how developing countries operated across "structural, discursive, and institutional levels" to effect change (Sell, 2004). Indeed, numerous accounts agree that, largely in response to the pro-intellectual property lobby's escalating assaults on their already limited policy autonomy, developing countries have also learned how to "become adept at playing the multil-level, multi-forum game" (Sell 2004, p. 364). Numerous works detail how developing countries sought alliances and collaborations with dissenting international and non-governmental organizations, as well as academics, whose provision of valuable knowledge and ideas helped facilitate a global questioning of the TRIPS' legitimacy and fairness by breaking the often-biased experts' technical "policy monopoly" over intellectual property (Deere, 2008; Dobusch & Quack 2013; Kapczynski, 2008; Matthews, 2011; Morin, 2014, p. 278; Sell, 2004, 2013; Sell & Prakash, 2004).

The end result of these post-TRIPS contestations was the deepening complexity of the global intellectual property rights regime. As the use of coercion for upward harmonization met growing defiance from a multitude of actors, and intellectual property growingly came to be associated with a wide range of issues, the institutional terrain within which intellectual property was discussed broadened

considerably, and inter- and intra-institutional dialogue became a widespread post-TRIPS reality. For instance, while the implications of the new international standards in intellectual property on technology transfer and industrial development triggered a good deal of debate in the UN Commission on Trade and Development (UNCTAD) and WIPO, the debates over biodiversity and food security mainly took place in the Convention on Biodiversity (CBD) meetings and the UN Food and Agricultural Organization (FAO) (Deere, 2008; Muzaka 2011, 119-123; Sell, 2004). The human rights regime has also not been slow to catch on to the implications of TRIPS rules, and various human rights commissions have witnessed fierce debates over the negative implications of intellectual property (Muzaka 2011, 119-123; Sundaram, 2020, p. 36-). However, while each of these areas of contention drew considerable scholarly and policy attention, it was particularly the relationship between intellectual property rights and pharmaceuticals that received distinct attention.

Why the issue of intellectual property rights in pharmaceuticals was the most politicized and publicized among them all (Muzaka, 2011, p. 110; Sell, 2004; Sell & Prakash, 2004)?[19] For one thing, intellectual property protection in pharmaceuticals has historically been an area in which the perennial dilemma between private rights and public benefits has been the most intense. Because access to medicines has a direct impact on public health, many developing countries intentionally exempted pharmaceuticals from patentability in order to ensure drug availability and affordability (Deere, 2008, p. 40; Shadlen, Sampat, & Kapcynski, 2019).

[19] There is a vast literature on the relationship between intellectual property rights and access to medicines. See: Coriat (2008), Coriat, Orsi, and d'Almeida (2006), Dreyfuss (2010), Dreyfuss & Rodríguez-Garavito (2014), Hein, Bartsch, and Kohlmorgen (2007), Ho (2011), Klug (2008), La Croix and Liu (2007), Lanoszka (2003), Löfgren and Williams (2013), Muzaka (2011), Sell and Prakash (2004), Shadlen (2004, 2007), Shadlen, Guennif, and Guzmán (2011), Sundaram (2020), 't Hoen (2002), and Wolf and Scholz (2017).

Unsurprisingly, the TRIPS Agreement's mandate to extend patent protection in all areas of technology ignited serious fears about the possibility of pharmaceutical patents increasing the prices of medicines, which could, in turn, lead to constrained public access and soaring national health care budgets. In effect, such fears were largely realized shortly after the signing of the TRIPS Agreement. By the end of the 1990s, the ongoing HIV/AIDS crisis reached pandemic levels in many developing countries. However, as the prices of patented antiretrovirals hovered around US$ 10.000 - 15.000 per patient per year, access to treatment for many HIV/AIDS patients in less developed countries was practically a sheer impossibility (Hein & Moon, 2013, p. 68).

In the 1990s, the new rules in pharmaceutical intellectual property rights faced strong criticism from a network of NGOs, which later came to be known as the Access Campaign. [20] Leveraging this crisis moment, the Access Campaign's relentless transnational mobilization to politicize the costs of pharmaceutical intellectual property is largely the reason why the TRIPS' rules over pharmaceuticals attracted tremendous public attention, and therefore, resulted in an unusually acrimonious contestation that eventually led to a revision in the TRIPS Agreement.

What did the Access Campaign accomplish, and how did its actions affect the evolution of rules governing pharmaceutical intellectual property? Notably, numerous scholars agree that this group of non-state actors devoted exclusively to redefining the terms of debate in pharmaceutical intellectual property has been extremely influential in igniting change at the global level (Sell & Prakash, 2004).

[20] The Access Campaign consisted of several different NGOs coming together. Main participants included Consumer Project on Technology (CPtech), Essential Action, Health Action International, Médecins Sans Frontières (MSF), Oxfam, and The Third World Network (Muzaka, 2011, p. 76). For a detailed overview of the emergence the Access Campaign, see: Muzaka (2011, p. 76), Sell (2003), and Sell and Prakash (2004).

Firstly, the Access Campaign has defined the problem of access as one that emanated from the new rules in pharmaceutical intellectual property. According to the Access Campaign, the primary cause of the public health disasters that ravaged the developing world was the global pharmaceutical industry “greediness," which prioritized its economic gains over avoidable deaths (Sell & Prakash, 2004). By questioning the TRIPS’ fairness and legitimacy, this coalition of NGOs reframed the issue of intellectual property as a contest between “patents vs. patients” (Sell, 2004, p. 396). Therefore, not unlike the business actors in the preceding decade, the Access Campaign crafted a novel link between intellectual property and public health (Sell & Prakash, 2004). The Access Campaign’s linking of strong intellectual property rights in pharmaceuticals to rising medicine prices and restricted access resonated particularly well within the broader context of the HIV/AIDS crisis and significantly bolstering the campaign's legitimacy.

Secondly, based on this definition of the problem, the Access Campaign provided a policy solution. Throughout the 1990s, the Access Campaign adamantly advocated that the effective interpretation and application of TRIPS flexibilities are necessary, if not sufficient, conditions for facilitating access to medicines (Chorev & Shadlen, 2015; ’t Hoen, 2002; Sell & Prakash, 2004). Notably, the Access Campaign emphasized the importance of compulsory licenses as a mechanism for domestically producing or importing generic versions of critical HIV/AIDS medications (Sell & Prakash, 2004). Indeed, one significant factor that bolstered the NGOs’ claims was the support provided by generic manufacturers such as India and China, which supplied low-cost generic drugs (Roemer-Mahler 2013, p. 132; Sell, 2004, p. 391). However, because pharmaceutical industry actors were vehemently opposed to the use of compulsory licenses to ensure access and frequently prosecuted those who

dared to issue compulsory licenses, the legal basis for compulsory provisions in TRIPS appeared to be highly ambiguous for developing countries to rely on (Sell & Prakash, 2004).

Thirdly, in order to achieve clarity and possibly expansion of the TRIPS treaty's existing flexibilities, the Access Campaign mobilized transnationally, attempting to build a global pro-health coalition capable of initiating change at the WTO. Indeed, the Access Campaign has expanded its presence in three distinct institutional fora since the 1990s: (i) in the public health regime, through the WHO; (ii) in the trade regime, through the WTO; and (iii), in the human rights regime, through certain resolutions (Muzaka 2011; Sell & Prakash, 2004).

More than anything, however, it was the South African case that bolstered the Access Campaign's public visibility and legitimacy. Importantly, in 1997, the South African government passed the Medicines Act that allowed for parallel importation and compulsory licensing to deal with the HIV/AIDS crisis, all of which were perfectly permitted policy choices under the TRIPS Agreement. Nonetheless, for pharmaceutical business actors, South Africa's Act was unquestionably inconsistent with the country's obligations under the TRIPS (Muzaka, 2011; Sell, 2006). Consequently, thirty-nine pharmaceutical companies sued the South African government in 1998, claiming that the Act was breaching their legitimate rights over their innovation. Predictably, they also succeed in persuading the US government to escalate pressures on the South African government, prompting the USTR not only to place South Africa on the "Watch List" but also to suspend its GSP benefits (Muzaka, 2011; Sell & Prakash, 2004).

Until the South African case reached the courtroom in 2000, the Access Campaign mobilized globally and made increasing use of global media, continuing

to reframe the issue as a trade-off between "economic gains and versus unnecessary death" (Sell, 2004, p. 396). Because South Africa was one of the hardest hit from the HIV/AIDS epidemic at the time, the case generated considerable controversy. To repair their eroding reputation, pharmaceutical industry actors offered to negotiate price reductions, arguing that access was a problem of poverty, not their monopoly rights. However, global public opinion was so appalled by the acts of the global pharmaceutical industry that these companies eventually dropped the case in April 2001 (Muzaka, 2011; Sell & Prakash, 2004).

The South African case and the mobilization of the Access Campaign proved to be so profound that they opened up a serious debate about what the TRIPS Agreement means for states' ability to respond to problems of public health: do the so-called TRIPS flexibilities are really permitted for developing countries to exploit? What are the precise meaning and scope of these existing flexibilities in the TRIPS? Unsurprisingly, in the same month that the companies withdrew the lawsuit, the African Group succeeded in securing a special TRIPS Council Session that would directly address the relationship between TRIPS rules and access to medicines, which eventually led to the Doha Declaration on the TRIPS Agreement and Public Health in 2001 (Muzaka, 2011; Sell & Prakash, 2004).

The Doha Declaration was a text of clarification: it neither established new rules nor removed the existing ones, but rather reiterated that compliance with TRIPS standards does not and should not preclude members from addressing public health concerns. In that regard, the Doha Declaration was a victory for the developing countries as it explicitly recognized the members' right to interpret the existing flexibilities in a way to address public health challenges (Abbott, 2001, 2005; Muzaka, 2011). Most importantly, the Doha Declaration stated explicitly that

members have autonomy in determining the grounds for granting compulsory licenses and the authority to issue compulsory licenses. With this hard-fought legal ground that reiterated their national policy autonomy, the developing countries sought for available options to address their public health problems.[21]

However, the Doha Declaration was, again, not the final settlement (Matthews, 2007; Muzaka, 2011; Reichman & Abbott, 2007). Indeed, the debates over compulsory licensing fueled yet another episode of conflict between the developed and developing countries, with the primary focus now on how countries lacking domestic pharmaceutical manufacturing capacity could take advantage of compulsory licensing flexibility. Indeed, much was still at stake as the approaching deadlines for the introduction of pharmaceutical patents effectively meant that even the low-cost alternatives to ensure access to medicines would cease to exist, leaving countries with no manufacturing capacity on their own. Ultimately, it took four years for these debates to settle formally. In 2005, the protocol made Paragraph 6 of the Doha Declaration, which allowed for countries with no ingenious manufacturing capacity to obtain cheaper generic versions of patented medicines by importation, a permanent waiver in the TRIPS (Muzaka, 2011).

The triumph of developing countries through the Doha Declaration, however, should still be approached with caution. Indeed, the Doha Declaration provides a legal ground for developing countries to interpret and use TRIPS flexibilities to formulate and implement health-oriented domestic policies. However, these flexibilities have only been used by a limited number of countries (Williams &

[21] The period following the Doha Declaration witnessed an explosion of studies seeking to clarify the policy options available to developing countries. See: Abbott (2009), Correa (2002), Reichman (2009), Scherer and Watal (2002), and Watal (2000).

Löfgren, 2013, p. 20; Beall & Kuhn, 2012). Why is the use of TRIPS flexibilities still marked by under-utilization, even after the Doha Declaration?

One explanation that the scholarship advances as to why developing countries still refrain from using TRIPS flexibilities points to the new forms of external pressures from developed nations (Drahos, 2003, p. 7). For instance, numerous scholars note that bilateral pressure from the US and the EU has hardly ceased in the post-TRIPS period, whereby "inadequate" intellectual protection for pharmaceuticals continues to be a major source of developed country dissatisfaction (Drahos, 2003; Muzaka, 2011; Sell, 2003).

A number of scholars also observe that, particularly in the post-Doha Declaration period, the bilateral and regional trade agreements with more stringent intellectual property provisions have become a widespread reality (Drahos, 2003; Dutfield & Suthersanen 2005, 133; Muzaka, 2011).[22] Importantly, by shifting the negotiation forum from the multilateral to the bilateral level, where greater trade concessions can be effectively exchanged for stronger intellectual property standards, the US and EU have increasingly viewed the use of regional and bilateral trade agreements as an effective way to circumvent developing country activism at the WTO (Drahos, 2003). While the specific provisions on pharmaceutical intellectual property vary by agreement, the following TRIPS-plus provisions are common: data exclusivity provisions, patent term extensions, broader patentability criteria, patent linkage, and restrictive compulsory licensing provisions. In effect, all of these provisions seek to reduce the leeway allowed for developing countries (Shadlen, Sampat, & Kapczynski, 2020).

[22] There is a vast literature on bilateral and regional trade agreement with TRIPS-plus intellectual property rules. See: Drahos, Lokuge, Faunce, Goddard, & Henry (2004), Drexl (2016), El-Said (2005, 2007), Krikorian & Szymkowiak, (2007), Mercurio (2006), Morin (2006, 2009), Roffe & Spennemann, (2006), Sell (2011), Seuba (2013), and Shadlen (2008).

Overall, what the evolution of the global intellectual property rights regime in the post-TRIPS era shows is that intellectual property rulemaking is still a political process, whereby structures do not always determine outcomes. While the fights over pharmaceutical intellectual property have rarely been fought on an even playing field and the imprints of developed country demands are visible on every level, the growing resistance of developing countries, aided by NGO participation, has nonetheless significantly altered global power relations and the policy autonomy granted by TRIPS (Sell, 2004, p. 364). Whose preferred stance ultimately prevails at the implementation stage, however, is still an open question that depends on how countries, facing these changing boundaries, make choices at the domestic level.

2.3 Diversity amid harmonization: Variation in patterns of compliance

Without a doubt, the changes in the global rules over intellectual in the last four decades have helped to create a world in which global protection of rights over intellectual property is now higher than ever before, both in terms of length and scope (Cardwell & Ghazalian, 2011; Morin & Gold, 2014; Park, 2008; Shadlen, Schrank, & Kurtz, 2005). Therefore, the TRIPS Agreement has largely succeeded in achieving its goal of minimum universality in standards over intellectual property by altering the terms of global debates fundamentally: while the 1980s and 1990s saw contestations over whether and how to construct new global rules in private intellectual property, conflicts in the 2000s was fought over how to effectively implement these new rules in private intellectual property.

The scholarship on the global politics of intellectual property successfully demonstrates how the conflicts at the global level continuously shaped the policy options available to developing countries. We now have a profound knowledge of

how TRIPS narrowed down the policy space available to developing countries and how TRIPS-plus pressures seek to further constrain this already-narrow policy space. Despite our extensive understanding of the factors that influence the changing parameters of permissible policy action, however, we know relatively little about how countries actually make policy decisions within these defined parameters. In other words, the existing literature is remarkably inadequate in causally and systematically explaining how countries actually choose to comply with their international commitments.

The main flaw in many existing accounts is that, focusing exclusively on the conflicts at the global level, they explain the question of implementation through a faulty assumption: that commonly experienced processes towards global convergence should result in commonly formulated policy outcomes. Often viewing developing countries as a single entity, much of the existing scholarship predicts that policy outcomes can be deduced from hypothesized preferences of this monolithic developing country bloc. According to these perspectives, given that many developing countries were expected to incur high economic and welfare costs as a result of the introduction of pharmaceutical patents, we should anticipate that they will fully exploit the available policy space. Alternatively, given that developing countries are economically and politically highly dependent on developed countries, we could forecast that they would surrender to the prevailing ethos of upward harmonization. However, the complexity of the empirical reality belies the credibility of these undifferentiated predictions: neither the strong developing countries always resist, nor the weak always yield (Chorev & Shadlen, 2015; Deere, 2008; Musungu & Oh, 2006; Shadlen, 2017). The question of implementation necessitates attention to the context-dependent domestic-level dynamics that one cannot predict ex-ante.

In responding to these commonly experienced global changes, developing countries showed a striking diversity in navigating the course to the new global order in private intellectual property. Importantly, in deciding how to translate the new global rules into their national legislation, developing countries differed considerably in the way they defined what type of knowledge can be owned as private intellectual property, the rights they conferred to the owners and users of intellectual property, and the administration and enforcement of these private rights over intellectual property (Shadlen, 2009, 2010, 2017).

Variation in patterns of compliance with new international standards in intellectual property rights is, perhaps, the most pronounced in the case of pharmaceutical patents. Importantly, developing countries widely differ in the way when they first introduced private rights over pharmaceutical intellectual property, the way they defined protectable subject matter in pharmaceutical intellectual property, the limitations they set for private rights in pharmaceutical intellectual property, and through what administrative and judicial procedures they chose to protect and enforce these private rights over pharmaceutical intellectual property. Moreover, variation in pharmaceutical intellectual property does not only stem from diverging decisions made in a single moment. Depending on how these provisions function in practice, many developing countries have often gradually adjusted their pharmaceutical intellectual property rules to reflect domestic realities, leading not only to a profound cross-national variation but also a longitudinal variation in the patterns of compliance with new international commitments.

Arguably, while variation in national intellectual property rules is widely acknowledged in the literature, research that causally and convincingly explains the

sources and mechanisms of variation is strikingly rare. In the following, I briefly summarize my review of the existing literature.

Firstly, the majority of the literature on the global politics of intellectual property rarely takes an interest in the question of implementation. Indeed, this is particularly true for the earliest generation of scholarship, which is primarily concerned with understanding how developing countries came to accept the new rules in private intellectual property (Chorev & Shadlen, 2015). As I showed in the preceding chapter, the core argument that unifies this strand of research is the centrality of asymmetric power balances at the international level in explaining the domestic change, whereby the vulnerability of developing countries to developed country pressures emanated from economic/political dependency or lack of technical and legal expertise.

However, the explanatory power of economic pressures to account for domestic policy choices is weak. Importantly, while some developing countries eventually succumbed to the USTR's pressures, some others clearly did not. A case in point is Argentina. Despite frequent appearances in the USTR's Special 301 reports and threats of losing GSP benefits, Argentina did not back down. After five years of intense domestic debate, Argentina passed a new pharmaceutical patent law that minimally satisfied its international obligations (Shadlen, 2017).

Furthermore, not all developing countries that exceeded their international obligations have faced bilateral pressures. For instance, while no African less developed country has ever been targeted by the USTR nor been the subject of WTO dispute settlement procedure, numerous African countries have enacted TRIPS-plus intellectual property rules (Deere, 2008). In that sense, the causality between the US pressure and the strength of a patent regime is not automatic and requires a close

examination of under what specific conditions external pressures could elicit a response from developing countries.

Explanations based on utter ignorance or lack of expertise are also not fully persuasive. While lack of knowledge about how to formulate concrete counter-proposals may have harmed the developing countries' bargaining power at the negotiation table, claiming that developing countries were unaware of the importance and implications of intellectual property rights is not entirely convincing, given that many developing countries have been calling for reducing the strength of international intellectual property rules in numerous institutional fora since the 1960s (Yu, 2006, p. 375-6). Moreover, their resistance also translated into some concessions under "TRIPS flexibilities" (Yu, 2006, p. 375-6). Furthermore, the argument that developing countries' lack of expertise rendered them particularly vulnerable to developed countries' technical expertise is also dubious in explaining the substance of final policy outcomes. While it is possible that biased technical advice from foreign experts serves as a source of socialization that may influence national practices, establishing a direct causal link between lack of expertise and strong patent regimes is difficult and requires deep empirical observation.

Additionally, much of the existing literature is overly focused on the TRIPS Agreement. Admittedly, TRIPS' prominence is justified in the sense that it is the first legally binding multilateral intellectual property agreement that incorporates a strong enforcement and dispute resolution mechanism. However, a focus on TRIPS may fail to capture the experiences of numerous developing countries whose intellectual property laws were either enacted prior to TRIPS or whose debates over it were not centered on meeting TRIPS obligations. For instance, Australia (1990), Canada (1980), Chile (1991), Mexico (1991), Singapore (1994), and South Korea (1986) are

early reformers whose intellectual property law-making often had little to do with satisfying TRIPS commitments (Global Development Policy Center, 2019). Furthermore, in some other countries, such as Turkey, debates over intellectual property policymaking did not center on how to comply with TRIPS commitments. Understanding such experiences necessitates a deep probe into the domestic debates not only to ascertain how these debates transpired to affect domestic change but also to discern the main impetus for policy change.

The literature's overemphasis on the pioneering role played by the US also obscures deep nuances in intellectual property policymaking processes. For one thing, confining the explanation of domestic change to the mere existence of external pressure from the US not only fails to ask how actually such pressures reconfigure domestic interests to influence change but also masks the critical role played by "prospects" in achieving change. While obtaining greater intellectual property concessions by offering prospects of enhanced market access is largely acknowledged as a pervasive post-TRIPS era reality, the literature is deficient in emphasizing the role of early trade agreements in effecting change. Although an argument could be made that early trade agreements with explicit intellectual property provisions are rare, they do exist and played an important role in shaping national practices (World Health Organization, World Intellectual Property Organization, & World Trade Organization, 2021, p. 253-7). Except for NAFTA in Mexico, studies investigating the role of trade agreements in intellectual property policymaking are strikingly rare (Shadlen, 2009, 2010, 2012, 2017).

Furthermore, an excessive focus on the US also obscures important details since the US was not the only actor responsible for changes in intellectual property policies in the developing world. While the literature acknowledges the EU's

preference for stronger intellectual property rights, it does not accord it the explanatory value it deserves. The dominant view in the literature on the EU's role is one of "soft power": it either carried "premises given to them by the US government" during the TRIPS negotiations or acted as an "honest broker" during the post-TRIPS contestations (Braithwaite & Drahos, 2000, p. 66; Muzaka, 2011, p. 83, 2013, p. 820).

While the EU's approach undoubtedly appears to be less coercive than that of the US, numerous scholars note that the EU also shares many of the same concerns as the US (Deere, 2008; Matthews, 2002; Muzaka, 2013; Pugatch, 2004). Instead, they argue that the differences in the US and EU approach to global harmonization are primarily due to institutional differences, not divergent interests. For instance, numerous scholars agree that, unlike the direct influence of industry on the US trade policy, corporate actors in the EC had to target a wide range of national and EC institutions to make their voices heard (Matthews, 2002; Pugatch, 2007). Moreover, Muzaka (2013) observes that the "soft IP approach" of the EU during the TRIPS negotiations was largely a reflection of internal divisions since member states claimed that the European Commission did not have the authority to negotiate new trade issues such as intellectual property rights (p. 829). Even so, however, this does not negate the fact that the EU was also instrumental in initiating change, particularly in those countries where it had close ties and integration projects. Understanding the nature, scope, and impact of the EU's role is also an interesting project that can shed light on the intellectual property policies of a number of countries, including post-communist countries and Turkey.

Overall, then, the common problem with these explanations is that their overemphasis on the global level conflicts leaves them insensitive to differences in

domestic level dynamics that result in variation in intellectual property rights policies. The inadequacy of these accounts, in turn, demonstrates the importance of incorporating domestic variables into the analysis to make sense of why and how countries respond differently to common external constraints.

However, what domestic variables are relevant in explaining variation? Importantly, both economics and legal scholarship have a long tradition of taking domestic variables into account in examining countries' intellectual property laws and policies. While these fields choose widely different variables to understand why and how developing countries devise the intellectual property rules that they do, the implication that arises from both of these fields is very similar: countries differ in their national intellectual property laws and policies because they already had diversity long before the new global rules took effect. However, these accounts that attempt to explain the present through reference to the past are largely unconvincing.

According to economists, a country's intellectual property policies are determined by a variety of domestic factors, including, but not limited to, the country's overall economic wealth, the relative weight of knowledge- and information-intensive imports and exports, the level of domestic technological capability, and the degree of industrialization (Fink & Maskus, 2005; Shadlen, Schrank, & Kurtz 2005). Economists anticipate stronger intellectual property rights in wealthier countries with greater innovative capabilities and a higher share of technology exports and laxer standards of protection in less developed countries with a greater share of technology imports (Fink & Maskus, 2005; Ginarte & Park, 1997; Mercurio, 2010, p. 66). Therefore, economists anticipate countries' patterns of compliance with the new global rules in intellectual property to reflect their levels of economic and technological development. While Japan, South Korea, and Singapore

appear to corroborate economists' predictions, the behavior of many other developing countries, however, significantly deviates from economists' expectations (Deere, 2008; Nagesh, 2003). Contrary to economists' expectations, a number of net technology importer developing countries with a moderate level of economic and technological development, for example, Brazil, Mexico, Uruguay, and Turkey, have adopted intellectual property laws that far exceed their technological capabilities (Deere, 2008).

It may also be unrealistic to expect explanations based on domestic economic factors to fully account for the patterns of compliance with the new global order in intellectual property, simply because these domestic factors often change very slowly. Indeed, as Shadlen, Schrank, and Kurtz (2005) observe, these largely static factors can no longer adequately account for what has transpired in the current era as the new obligations of countries by virtue of their membership in various international institutions now necessitate a significant restructuring of domestic intellectual property practices to be completed within strikingly short period of time.

As with economic explanations, the legal scholarship also falls short of adequately capturing the complex nature and rapid pace of the dramatic changes that have taken place since the 1990s. Importantly, the reliance on historical diversity to account for contemporary variation is a much more pronounced reflex in legal scholarship as numerous scholars cite long-standing divergences in cultural and philosophical understandings of ownership over the intangible and living property (Gooday & Wilf, 2021; May, 2004) and commercial legal traditions (Lerner, 2000), as well as predispositions or resentments towards intellectual property engendered by colonial legacies (Beatty, 2020; Escobar Andrae, 2020), as to imply why it is only natural to see variation. Admittedly, these explanations are not entirely irrelevant, as

efforts to comply with the new obligations in countries with profoundly antagonistic views on private ownership of intellectual property may encounter difficulties in enforcing, if not in legislating, the new rules in intellectual property (May, 2004).

However, the world has changed rapidly and dramatically, wherein countries now have to make choices they do not have to be enthusiastic about. The issue is to explain why they make these particular choices in response to the exigencies of this new world. In this regard, purely descriptive analyses of laws and policies also contribute little to our understanding of the complex processes of intellectual property policymaking (Conde, 2019; Dreyfuss & Pila, 2018; Mitsumori, 2018; Liu & Racherla, 2019; Gooday & Wilf, 2021; Sundaram, 2020). Because laws as texts are the end results that only reveal what kind of actions are permitted and sanctioned, they say little about the dynamic political and social processes that produced them. Therefore, to understand the causes of variation, it is necessary to understand, first, the processes of political contestation over intellectual property and, second, what accounts for their diversity.

Yet, political scientists have been remarkably slow to catch on with the dramatic changes in countries' intellectual property rights policies. This lack of attention is striking not only because the earliest debates over the making of TRIPS have been significantly enriched by political scientists. Also, because intellectual property rights now constitute the building blocks of national systems of innovation, keys to international competition, and influence prospects for human welfare, the rulemaking processes in intellectual property merit political scientists' attention.

Only recently, there have been visible efforts to turn attention to political analysis (Chorev & Shadlen, 2015). While this new generation of research is highly eclectic in its approach and selection of variables to explain implementation and

variation, it nonetheless provides profound insights into the complexities of intellectual property policymaking on the ground. Broadly, this new generation of research can be divided into three categories, each of which offers significant depth and detail on processes of preference formation, political mobilization, patterns of coalition-building, as well as the analytical role of time in the making of intellectual property laws and policies. Because this study seeks to build on this new generation of scholarship, I will now summarize the key insights that have emerged from this new body of literature. My objective is not to conduct a comprehensive review of the literature but to present studies selectively in order to reveal the critical insights provided by these studies.

The first group of this new scholarship examines the international factors that influence domestic intellectual property policy decisions, enhancing our understanding of how the biased technical assistance and capacity programs actually work in practice (Matthews & Munoz-Tellez, 2006). For instance, in her comprehensive analysis of variation in intellectual property implementation across the developing world, Deere (2008) argues that the role of biased technical assistance in influencing national decisions was particularly pronounced in the case of countries with low technical capacity (p. 311). According to Deere (2008), both financial reliance on foreign sources of income, namely fees paid by foreign intellectual property holders and grants from international donors, and personal connections formed through training, seminars, and conferences prompted these countries to internalize the norms and standards promulgated by these developed country experts, resulting in a "compliance-plus" approach to intellectual property (p. 200, 311).

Drahos (2008; 2010) extends and refines this argument further. Through a comprehensive field-work analysis with an in-depth, interview-based study of forty-

five patent offices in both developed and developing countries, Drahos (2010) demonstrates that technical assistance programs are often an important source of socialization that clearly influence national choices because the steady stream of technical assistance over the years leads to a "technocratic trust," a form of impersonal trust derived from the perceived quality and reliability of the decision-making, that often results in the imitation of developed country patent offices' decision-making processes. Indeed, this imitation of practices serves the goal of technical assistance projects extended by developed country parties to serve the interests of multinational corporations: global convergence in administrative systems and, therefore, patent rules and procedures to "make it cheap to obtain patents, that maximize the scope of patentable subject matter and that minimize state control over the technology" (Drahos, 2010, p. 3).

The second group of works in this generation of scholarship examines the influence of non-state actors – both global and domestic – on national decisions about intellectual property. Importantly, while the actors and relationships they examine are wide-ranging, they are often those we would expect to see suspicious of stronger intellectual property rights in pharmaceuticals. Two subsets of this body of scholarship highlight the perils of ex-ante preference identification in analyzing national policy choices and encourage us to examine how local dynamics shape the formation of interests and preferences that may result in unexpected alliances and outcomes.

The first subset of this second group of works examines the relationship between global and domestic health activists and explores the influence of this alliance on policy choices. Numerous case studies of countries that successfully made effective use of TRIPS flexibilities attest to the important role of transnational

health activists in pro-health policy choices (Andia, 2015; Krikorian, 2009; Nunn, 2009; Godoy, 2015). For instance, Krikorian (2009) reveals how Thai activists with close ties to global NGOs succeeded, first, in drawing the government's attention to the pressing issue of the HIV/AIDS crisis and then in capitalizing on a political opportunity created by a unique domestic context. By examining the unusual domestic setting in which the post-coup Thailand government issued compulsory licenses for three HIV/AIDS drugs even though negotiations on US-Thailand FTA were ongoing, Krikorian (2009) demonstrates how, even when conditions appear unfavorable for pro-health policies, domestic actors aided by transnational networks can influence patterns of policymaking.

This subset of works also shows that such alliances do not arise automatically and may easily fail to materialize due to divergent interests, priorities, and strategies between global and local health activities. Indeed, numerous analyses of "failure" cases, those that failed to implement pro-health policy flexibilities, illustrate how discrepancies in understandings, objectives, and preferred approaches can result in an inability to form broad alliances. As Andia (2015) demonstrates, when transnational activists recruit local allies in the fight for access to HIV/AIDS treatment, the resulting alliances may be more fragile and less successful than when local activists reach out to transnational activists, as in Brazil and Thailand. She shows that it took considerable effort on the part of global activists to persuade and educate local activists in Columbia and Ecuador about the problem with pharmaceutical patents, as they were more focused on relying on the state to provide health services and medicines than on using compulsory licensing as a tool for access to medicines.

Godoy's (2015) analysis is just as elucidating. Examining Central American countries' puzzling lack of opposition to CAFTA's highly robust intellectual

property provisions in pharmaceuticals, Godoy (2015) illustrates how differing understandings about the best way to protect public health resulted in a lack of interest on the part of local activists in global access campaign's claims. According to Godoy (2015), the global access to medicine campaign's focus on facilitating generic competition through the relaxation of intellectual property standards failed to pique interest in Costa Rica, El Salvador, and Guatemala simply because local health advocates were trained to approach access issues from a perspective that prioritized resolving underlying societal inequalities and injustices, rather than market-based solutions like relying on the generic competition.

The second subset of this second group of works turns its attention to domestic pharmaceutical companies and examines whether and how they fit into the broader network of pro-health alliances (Chorev, 2015; Eimer & Lütz, 2010; Eren-Vural, 2007a, 2007b; Godoy, 2015; Horner, 2014; Shadlen, 2010, 2011, 2012, 2017). Importantly, domestic pharmaceutical companies in developing countries are also expected to oppose stronger intellectual property protection for pharmaceuticals and favor exploitation of existing policy flexibilities, as the majority of their activities are focused on the manufacturing of generic drugs. Indeed, the experiences of some developing countries corroborate this prediction. For instance, in his analysis of the introduction of pharmaceutical patents in Argentina, Shadlen (2017) shows how domestic pharmaceutical companies fought tooth and nail against stronger intellectual property rights in pharmaceuticals to defend their market survival and ultimately prevailed due to their historically strong market dominance.

However, numerous studies also show that domestic pharmaceutical companies do not always behave as predicted. For instance, Eren-Vural (2007a; 2007b) shows that the primary reason why the economically and politically most

powerful group of Turkish pharmaceutical companies succumbed to pressures for stronger intellectual property rights in pharmaceuticals was their high degree of technological dependence on transnational pharmaceutical companies, who saw their future survival as now dependent on maintaining close relationships with their transnational partners. Alternatively, as Shadlen (2017) shows in the case of Mexico, domestic pharmaceutical companies may eventually surrender to accepting strong patent protection in pharmaceuticals because of their weak market position that made them vulnerable not only to pressures from transnational companies but also the government's promises to continue drug purchasing practices if they concede to the introduction of patents.

Domestic pharmaceutical companies' preferences and strategies for political mobilization may also undergo significant changes in the subsequent decades, depending on how well they adjust to the new status quo in which pharmaceutical innovation is now a privately protected property. Chorev (2015) demonstrates, for example, that while the local pharmaceutical industry in Kenya initially supported the use of flexibilities in debates over how to introduce pharmaceutical patents, they later allied with multinational companies in debates over the country's Anti-Counterfeit Act as they stood to gain from keeping the less expensive imported drugs out of the local market.

Finally, the third group of works demonstrates that coalitions on the ground are not limited to non-state actors only, but various state actors are also important coalitional actors in debates over pharmaceutical intellectual property (Bergallo & Michel, 2014; Flynn, 2013; Shadlen, 2017). For instance, Shadlen's (2017) examination of the introduction of pharmaceutical patents in Brazil demonstrates the critical role played by the Executive, as the political agency of Cardoso was the key

factor that succeeded in passing stronger patent protection in pharmaceuticals in the legislative branch, despite widespread opposition from both domestic pharmaceutical industry and actors in civil society.

Moreover, these studies serve as a corrective to a common fallacy particularly prevalent in earlier works, which view states as unitary actors without differentiating how and to what extent the incompatibilities between the interests of various state actors might affect policy outcomes. Indeed, as many scholars demonstrate, despite deep commitment from the Executive to enact strong intellectual property laws, the opposition put by other state actors may undermine the Executive's ability to achieve desired policy outcomes. For instance, both Bergallo and Michel (2014) and Shadlen (2017) show that while Menem was very much enthusiastic about introducing a pharmaceutical intellectual property law that would conform to the extremist demands of the US, legislative dissent eventually prevailed in passing a pharmaceutical patent law that minimally complied with the TRIPS requirements.

Together, these three lines of inquiry add much to our understanding of how countries implement their externally-derived obligations. They bring into attention the wide range of actors involved in debates over pharmaceutical intellectual property, the importance of the relationships among these actors to understand policy outcomes in pharmaceutical intellectual property, and the analytical role of time in making sense of the trajectories of change in pharmaceutical intellectual property.

However, despite these important contributions, this growing body of literature still fails to provide a coherent, comprehensive, and systematic framework that could causally explain differing patterns of compliance with new international standards and the consequences of these policy choices (Chorev & Shadlen, 2015). Most importantly, as the majority of these works focus excessively on the link

between pharmaceutical patents and concerns over public health, they often fail to capture the complexity of the processes in which diverse actors interact with one another with varying intentions.

Indeed, patents are only partly about pharmaceuticals and concerns over public health. As both monopoly rights that imply restricted access to knowledge and information by the society and keys to participation in the new international economy, the making of the patent laws also entailed discussions about economic cooperation, market access, international competitiveness, and industrial development in a changing global economic context. The breadth of implications that patent rights gave rise to has not only mobilized actors with immediately concerned about patent protection in pharmaceuticals but also prompted actors with no direct relationship with intellectual property to participate in debates over pharmaceutical patents. With few exceptions, our understanding as to how economic considerations, rather than public health concerns, influence policymaking processes in pharmaceutical patents is limited.

The challenge at hand, therefore, is to synthesize and develop these explanations to devise an analytical framework and set of arguments to account for the differing national patterns of compliance with the new rules in pharmaceutical intellectual property. To accomplish this, analyses must transcend beyond the narrow focus on both the international conflicts and public health concerns and delve deeply into how these externally-derived rules are domestically negotiated among a diverse array of actors with different stakes over pharmaceutical intellectual property.

CHAPTER 3

THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS IN MEXICO AND TURKEY: A FRAMEWORK FOR ANALYSIS

National patterns of compliance with the new global standards in intellectual property exhibit a profound cross-national and longitudinal diversity. While each country now abides by the imperatives of minimum obligations set by the global changes in the 1990s, they nevertheless navigated the course to this new global order differently. What accounts for this wide variety of national responses to commonly experienced global shifts in the politics of intellectual property?

Mexico and Turkey's experiences in pharmaceutical intellectual property policymaking provide a unique terrain to understand how the changing global landscape can transform long-standing domestic principles and practices governing pharmaceutical knowledge and how, in turn, this transformation can leave lasting legacies on countries' ability to adjust these rules to their domestic realities in the future.

In the 1990s, both Mexico and Turkey radically reversed their long-standing opposition to pharmaceutical intellectual property. The new pharmaceutical patent rules these countries enacted conferred strong exclusionary rights to the owners of pharmaceutical innovation. Yet, despite their shared origins, Mexico and Turkey's policy trajectories diverged considerably in the 2000s. While Mexico further strengthened its already strong pharmaceutical patent system, Turkey gradually reversed its previous extremist stance. What explains Mexico and Turkey's similar beginnings but diverging pathways in pharmaceutical intellectual property?

This chapter presents an analytical framework to explain Mexico and Turkey's experiences in pharmaceutical intellectual property policymaking in two periods of change. The core argument of this chapter is that the politics of pharmaceutical intellectual property should be understood as a complex interplay between the broader global economic dynamics and domestic political negotiations. Three sub-arguments are advanced that tie back to this broader argument.

The first contention of this chapter is that a conceptualization of intellectual property rights as a second-stage economic policy reform provides a superior explanation to causally account for the timing, objectives, and implementation of pharmaceutical intellectual property rights. As a "rule of globalization" reflecting the growing centrality of institutions in governing the global economy, this chapter argues that depending on which route the intellectual property rights reforms were disseminated determined the broader policy options available to developing countries.

The second contention of this chapter is that, because the primary impetus for intellectual property reform in Mexico and Turkey occurred through the regional route, the "intense bargain" they commonly faced led to a similar politics of coalitional clash that led to similar outcomes in the 1990s.

Lastly, the third contention of this chapter is that, because the magnitude of the initial shock and the temporal proximity between the introduction and modification efforts varied in Mexico and Turkey, the different patterns of adjustment of domestic actors led to different coalitional-building possibilities, which resulted in divergent outcomes in the 2000s.

This chapter is organized into three parts. The following section starts with a brief definition of intellectual property rights, followed by a brief overview of the

nature of conflicts surrounding pharmaceutical intellectual property rights. The second section explores the existing scholarship on pharmaceutical intellectual property policymaking in Mexico and Turkey and evaluates the explanatory power of these accounts for understanding Mexico and Turkey's experiences in two periods of change. The third section presents the study's analytical framework to explain Mexico and Turkey's patterns of compliance with the new rules on pharmaceutical intellectual property.

3.1 Pharmaceutical intellectual property rights: The nature of conflicts

Intellectual property rights are private rights in knowledge and information. They are legal instruments that confer owners of a wide range of industrial and intellectual property the right to exclude third parties from unauthorized production, use, sale, and dissemination of their intellectual property. But can knowledge and information, which are essentially public goods in nature, can be fully owned privately? If so, what are the foundations upon which this legal construction of property relations is built?

As legally constituted private rights that define who can own, use, and control knowledge and information, the exclusionary nature of intellectual property rights renders them immensely contested political institutions (Braithwaite & Drahos, 2000, p. 40; Muzaka, 2011; Sell & May, 2001). The nature of contestation in intellectual property rights lies in the seemingly incompatible interests of users and owners of intellectual property. Importantly, because the extent to which public access to knowledge- and information-intensive products often determines the pace and scope of scientific innovation and technological change, patterns of industrial development, improvement of human capital, and provision of public goods such as education and

public health, the society has a clear welfare interest in the free dissemination of knowledge and information (Braithwaite & Drahos, 2000, p. 75; Muzaka, 2011, p. 62). For the owners of intellectual property, however, because intellectual property is a product of individual labor that merits commercial return, adequate satisfaction of owners' interests in their intellectual property depends upon restricting public access to create an artificial scarcity (Kinsella, 2013). As a result, the conflicts over intellectual property take on the character of a perpetual conflict between public-regarding dissemination and private-oriented exclusion of knowledge and information.

What further complicates this contestation is the essentially public good nature of knowledge and information. Indeed, unlike ownership in tangible property that can be readily separable from the realm of commons, knowledge and information are neither excludable nor rivalrous (Stiglitz, 1999). In other words, once created, knowledge- and information-intensive goods, can be used by anybody whose consumption leaves the same quantity and quality for others to benefit from (Muzaka, 2011; Stiglitz, 1999). So, the central questions that arise in the legal construction of intellectual property rights are how to privatize knowledge and information that clearly carry the characteristics of public goods and justify these private property relations over what was once public goods.

There are different philosophical justifications for intellectual property rights (Kinsella, 2013, p. 1329-34; Sundaram, 2020, p. 18-32). While moral arguments emphasize the moral imperative to recognize the property rights of the owner's labor, utilitarian arguments underline the critical role that intellectual property rights play in correcting market failures that arise in the absence of clear and secure private property rights. For a utilitarian perspective, the pervasive free-riding problem

engendered by the non-rivalrous and non-excludable nature of knowledge and information triggers fears of misappropriation, which, in turn, deters incentives to undertake inventive activity (Greenhalgh & Rogers, 2007; Sherwood, 1993). According to utilitarian arguments, then, intellectual property rights as monopoly rights over intangible property, are justifiable as the prices that societies have to pay to ensure the continuity of socially valuable inventive activity and the subsequent public dissemination of the knowledge and information contained in that property, although this monopoly results in a temporary underutilization of knowledge (Arrow, 1962; Chang, 2001, p. 294).

Thus, intellectual property rights emerge as a long-term "bargain", a contract between the owner and governments in which the owner agrees to disclose all information of his or her invention in the future in return for the government's commitment to legally protect their private rights of ownership in intellectual property (Archibugi & Filippetti, 2010).

This bargain is, perhaps, best illustrated by patents. As temporarily-limited and territorially-defined legal rights of ownership over new, inventive, and industrially applicable inventions, granted in return for full disclosure of information related to innovation, the static costs that patents introduce in the form of higher prices and limited access are justified because patents ensure dynamics benefits in the form of incentives for innovation (Cockburn, 2009; Shadlen, Sampat & Kapczynski, 2020, p. 77). As with other intellectual property, however, to what extent dynamics benefits are prioritized over static costs depends on how nations determine the strength and weakness of their patent rules.

However, assessing the strength or weakness of any patent system is difficult (Cockburn, 2009; Ginarte & Park, 1997; Park, 2008; Lerner, 2000). For one thing,

governments balance the exclusionary nature of patents through a variety of policy levers and complementary laws, including, among others, competition and antitrust, trade, labor, and privacy laws (Cockburn, 2009). Furthermore, understanding law as a text reveals little about how it operates in practice, as the interpretation and enforcement of patent laws by courts, administrative agencies, and other stakeholders can significantly impact the actual "strength" of a patent system (Cockburn, 2009; Shadlen, 2017).

Nonetheless, the extent to which knowledge becomes private property and the extent to which exclusionary rights over private property can be an effective proxy for assessing the strength and weakness of patent systems (Dutfield & Suthersanen 2005, p. 144; Shadlen, 2010, 2017). Notably, while patents transform knowledge into private property and the patent right confers on the owner a private right of exclusion over their invention, this does not happen naturally without administrative procedures. Patents are granted by nation-states to inventions that fall within the patentable subject matter range. Thus, the rules defining what constitutes a patentable invention and how patentability criteria are applied during examination procedures significantly impact the strength and weakness of any patent system.

Additionally, patents protect inventions by granting the owner an exclusive right to prevent others from manufacturing, importing and exporting, distributing, and selling their property during the patent term. However, countries generally restrict these exclusionary rights through various exceptions that restrict the ability of right owners to control their property. Consequently, patent systems that allow for more knowledge and information to be privately owned and offer more rights of exclusion over knowledge and information are said to provide stronger patent rights (Dutfield & Suthersanen 2005, p. 144; Shadlen, 2010, 2017).

Well until the 1990s, levels of economic and technological development were important factors that determined the strength of national patent systems. Indeed, the widely witnessed pattern across the globe was a strong patent system being the norm only in technologically and economically advanced countries, whereby less developed countries often saw great harm in strong patent rules for national trajectories of technological and industrial development (Shadlen, 2017; Shadlen, Sampat & Kapczynski, 2020). Therefore, with a large policy autonomy in intellectual property policymaking, the patent systems of many developing countries were marked by either high restrictions on the scope, range, and duration of exclusive patent rights or outright exclusion of specific strategic or vital sectors such as pharmaceuticals (Eren-Vural, 2007a, 2007b).

However, since the 1980s, tolerance for this significant national policy discretion favoring lax patent protection largely waned. The TRIPS Agreement established new standards for patent rights, uniformly extended patent protection to twenty years, broadened the scope of patentability to all technology areas, and limited the scope and extent of exceptions to patent owners' rights. This constraint on national policy space that necessitated the establishment of stronger patent rights sparked heated debates between state and non-state actors over how to comply.

The most acrimonious battles fought over the new patent standards have been in the area of pharmaceutical patents. Because public access to medicines directly impacts public health, many developing countries have long exempted pharmaceuticals from patent protection to ensure their availability and affordability, which they also hoped would result in the development of domestic manufacturing capabilities and increased market participation for local producers (Eren-Vural, 2007a, 2007b; Shadlen, 2017). As a result, several countries in the 1960s and 1970s,

including the Andean Pact countries, Argentina, Brazil, India, Mexico, and Turkey, either weakened or abolished patent protection for pharmaceuticals (Deere, 2008, p. 40; Nogués, 1990; Roemer-Mahler, 2013, p. 129; Shadlen, Sampat & Kapczynski, 2020).[23] Unsurprisingly, the TRIPS Agreement's mandate to expand patent protection to all areas of technology sparked grave concerns about the theoretical possibility of pharmaceutical patents increasing drug prices and therefore resulting in limited access to medicines.

Who wants patents on pharmaceuticals? Numerous studies have demonstrated that, in contrast to other industries, where first-mover advantages, lead time, secrecy, and other factors assist firms in maximizing returns on R&D investments, the pharmaceutical industry is critically—and almost uniquely—reliant on patent protection (Cohen, Nelson, & Walsh, 2000; Grabowski, 2002; Lanjouw & Cockburn, 2001; Lanjouw & Macleod, 2005; Mansfield, 1986). Therefore, it is not surprising that the pharmaceutical industry was a strong advocate for patents in pharmaceuticals given that the absence of international patent protection alongside their global operations posed a significant threat to their commercial viability. But why are patents so fundamental to the pharmaceutical industry's business model?

Two arguments are often advanced to explain why pharmaceutical patents are critical for the pharmaceutical industry at both the pre- and post-marketing stages. Firstly, the R&D process for pharmaceutical innovation is lengthy, costly, and risky (Cockburn & Long, 2015; Grabowski, 2002). Not only is drug research and development, i.e., bringing a new molecule entity (NME) to market, riskier than any other industry as the majority of research does not result in marketable products, but

[23] Indeed, well until the 1970s, even the developed countries did not offer patent protection for pharmaceuticals. For example, France allowed pharmaceutical patents in 1960, Ireland in 1964, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy and Sweden in 1978, and Spain in 1992. (Dutfield & Suthersanen, 2005, p. 135; Shadlen, Sampat & Kapczynski, 2020, p. 78).

the stringent regulations requiring safety and efficacy proofs require pharmaceuticals to undergo costly clinical trials lasting over a decade (DiMasi, Feldman, Seckler, & Wilson, 2010; DiMasi, Hansen, & Grabowski, 2003; DiMasi & Grabowski, 2007; DiMasi, Grabowski, & Hansen, 2016; Muzaka, 2011; Scherer, 2000). [24]

Secondly, despite the difficulties associated with innovation, pharmaceutical innovation is easily codifiable, making it extremely susceptible to reverse engineering (Cockburn & Long, 2015; Grabowski, 2002). As a result of the relative ease with which patents can be replicated, patents are critical for companies to ward off competition and thus reap the benefits of their investments in technological innovation and product development. To prevent free-riding, pharmaceutical companies file for patent applications as early as the pre-clinical stage, when the main molecule is isolated, even though this results in a significant delay between the time of invention and the time when a patent-protected drug reaches the market that reduces the effective term of patent protection (Shadlen, Sampat & Kapczynski, 2020). Together, the high costs of R&D and the relative ease of replication of pharmaceutical innovation encourage innovator firms to regard patent protection as a vital tool for recouping R&D expenses and thwarting competition.

Adding to this inherent necessity of patents for the pharmaceutical industry, two market trends in recent years are said to increase pharmaceutical companies' need for other forms of intellectual property protection. These trends, which alter the dynamics of innovation and competition in the industry, prompt original producers to

[24] A typical pharmaceutical R&D project consists of one pre-clinical stage and four clinical stages. At the pre-clinical stage, scientists attempt to isolate new chemical or biological entities. This stage also involves safety and toxicology tests. Clinical phases involve safety trials on volunteers (phase I), small patient groups (phase II), large patient groups (phase III), and regulatory and post-marketing studies (phase IV). For a detailed analysis of clinical stages in pharmaceutical innovation, see: Muzaka (2011, p. 25).

respond through market-oriented decisions and strategic use of intellectual property rights.

The first trend is the declining productivity in pharmaceutical innovation, despite increasing R&D expenditure (Bradfield & El-Sayed, 2009, p. 201-2; Malerba & Orsenigo, 2015). While the exact reasons for this decline in the effective commercial return for R&D investments are being debated and largely center on the "biotechnology paradox," there is clear evidence that this perceived "crisis" prompts action from pharmaceutical companies (Quéré, 2003). Notably, as productivity declines and the number of drugs in a company's pipeline dwindles, market-based responses include i) market consolidation to increase operational scale and market share to offset the risk of lost market opportunities, and ii) R&D collaborations with specialized firms to facilitate innovation (Bradfield & El-Sayed, 2009, p. 204; Kumar, 1996, 2012; Muzaka, 2011; Yoon, Rosales, & Talluri, 2018).

On the intellectual property front, declining productivity compels pharmaceutical companies to pursue strategies aimed at extending their monopoly status over existing drugs and securing protection for incremental improvements to existing drugs. As a result, patent term extensions and secondary patenting, patenting different aspects of a single drug, have become increasingly important to pharmaceutical companies (Beall, Nickerson, Kaplan, & Attaran, 2016; Sampat & Shadlen, 2017).

Secondly, a constellation of factors, including aging populations, rising costs of new drugs and medical technologies, and slowing economic growth, have put pressure on governments to contain health care spending (Bradfield & El-Sayed, 2009, p. 202; Wouters, Kanavos, & McKee, 2017). Especially since the 2008 crisis, mounting health care costs put attention on pharmaceutical expenditures, prompting

various cost-containment measures to curb the burden on public finances. While cost-containment measures widely differ across countries and over time, a common trend is the price controls and shift to cheaper generic substitutes (Bradfield & El-Sayed, 2009, p. 202; Grabowski, Long, & Mortimer, 2014; Lu, Comanor, Cherkas, & Phillips, 2020; Saha, Grabowski, Birnbaum, Greenberg, & Bizan, 2006; Wouters, Kanavos, & McKee, 2017, p. 133-9). The declining market growth in the developing countries, when coupled with declining productivity rates, prompts pharmaceutical companies to respond by i) turning to developing country markets to compensate for market losses in developed country markets and ii) mergers and acquisitions of generic manufacturers in developing country markets (Malerba & Orsenigo, 2015; Tannoury & Attieh, 2017).

On the intellectual property front, innovators are looking for new ways to stall generic competition. Data exclusivity is the primary mechanism for accomplishing this, as it enables originator companies to obtain an additional marketing monopoly by denying generic companies access to the data they submitted for regulatory approval (Shadlen, Sampat, & Kapczynski, 2020). In other words, data exclusivity precludes generic companies from relying on the originator companies' test data when they seek market approval for their generic drugs after patents expire. Thus, data exclusivity enables an additional or alternative tool for extending exclusivities and delaying the entry of generic producers into the market, as generic producers must now either wait for the exclusivity term to expire or produce such data themselves, which is typically a very costly process.

What does this high and growing reliance of the pharmaceutical industry on exclusionary rights over their innovation mean for making domestic rules in pharmaceutical intellectual property? How does the transition to a world in which

knowledge associated with medicines shifts from being a public good to privately owned and controlled take place, and what types of conflicts should we anticipate?

Access to medicines is contingent on a variety of factors, including the state of public health infrastructure and insurance schemes, and only price is directly related to intellectual property. However, given the highly oligopolistic nature of the pharmaceutical market and the lack of substitutability in medicines, we could anticipate that the creation of legal barriers through intellectual property rights is likely to result in high costs in terms of human well-being and national health care spending (Beall, Nickerson, Kaplan, & Attaran, 2016; Shadlen, Sampat, & Kapczynski, 2020). More specifically, because the introduction of pharmaceutical intellectual property rights entails granting exclusive legal rights to manufacture, distribute, and sell medicines, these monopoly rights that create single or few medicines suppliers may raise concerns for citizens and health policymakers. This may prompt intense conflicts between owners and users of pharmaceutical innovation.

Additionally, the introduction of pharmaceutical patents may result in the proliferation and strengthening of transnational actors in domestic markets, threatening the market share of domestic industry players. Compared to this broad and diverse group of domestic manufacturers likely to advocate for laxer intellectual property rights, we might expect transnational pharmaceutical companies to be relatively smaller but more organized and resourceful and thus better able to organize to achieve their desired policy outcomes.

However, conflicts over pharmaceutical patents may also lead to surprising outcomes. Unexpected alliances between domestic actors, as well as domestic and transnational actors, are not uncommon. In that sense, understanding the political

behavior of different actors and their processes of interest formation, political mobilization, and alliance-building may require going beyond the apparent conflicts of interest. Understanding the points of convergence and divergence in the preferences of various groups of actors and their coalition-building strategies within various institutional contexts is critical for explaining the implementation processes of pharmaceutical patent policies.

In these political processes whereby different actors with competing interests confront and negotiate, the role played by policymakers is also crucial. How static costs to consumers in the form of higher prices are balanced against dynamic benefits from the encouragement and provision of new innovative products requires an understanding of policymakers' preferences and whether they have been diluted or accentuated by legislative processes. Attention to these dynamics may reveal how different political institutions in different countries mediate divergent demands over intellectual property.

A political economy perspective on the study of intellectual property laws can better illuminate the complex and distinct collective action and regulation problems encountered in the politics of intellectual property. Global pressures for change may unexpectedly interact with domestic variables and lead to unconventional politics in conflicts over ownership, control, and use of intangible property. Mexico and Turkey's experiences offer a unique window into understanding how the changing global landscape may alter domestic preferences and result in surprising outcomes with potentially long-lasting consequences.

3.2 Explaining implementation and change in Mexico and Turkey: Assessing rival explanations

Prior to the 1990s, neither Mexico nor Turkey offered patent protection for pharmaceuticals. Conforming to the broader pattern observed across the developing world throughout the postwar period, successive governments in Mexico and Turkey have long maintained a staunch opposition to pharmaceutical patents. For instance, well until the 1990s, Mexico viewed lax patent rules as a means of facilitating technology diffusion among local actors (Baca, 1994; Bacalski, 2006, p. 725; Shadlen, 2010, p. 826). In that regard, the absence of product and process patents in Mexico's first formal patent legislation in 1976, Law on Inventions and Trademarks (Ley de Invenciones y Marcas, LIM), reflected the established state policy that excluded pharmaceutical patents since 1943 (Bacalski, 2006; Shadlen, 2017; Zúñiga & Combe, 2002, p. 201).[25]

Similar to Mexico, Turkey also viewed lax patent policies as a mechanism for increasing the production capabilities of domestic actors and as a safeguard against the high prices allowed under patent monopoly (Eren-Vural, 2007a, 2007b; Sezgin Huysal, 2009). Consequently, in Turkey, while pharmaceutical products have been non-patentable since 1879, process patents have also been prohibited since 1961 (Eren-Vural, 2007).[26]

Despite their professed commitment to non-patentability in pharmaceuticals, however, both Mexico and Turkey fundamentally altered their approach to the ownership and control of pharmaceutical intellectual property in the 1990s. In 1991

[25] The 1943 Industrial Property Law of Mexico disallowed patent protection for pharmaceuticals and chemicals but granted protection for industrial processes. See: Zúñiga and Combe (2002, 201). For a detailed review of Mexico's earlier intellectual property laws, see: Baca (1994), Farolan (2001).
[26] Arguably, Turkey's reluctance to become parties to many of the international arrangements that would have implications for patent protection in pharmaceuticals reflects this concern. See: SPO (1995, p. 57-8) and Togan (2012, p. 12).

and 1995, Mexico and Turkey finally conceded to patent protection in pharmaceuticals. However, what distinguishes Mexico and Turkey from other developing countries is not that they finally relinquished non-patentability in pharmaceuticals, as this was a precondition for all developing countries willing to participate in global commerce.

Mexico and Turkey's experiences with pharmaceutical intellectual property in the 1990s are remarkable primarily because how they chose to comply with the shifting global rules in intellectual property strikes many as a clear example of extreme compliance that mismatched not only their economic and technological capacities but also specific socioeconomic needs. When Mexico and Turkey finally enacted their new patent laws in the 1990s, the approach they chose to do so was highly exclusionary, marked by little or no use of various public-regarding safeguards, such as delaying the start date of patentability, exempting some areas of pharmaceutical knowledge from patentability, and establishing certain exceptions to the owners' rights over their intangible property.

In spite of their similar decisions in the 1990s, Mexico and Turkey's policy trajectories in pharmaceutical intellectual property diverged significantly in the 2000s. While Mexico further strengthened its already strong pharmaceutical patent system, Turkey gradually moved away from its formerly extremist stance. More specifically, Mexico's pharmaceutical intellectual property regime evolved in a way to significantly increase the owners' exclusionary rights over their pharmaceutical intellectual property by making it more difficult to exclude more knowledge from patentability, lengthening the terms of patent protection in intellectual property, and reducing the restrictions on owners' private rights in their intellectual property. What transpired in Turkey was the opposite of what took place in Mexico.

What explains Mexico and Turkey's similar beginnings but diverging pathways in pharmaceutical intellectual property? More specifically, why did both Mexico and Turkey, despite long-standing opposition to pharmaceutical patentability, exceed global minimum standards in intellectual property when they first enacted new patent laws in the 1990s but diverged significantly in their subsequent efforts to modify these rules in the 2000s?

Following the initial tendency in the existing literature on intellectual property, an obvious explanation for Mexico and Turkey's initial over-compliance with pharmaceutical intellectual property rules would be the incessant pressures from the US and the EU towards stronger intellectual property rights since the late 1980s. Indeed, as will be shown in the next chapter, both Mexico and Turkey came under intense external pressure to pass new intellectual property laws with satisfactory patent protection for pharmaceuticals. Furthermore, both were threatened to lose their existing trade benefits and future inflow of foreign direct investment if they refused to abide. Given their high trade dependence on the US and the EU markets and their need for expanding market access to sustain their trade and investment regimes, these threats undoubtedly resonated in both countries.

However, external pressures can explain neither the timing and outcomes of policy changes nor the long-term policy trajectories in Mexico and Turkey. External pressures on both countries have been steadily increasing since the late 1980s, yet neither Mexico nor Turkey responded to these calls well until the 1990s. Additionally, the mere existence of external pressures for stronger pharmaceutical patent protection cannot account for the breadth and complexity of decisions Mexico and Turkey made in various aspects of these laws, as these calls for change did not provide a clear-cut, comprehensive "template" defining the "strength" that Mexico

and Turkey had to abide. Furthermore, external pressures have limited explanatory power when it comes to understanding long-term policy trajectories of change, not only because external pressures were rarer and weaker in the 2000s but also because they were not the main impetus for change in pharmaceutical intellectual property laws and policies in both countries. Indeed, what explains the divergent patterns of change in Mexico and Turkey is not so much the varying degrees of external pressure for stronger intellectual property protection but more so how countries differentially responded to the situational exigencies produced by the way these rules were functioning.

The existence of trade agreements that conditioned the passage of a new patent law with pharmaceutical patent protection may provide a more complete explanation for Mexico and Turkey's experiences. As will be demonstrated in the following chapter, both the US and the EU made the provision of pharmaceutical protection, or at least the promise to do so, a condition of initiating and/or concluding NAFTA and Customs Union. Therefore, one could argue that trade agreements that required the provision of pharmaceutical patent protection were the primary catalyst for change in Mexico and Turkey, which would also explain the timing of pharmaceutical patent law reforms in the 1990s. Besides that, NAFTA and the Customs Union can also account for why Mexico and Turkey introduced relatively stronger pharmaceutical patent rules in the 1990s since the intellectual property provisions of NAFTA and the Association Council Decision No. 1/95 establishing the Customs Union eventually prompted these countries to enact stronger pharmaceutical intellectual property laws.

Nonetheless, there are a few points that need further clarification. For one, there is an issue of ambiguity regarding intentions, which complicates attributing

direct causality to the role of trade agreements in accounting for over-compliance. Importantly, by the 1990s, it had become clear that trade agreements in which the US and the EU are dominant parties require more stringent intellectual property provisions than what would be required in GATT's intellectual property agreement. Therefore, why Mexico and Turkey, both of which appear to seek international economic cooperation, did not prefer the less costly multilateral route to achieve global integration (Shadlen, 2004, 2005)? Did Mexico and Turkey enter into NAFTA and the Customs Union knowing and willingly, and if so, why?

These questions are crucial to understanding not only why Mexico and Turkey passed more stringent pharmaceutical patent laws but also why they exceeded even some of their obligations under these arrangements. Indeed, while NAFTA and Association Council Decision No. 1/95 establishing the Customs Union defined the permissible parameters within which Mexico and Turkey could act narrower, Mexico and Turkey's choices were still not by-the-book compliance. Even within these permissible parameters, Mexico and Turkey did not fully exploit all available flexibilities to their advantage. What explains their policy choices is not the mere existence and conditionalities of trade agreements but rather what they meant to them that produced these policy outcomes.

Concerning the long-term trajectory of policy changes, trade agreements also have limited explanatory power. Notably, both countries' efforts to revise their pharmaceutical intellectual property laws and policies in the 2000s remained within the permissive parameters defined by these trade agreements. In other words, it was hardly the impact of NAFTA and the Customs Union in the 2000s that led to divergent trajectories of change in Mexico and Turkey. What explains why Mexico further strengthened its pharmaceutical intellectual property rules despite

opportunities allowed by NAFTA, but Turkey reduced its over-compliant position while remaining within the parameters of directives set out by the EU is not the trade agreements per se but rather the different legacies of these trade agreements that led to differences in the governments' ability to respond domestic situational exigencies.

Existing scholarship studying Mexico and Turkey's experiences in pharmaceutical intellectual property is scarce. While legal analyses of pharmaceutical patent laws and analyses of the pharmaceutical industry dynamics exist, only two scholars interested in the question of pharmaceutical intellectual property policymaking were encountered in the literature review process (Eren-Vural, 2007a, 2007b, 2013; Shadlen, 2017). Notably, both scholars shed light on the complexities of pharmaceutical intellectual property policymaking on the ground. Asking similar questions and adopting similar coalition-based approaches to explain policy changes in distinct contexts, both scholars demonstrate i) how industrial legacies heavily influenced the ability of the domestic pharmaceutical companies to formulate and defend their interests at the time of policy change, and thus to mobilize against strong pharmaceutical patents (Eren-Vural, 2007a, 2007b; Shadlen, 2017), ii) why and how actors with no immediate stakes in pharmaceutical intellectual property participate in such debates to accomplish their objectives (Eren-Vural, 2007a, 2007b; Shadlen, 2017), iii) how Executives are key coalitional players with their own preferences that sought to build a coalition to realize their preferred policies (Shadlen, 2017), and iv) how time emerges as a valuable analytical variable in understanding pharmaceutical intellectual property politics (Shadlen, 2017).

While these studies excellently show how different actors with competing claims engage in debates about pharmaceutical intellectual property, how they form alliances to accomplish their objectives, and whose preferences ultimately prevail

and why, there are also minor shortcomings in their explanations that could be further refined. For instance, Eren-Vural's (2007a, p. 130; 2007b) intentional conceptualization of the state as "a material condensation of class relationships and forces" and its policies "a result of class contradictions" denies the very existence of the state actors and their preferences in the unfolding of the policy processes, seeing them largely as reflections of the Turkish conglomerate capital's preference for "outward oriented capital accumulation strategy" and its pursuit of "the European integration as a hegemonic project in the Gramscian sense of the term".

However, as Shadlen (2017) demonstrates, the Executive may also share such concerns, and it may be the overlapping of the Executive's preferences and the business interests that determines the policy outcomes, not necessarily vice versa. Rather than assuming a direct causal relationship between business interests and policy outcomes, it is necessary to explain to what extent there is a compatibility of business interests and the Executive's preferences in, for instance, foreign policy, economic policy, health policy, and industrial policy that might lead to a constructive collaboration in producing outcomes. Given that each of these areas that interest the Executive is sensitive to, among others, the satisfaction of the domestic constituency for possible electoral payoffs or foreign partners for economic and political support, the Executive's domestic calculations may extend beyond seeking support solely from the business.

Such a conceptualization of the state also becomes more problematic in explaining the subsequent policy trajectory in Turkey since there is clear evidence that the Executive's preferences significantly influenced the policy outcomes during the 2000s. While the Executive's ability to shape intellectual property policies in the 2000s was constrained by the prior commitments that defined the universe of feasible

policy options, the policy outcomes in Turkey clearly illustrate the imprints of the AKP government's preferences on the issues. Because the time frame of Eren-Vural's (2013) analysis does not include the period in which subsequent contestations reached a formal conclusion, we lack any analyses that explain what dynamics were at play in making of Turkey's 2016 Industrial Property Law.

Furthermore, both Shadlen (2017) and Eren-Vural (2007a; 2007b) acknowledge the centrality of trade agreements in debates over pharmaceutical policy and demonstrate how actors with no direct stake in pharmaceutical patents became involved in these debates to facilitate the conclusion of trade agreements. However, it is unclear why and how these actors became so sensitive to their regional blocs and why they faced such stringent conditions. While Shadlen (2017) makes a compelling case for exporters' desire to avoid trade sanctions as an explanation for their strong political mobilization, it still needs to be explained more convincingly how exporters developed such sensitivity to trade sanctions and enhanced market access and why precisely the Executives turned to ardent supporters of pharmaceutical patents.

As the literature on intellectual property policymaking increasingly recognizes, and the cases of Mexico and Turkey demonstrate, the issue of intellectual property rights in the twenty-first century has always been inextricably linked to the broader dynamics of global political economy, an inseparable aspect of countries' decision to integrate into the world economy. Very often, however, just as the literature on the global political economy of intellectual property rights largely ignores the domestic variables at play, the growing body of literature on intellectual property policymaking also overlooks the significant influence of broader global economic changes on domestic choices. As a result, there is a dearth of convincing

and systematic explanatory frameworks to account for the complex political processes surrounding intellectual property policymaking.

3.3 The explanatory framework

To account for Mexico and Turkey's experiences without falling trap to the shortcomings of the existing research, this thesis first divides Mexico and Turkey's efforts in pharmaceutical intellectual property policymaking into two periods of change: i) period of introduction in the 1990s and ii) period of modification in the 2000s. The first stage of conflicts that centered on how to comply with the new externally-derived obligations is causally linked with the subsequent efforts of modification in the sense that the permissible policy options defined by the trade agreements in the 1990s continued to condition the universe of feasible policy options in the 2000s not only by setting the legal parameters of permissible action but also by shaping and changing the preferences of domestic actors.

Explaining these two periods of change in Mexico and Turkey necessitates understanding the complex interplay between the broader global economic dynamics and the domestic political negotiations in making pharmaceutical intellectual property laws. Based on this two-stage division and global-domestic linkage, three broad arguments are advanced to explain the policy outcomes in Mexico and Turkey.

The first argument of this thesis is that conceptualizing intellectual property rights as part of the second-stage economic policy reforms in the broader context of the economic liberalization process since the 1990s is key to make sense of the timing, multidimensionality of objectives, complexity of implementation processes, and costly consequences of the intellectual property reforms.[27]

[27] One of the very few studies that explicitly conceptualize intellectual property rights as a second-stage economic reform belongs to Wilcox (2005).

Importantly, the shifting course of economic liberalization in the 1990s resulted from the growing emphasis on how "institutions matter" in establishing and maintaining functioning market economies. The new economic paradigm pushed for the dissemination of new forms of economic policy reforms to reconstruct and transform dysfunctional market institutions, particularly those relating to property rights, in order to "level the global playing field" and intensify cross-border economic activity (Naim, 2000; Wilcox, 2005). This particular set of economic reforms, in turn, sought to harmonize the national rules governing economic activity on a global scale and are frequently referred to as the rules of globalization (Braithwaite & Drahos, 2000, p. 3; Wilcox, 2005). With the goal of achieving global regulatory convergence in areas that previously belonged to the realm of sovereign discretion, the second phase of economic liberalization implied profound transformations for many developing countries, reshaping the established domestic arrangements that had previously governed these issue areas.

Unsurprisingly, one of the most significant developments since the late twentieth century has been the proliferation of and convergence in new international rules aimed at facilitating and coordinating cross-border economic activity across a range of issue areas, including labor standards, environmental standards, financial standards, investment rules, competition policy, public procurement policies, and anti-corruption measures (Drezner, 2001; Simmons, 2001, 2014; Wilcox, 2005). However, intellectual property rights are perhaps the most interesting example of the second phase of the economic policy reforms. As a form of private property right, the growing global prominence of intellectual property rights since the 1990s also reflects the need to ensure the functioning of the global market economy. However, as a form of monopoly right over intangible assets, the globalization of intellectual

property rights sits uneasily within the broader course of liberalization. In that sense, it is possible to see efforts toward the globalization of intellectual property rights as a process of globalizing monopoly rights to create the necessary conditions to allow the liberalization of trade in intangible property.

Importantly, in many developing countries, the primary impetus for intellectual property reform was external influences. Without the compelling impact of these international obligations, it is doubtful that developing countries' historically resistant intellectual property policies would change (Shadlen, 2017, p. 23). As previously shown, the main impetus for intellectual property reforms in many developing countries was the TRIPS Agreement. Indeed, by obliging countries to satisfy a set of minimum standards in intellectual property rights, the TRIPS Agreement sought to achieve a trade-based global uniformity in rules. In many developing countries, these externally derived obligations sparked serious domestic debates about the political viability, socioeconomic appropriateness, and possible negative consequences of implanting these essentially coerced rules. Often lacking domestic support, the making of intellectual property rights in many developing countries turned into a question of how willing a state is to forfeit its sovereign policy autonomy to integrate with the global economy (Wilcox, 2005). In so doing, enacting these reforms was often marked by extensive Executive political maneuvering to bypass the legislative bottlenecks (Wilcox, 2005).

In Mexico and Turkey, the primary driving force for intellectual property reform was a regional, rather than a multilateral, trade agreement. Although Mexico and Turkey's experiences are broadly consistent with those of other developing countries that have implemented their international obligations in intellectual property to comply with TRIPS standards, the fact that Mexico and Turkey's

intellectual property obligations stemmed mainly from the terms of their regional agreements posed fundamentally different sets of questions for these countries to face.

As noted in Chapter 2, the bargain that faced many developing countries that complied with the standards of TRIPS was to concede to greater regulatory convergence in return for enhanced market access under the multilateral trade regime. However, the bargain that faced Mexico and Turkey was much more intense. Because regional trade agreements offer greater and discriminatory market access than could be obtained via multilateral agreement, they often require greater regulatory convergence than what is required by the multilateral arrangements (Manger & Shadlen, 2014; Shadlen, 2005). Indeed, this intense bargain that faced Mexico and Turkey is well-documented by Eder (2001), who shows that Mexico and Turkey faced "rising barriers to entry" in various issue areas to enter into these arrangements. For Mexico and Turkey, then, greater legislative harmonization in areas of labor, trade, investment, competition, and environmental standards were "deep concessions" to be paid to institutionalize cooperative arrangements with their regional blocs (Eder, 2001). Seen from this perspective, the fact that the US and the EC also required greater regulatory convergence from Mexico and Turkey in the area of intellectual property rights turns Mexico and Turkey's patterns of compliance with the global sea change fundamentally a question of regional integration: how to satisfy the much narrower permissible policy space defined by NAFTA and the Customs Union in a way that would not risk their regional integrations.

Understanding these global changes that faced Mexico and Turkey reveals that they were not choosing from a menu of options, and the options for Mexico and Turkey were more so constrained. The standards they faced were higher than what

would be under TRIPS, not just legally but also politically. However, even in this much-restricted policy space that was primarily received from above, Mexico and Turkey still needed to translate these requirements into their national law. In that sense, while part of the question is to understand what the broader parameters of allowable acts were, the other is to understand why these policy outcomes within these boundaries of policy space.

Therefore, the second argument of this thesis is that the similar policy choices of Mexico and Turkey in the 1990s was the outcome of similar domestic coalitional alignments, whereby the prospects of regional trade agreements asymmetrically empowered the pro-patent coalitions at the expense of anti-patent coalitions.

In both Mexico and Turkey, the key players in the pro-patent coalitions were the Executives. Quite surprisingly, both the Mexican and Turkish Executives demonstrated a remarkable reversal of their countries' long-standing policy stance toward pharmaceutical patents in the 1990s. Throughout the period, debates over pharmaceutical intellectual property witnessed participation from various actors in the Executive, who also dealt with countries' strategies of integration in the global economy. These actors included leaders and officials in foreign affairs, economy, and industry ministries. What explains this radical shift in the Mexican and Turkish executives' attitude that saw an enthusiastic rush to introduce pharmaceutical patents?

On the one hand, the shift in executive preferences in Mexico and Turkey exemplifies how developing countries with economically and politically asymmetric relationships with wealthier and more powerful countries may regard second-stage economic policies in general and pharmaceutical patents in specific as necessary

sacrifices to be made in order to sustain their ongoing economic liberalization processes (Shadlen, 2017).

Indeed, Mexico and Turkey entered NAFTA and Customs Union negotiations out of fears of isolation and marginalization in the global economy, as rising regionalism and protectionism loomed large in the 1990s (Eder, 2001; Mansfield & Milner, 1999; Mansfield & Solingen, 2010). While the main threat to Mexico was the US-Canada trade agreement and Europe's growing disinterest, Turkey's main concern was the integration of Europe and growing hardships in entering the increasingly competitive EU market (Eder, 2001; Ortiz Mena, 2004; Shadlen, 2006). Together, these changes in the 1990s produced grave concerns for Mexico and Turkey, as accessing export markets without fear of retaliation and attracting steady FDI inflow became all the more critical for them following their extensive trade liberalization (Eder, 2001; Ortiz Mena, 2004).

On the other hand, the shift in the executive preferences in Mexico and Turkey demonstrates how trade agreements may also be viewed as a mechanism for securing the continuity of further economic reforms, an issue of stigmatizing foreign policy, and a matter of personal prestige at home (Benson, 1994, p. 571; Castro-Rea, 2017; Eder, 2001; Karabulut, 2011; O'Brien, 1995, p. 712; Tirali, 2016; Tornell and Esquivel Hernandez, 1995, p. 27). These aspects of trade agreements resonated with the Mexican and Turkish Executives to varying degrees that made NAFTA and the Customs Union even more desirable, and thus, pharmaceutical patents as readily expendable.

However, because economic reforms, especially the second-stage economic reforms that require deep regulatory converge, have significant distributive consequences, the political viability of reforms heavily depends on the ability of

Executives to muster domestic support and manage opposition to secure their desired policy changes (Haggard & Webb, 1993, p. 143; Shadlen, 2017; Wilcox, 2005). Therefore, explaining the introduction of pharmaceutical patents necessitates understanding the preferences and relative capacities of the underlying societal base.

The key societal actors that contested pharmaceutical patents in both Mexico and Turkey were the transnational and domestic pharmaceutical companies. While the transnational pharmaceutical companies sought to secure maximum possible patent protection for pharmaceuticals at the earliest possible time, the domestic pharmaceutical companies were arrayed against them, resisting their push for stronger rights in pharmaceutical intellectual property. In both countries, because the business models of domestic pharmaceutical companies benefited from the non-patentability of pharmaceutical products and processes, the introduction of pharmaceutical patents posed a significant threat to their commercial viability. To what extent these coalitional actors prevailed in realizing their objectives, however, depended on their economic and political resources at the time of policy change.

Measures such as the relative share of market sales and position in the overall domestic market help assess the relative economic strength of domestic and transnational pharmaceutical companies. However, economic power alone often does not determine the political capacity to influence policymaking processes. For one thing, the good economic standing of domestic pharmaceutical companies vis-à-vis transnational pharmaceutical corporations may be one of fragile market dominance, marked by high degrees of technological or marketing dependency on other actors. Alternatively, the weak market position of domestic pharmaceutical companies might be compensated by strong links with distribution channels, pharmacists, doctors, and hospitals, all of which may contribute to the ability of domestic

pharmaceutical companies to mobilize their available resources against pharmaceutical patents (Shadlen, 2017).

More often than not, however, these factors that determine the political capacity of domestic pharmaceutical companies are historically rooted, heavily influenced by the dynamics of industrial development in countries. Therefore, how domestic industries evolved and what kind of legacies these patterns of development created are crucial for the relative political power of domestic pharmaceutical companies since the extent to which companies reached self-sufficiency in technology or marketing determines their ability to defend their own interests independently from other actors and mobilize politically to cultivate alliances in the broader state and society.

Although local manufacturers captured large shares of the domestic market sales in both Mexico and Turkey, the transnational pharmaceutical companies' unmatched economic, political, and technological dominance in the 1990s significantly reduced the domestic actors' ability to advance resistance to pharmaceutical patents. While the increasing competition in the industry due to the economic liberalization policies decreased the number and power of actors that could resist pharmaceutical patents, NAFTA and the Customs Union opened up a new context that strengthened the hand of transnationals vis-à-vis domestic manufacturers. With a lack of complete self-sufficiency in the production and marketing of pharmaceuticals, the domestic pharmaceutical companies' fears for their own survival deterred their ability to continue their protest against patent protection in pharmaceuticals.

Further weakening the relative strength of the domestic pharmaceutical companies was the broadening of the pro-patent coalitions vis-a-vis anti-patent

coalitions. Because intellectual property rights were bundled with greater and more stable market access under regional trade agreements, the winners of these arrangements were frequently well aware of how they stood to gain or lose if these agreements did not materialize (Mansfield & Milner, 1999, p. 602; Shadlen, 2006). In that sense, exporters who are highly reliant on a single market and vulnerable to threats of diminished market access may mobilize to secure policy changes not only in areas where they have a direct stake but also in areas in which they believe are necessary to secure trade agreements (Mansfield & Milner, 1999; Shadlen, 2017).

The behavior of the Mexican and Turkish exporters corroborates with this anticipation. With their high dependence on the US and the EU markets, whereby around 89% of Mexican exports went to the US, and more than 50% of Turkey's exports went to the EU, the exporters were the primary supporters of NAFTA and the Customs Union in Mexico and Turkey (Eder, 2001; Pamuk, 2018; Shadlen, 2017). However, because the conclusion of NAFTA and the Customs Union was conditioned on the satisfactory provision of pharmaceutical patents, these exporters also pressured their governments to complete the necessary adjustment to not risk the conclusion of these regional arrangements. With their large size and well-organized structures, exporters constituted a significant source of support to the pro-patent cause and contributed significantly to stifling dissent against pharmaceutical patents.

In comparison to this formidable pro-patent coalition, the anti-patent coalition's civil society allies, when they existed, were of questionable value. While civil society actors were absent from debates over pharmaceutical patents in Mexico, the pharmacists' involvement in the anti-patent coalition in Turkey did not serve as a significant countervailing force in deterring the government from enacting stronger pharmaceutical patent laws. Therefore, policy choices in the 1990s was an outcome

of the strong pro-patent coalitions triumphing over the anti-patent coalitions in both Mexico and Turkey, as the domestic contexts created by these regional trade agreements served to asymmetrically strengthen pro-patent coalitions.

In the 2000s, both Mexico and Turkey experienced a new wave of pharmaceutical intellectual property reforms. Unlike the 1990s, most reforms in the 2000s were motivated by the domestic challenges posed by the countries' disproportionate pharmaceutical patent regimes. Put differently, because Mexico and Turkey chose to offer strong exclusionary ownership rights to intellectual property owners in the 1990s, the problems resulting from the mismatch between countries' economic and technological capabilities, on the one hand, and socioeconomic needs and goals on the other, became increasingly apparent in the 2000s and precipitated efforts to adjust these rules to domestic realities.

Throughout the period, the most visible and pressing concern that motivated reform efforts in both countries was the public health challenges. As countries began to allow for pharmaceutical products to be patentable, rising drug prices put a growing strain on national health care budgets. Unsurprisingly, increasing burdens on public health finances precipitated greater awareness and assertiveness from health authorities about the pernicious impacts of pharmaceutical intellectual property rules. The global changes brought about by the Doha Declaration and the illustrative effect of countries such as Brazil inspired and empowered health officials to advocate for more health-friendly modification initiatives.

However, while the WTO's pro-health turn bolstered the Health Ministries' ability to formulate and implement more health-oriented intellectual property policies, the US and the EU have often reacted to Mexico and Turkey's modification efforts with profound hostility, despite the fact that these reform attempts remained

strictly within the permissible boundaries of their international and regional obligations. Indeed, the US and EU maintained trade pressure to deter efforts to weaken the private rights in pharmaceutical intellectual property and actively pushed Mexico and Turkey to adopt "TRIPS-plus" provisions in their national laws.

From a broader perspective, the growing aggressiveness of the US and the EU through the bilateral route was not unique to Mexico and Turkey. Rather, their increasing bilateral pressure resulted from global economic shifts that threatened their ability to unilaterally impose their preferred policies on developing nations. Indeed, starting with the impasse in the Doha Round negotiations and further intensifying after the 2008 crisis, the growing counter-offensive from the developing countries to the constraining impact of global economic rules contributed to a global rebalancing process that served to de facto expand their policy space (Hartman, 2013; Hopewell, 2015; Gallagher, 2007, 2013; Goldstein, 2017; Kahler, 2013; Narlikar, 2013). This turning point in the globalization process is often captured by phrases like the shift to a “new global economic” order, whereby alternative developmental strategies, most prominently that of the state-driven industrialization model of China, gained prominence (Aiginger & Rodrik, 2020; Narlikar & Kumar, 2012; Pieterse, 2011). These broader changes in the global political economy were relevant for developing countries’ efforts in intellectual property policymaking in the sense that the making of new patent laws was often seen as part and parcel of new industrial developmental strategies to thrive in a growingly knowledge-based global economy (Güven, 2016; Öniş, 2019; Wade, 2003).

As a result, coming to the 2000s, global and domestic contexts were fundamentally different and, arguably, more complex than in the previous decade. On the one hand, pressing public health challenges demanded an effective response.

On the other hand, the changing dynamics of the global political economy meant new opportunities and obstacles for policymaking at home. Furthermore, despite the broadening of issues that shaped the Executive's preferences on the appropriate pharmaceutical intellectual property policy for the country, their ability to pursue their policy objectives was, again, contingent on garnering support from a variety of domestic actors in the state and society.

The third argument of this thesis, therefore, is that the divergent pathways of Mexico and Turkey's pharmaceutical intellectual property policies were an outcome of the differing strength of the competing coalitions mobilized for and against the Executive's preferred pharmaceutical intellectual property policy changes.

In both Mexico and Turkey, transnational pharmaceutical companies were the primary opponents of the Executives' modification efforts. After successfully acquiring strong patent rights from both Mexico and Turkey in the 1990s, the transnational pharmaceutical companies turned their attention to retaining and possibly expanding the strength of their exclusivities. Thus, throughout the period, transnational pharmaceutical companies were not only on the defensive to oppose health-oriented modification reforms but also on the offensive to reap stronger and more comprehensive private rights for their innovations. As the changes brought about in the 1990s allowed these actors to accumulate substantial material gains, most notably an increase in local market share, transnational pharmaceutical companies entered the 2000s with an upper hand.

In contrast, the domestic pharmaceutical companies in both countries largely supported the modification efforts of the Executives. Importantly, the changes of the 1990s also affected the preferences and capabilities of domestic pharmaceutical companies. Since their previous manufacturing practices centered on copying

patented products were no longer viable in the age of privately protected pharmaceuticals, their prospects for market survival have become increasingly dependent on creating new ways to compete by finding new strategies to market and distribute their own products. Consequently, in the 2000s, both Mexican and Turkish manufacturers increasingly focused on the terms of exclusivities granted by pharmaceutical patents that determined their entry into the market.

However, while Mexican and Turkish manufacturers' attention has similarly shifted to the effective duration of pharmaceutical patents in the 2000s, the specific issues that motivated them to mobilize, as well as their capacities to mobilize, were determined by their patterns of adjustment to the new status quo. Importantly, how these actors adapted to this new environment that determined their ability to participate in and influence the outcome of reform efforts was a result of two factors: i) the extent of the exclusionary nature of policy choices in the 1990s that determined the magnitude of the initial shock they faced, and ii) the length of time between the introduction of pharmaceutical patents and modification efforts that determined the extent to which these shocks influenced them. Because Mexico and Turkey differed in these two aspects, local manufacturers' capabilities for political mobilization and alliance-building varied.

While both Mexico and Turkey similarly adopted strong pharmaceutical patent rules in the 1990s, the extent to which they conferred exclusionary rights of protection to the owners varied. Mexico's choice to introduce pharmaceutical patents immediately in 1991 and retroactively with pipeline protection mechanism made the negative impacts of pharmaceutical patents felt earlier and more intensely than in Turkey, which granted a three-year transition period for the start date of pharmaceuticals and accepted to process patent applications after 1995.

Furthermore, Mexico's first attempt to modify its pharmaceutical patent rules took place in 2004, approximately thirteen years after the start date of patent protection in pharmaceuticals. In contrast, Turkey's reform efforts in 2004 were only five years after the starting date of pharmaceutical patents in 1999. In that sense, by the time Mexico and Turkey decided to adjust their pharmaceutical regimes to their domestic realities, the degree to which domestic actors' capacities had been transformed varied. Therefore, compared to Turkey, the longer time lag between the start date of patent protection and reform efforts in Mexico led to a more dramatically reconfigured domestic pharmaceutical industry that left domestic manufacturers much powerless vis-a-vis the transnationals. The diminished capacities of the domestic manufacturers, in turn, hindered their ability to mobilize to weaken the strength of pharmaceutical patents.

To summarize, although Mexico and Turkey's behaviors were similar in the 1990s, the extent of the disruptions their choices created was not. While in both countries, the way pharmaceutical patents increased the presence of transnational pharmaceutical companies in the domestic markets, the differences in the extent of exclusionary nature and the timing of pharmaceutical patents in Mexico and Turkey led to a variation in the subsequent coalition-building possibilities that resulted in different outcomes. In that sense, while what mattered in the 1990s was the interaction between the changing global context and the industrial legacies, what mattered in the 2000s was the magnitude of the initial shocks and the temporal proximity between policy decisions that ultimately determined the ability of the Executives to secure policy changes (Pierson 2003; 2004; Shadlen, 2017). Coalitional approach to policymaking processes helps us understand these changing

balances of power in the domestic setting that ultimately determine the policy outcomes across space and time.

CHAPTER 4

EXTERNAL PRESSURES, REGIONAL INTEGRATIONS, AND SIMILAR OUTCOMES: INTRODUCTION OF PHARMACEUTICAL PATENTS IN MEXICO AND TURKEY

Mexico and Turkey's patterns of compliance with the new global rules in intellectual property were one of enthusiastic conformance. In both countries, the long-standing rules governing the ownership, control, and use of pharmaceutical intellectual property were radically and abruptly transformed in the 1990s, turning pharmaceutical innovation into a strongly protected form of private property. However, what transpired in Mexico and Turkey are unique not only for their policy outcomes but also for their processes.

In December 1990, Mexican President Carlos Salinas de Gortari (1988-1994) proposed a new patent law to Congress. The draft proposal envisioned immediate patent protection for both pharmaceutical products and processes, included a pipeline protection mechanism that allowed for retroactive protection of patents that are granted or already filed outside of Mexico, and contained compulsory licensing provisions that are highly difficult to issue. When the proposed law elevated to the main agenda of Congress, it passed with virtually no legislative deliberation and entered into law in June 1991 as the Law for the Development and Protection of Industrial Property (Ley de Fomento y Protección de la Propiedad Industrial, LFPPI).

In December 1992, Turkish Prime Minister Süleyman Demirel (1991-1993) proposed a new patent law to the Parliament. The patent law draft included a five-year transition period for patent protection in pharmaceutical products and processes and allowed for retroactive protection of patents through the 'mailbox' application

system. Unlike the swift passage of the patent law draft in Mexico, however, Demirel's proposal could not pass the Parliament for two and a half years. Patent protection for pharmaceuticals was introduced in Turkey on June 24, 1995, through a decree-law. The June 1995 decree-law envisioned a five-year transition period for process patents and a ten-year transition period for product patents and contained restrictive provisions for compulsory licensing. However, three months later, on September 22, 1995, a second executive decree was issued that reduced transition periods for both product and process patents to mere three years.

This chapter explains Mexico and Turkey's enthusiastic compliance with the new global rules in intellectual property in pharmaceuticals as an outcome of a zealous commitment to regional economic integration. Simply put, as the prospects offered by NAFTA and the Customs Union in the turbulent context of the 1990s altered the preferences and perceptions of all stakeholders in the state and society, the new context that asymmetrically empowered the pro-patent coalition led by transnational companies at the expense of the anti-patent coalitions of domestic pharmaceutical companies created the conditions amenable for the passage of strong pharmaceutical patent laws in the 1990s.

This chapter is divided into three sections. The following section of this chapter details the transformation in Mexican and Turkish executive preferences and the legislative processes by which the new patent laws in the 1990s. The second section is devoted to the clashes between transnational and domestic pharmaceutical companies. The third section analyzes how and why the pro-patent coalitions in Mexico and Turkey expanded through the participation of exporters and the business community in debates over pharmaceutical intellectual property.

4.1 From staunch opposition to enthusiastic submission: Changing Executive preferences and (lack of) Legislative resistance

External pressures on Mexico and Turkey to alter their pharmaceutical patent laws started in the early 1980s. This was, in many ways, unsurprising. For multinational pharmaceutical companies with a long presence in the Mexican and Turkish domestic pharmaceutical markets, rising per capita incomes and populations made Mexico and Turkey potentially lucrative markets. Moreover, Mexico and Turkey's enthusiastic embrace of market-oriented policies to rapidly integrate with the global economy also made them potentially receptive candidates for adopting international "best practices" (Lustig, 1992; Moreno-Brid & Ros, 2009; Pamuk, 2018). Yet, in both Mexico and Turkey, external pressures for stronger pharmaceutical patents in the early 1980s failed to induce any significant policy change in pharmaceutical intellectual property.

In Turkey, when the issue of pharmaceutical patents entered the national agenda, the enduring problem of high drug prices rendered any attempt to offer pharmaceutical patents a step too far. With neither a global framework requiring patent protection for pharmaceuticals nor a domestic demand for patent protection in pharmaceuticals, Özal Government (1983-1987) has largely remained indifferent towards the issue (Eren-Vural, 2007a, p. 128; 2007b, p. 365). Similarly, in Mexico, the mounting threats from the USTR failed to receive any satisfactory response.[28] Indeed, even when the USTR's threat to withdraw Mexico's GSP benefits finally elicited a response in 1986, President de la Madrid's (1982-88) accession to reform the 1976 Law of Inventions and Trademarks (Ley de Invenciones y Marcas, LIM)

[28] Mexico's lax intellectual property laws have long been a target of the USTR. In 1984, the Pharmaceutical Manufacturers of America (PMA) complained about Mexico's lack of pharmaceutical patent protection and requested the USTR to identify Mexico as a priority target (Shadlen, 2017, p. 91).

was still a reluctant reply to relieve external pressures (Baca, 1994, p. 193; Farolan, 2001, p. 57; Shadlen, 2017, p. 91-3). Despite the US' demands for immediate protection for both pharmaceutical product and process patents, de la Madrid insisted on a ten-year transition period to introduce patent protection for pharmaceutical products, retained the local manufacturing requirement in the compulsory licensing provisions, and did not establish an autonomous patent office (Shadlen, 2017, p. 93).[29]

Unsurprisingly, external pressures on Mexico and Turkey were exacerbated in the late 1980s. Mexico's refusal to abide by the US' demands led the USTR to withdraw GSP benefits on US$ 200 million worth of Mexican exports and a rejection of Mexico's application for an additional preferential benefit scheme (Lustig, 1992, p. 129; Shadlen, 2017, p. 93; Silbermann, 1996, p. 618-9). Furthermore, the USTR put Mexico on the Priority Watch List of its first Special 301 report in 1989 for its lack of pharmaceutical patent protection (Baca, 1994, p. 193; Shadlen, 2017, p. 93; Silbermann, 1996, p. 619; USTR, 1989).

The US pressure on Turkey has also escalated. Several high-profile meetings between Turkish business people, government officials, and the US business community saw US investors complaining about Turkey's lax intellectual property rights laws for not providing a credible investment climate and threatening to withhold investment in Turkey unless a stronger patent law was forthcoming. As US Ambassador Abramowitz succinctly stated, what the US investors implied was, "if Turkey wishes to play this game, it has to play according to its rules" (Güldemir,

[29] The 1986-7 LIM reform entered into effect in January 1986. While the 1986 reforms extended patent terms from ten to fourteen years and improved criminal penalties, the improvements concerning pharmaceutical patents were only minor (Baca, 1994, p. 193; Liebermann, 1996, p. 618; Lustig, 1992, p. 129). The 1986 reforms only allowed immediate patent protection for processes but envisioned a ten-year transition period for product patents. For a detailed examination of the 1986-7 LIM reform, see: Baca (1994), Shadlen (2017, p. 91-3) and Silbermann (1996, p. 618).

1990). Therefore, it is also not surprising to see Turkey on the USTR's 1989 Special 301 report, placed as a Watch List country for its lacking patent protection in pharmaceuticals (Geray, 1992a, 1992b).

Within this broader context of unabated external pressures for pharmaceutical patent policy change, the decisive moment that converted the Mexican and Turkish Executives into ardent proponents of pharmaceutical patents came with the prospects offered by the regional trade agreements with their largest trade partners. For both Mexican and Turkish Executives, the possibility of establishing and expanding institutionalized relationships with the US and the EU via trade agreements presented a myriad of potential benefits, particularly so given the rising regionalism and protectionism in the 1990s (Eder, 2001; Ortiz Mena, 2004; Shadlen, 2006).

Indeed, the potential material rewards NAFTA and the Customs Union proffered were substantial: stable, durable, and expanded access to the US and the EC markets, which would reduce the risk of trade retaliation and help sustain their liberalized trade regimes (Eder, 2001; Manger & Shadlen, 2015; Shadlen, 2017, p. 93-4); steady inflow of foreign direct investment, which would reinvigorate economic recovery and increase international competitiveness (O'Brien, 1995, p. 710); and a tool to undertake further, and often costly, economic reforms, by acting as "commitment devices" (Eder, 2001, p. 51; Tornell & Esquivel Hernandez, 1995, p. 27). Thus, because NAFTA and the Customs Union provided pathways to economic advancement and a place on the global investment map, they made economic sense for both the Mexican and Turkish governments.

NAFTA and the Customs Union also made political and ideological sense that pushed the Mexican and Turkish Executives to put the conclusion of these regional arrangements on top of their agendas. For example, it is widely known that

Salinas viewed NAFTA as the "crown jewel" of his neoliberal counter-revolutionary legacy, which would vindicate him and his technocrats (Castro-Rea, 2017; O'Brien, 1995, p. 712). For Çiller, on the other hand, the finalization of Turkey's "monogamous relationship" with Europe was not only about achieving the long-awaited "Westernization" of Turkey (Tirali, 2016) but also about eventuating a growingly contentious foreign policy issue due to Greece's accession to EU and the unfolding of the Cyprus issue (Karabulut, 2011). Therefore, it would not be inaccurate to suggest that NAFTA and the Customs Union also became a matter of personal prestige for these Executives, prompting them to declare the conclusion of these trade agreements a top priority in their agendas (Benson, 1994, p. 571; Eder, 2001; Ortiz Mena, 2004).

However, these "deep integrations" required deep concessions from both Mexico and Turkey (Eder, 2001; Eren-Vural, 2007a, 2007b; Lustig, 1992; Shadlen, 2005, 2017). For Mexico, for instance, it became very early on that introducing a new patent law, or at least the promise to do so, was a major precondition for NAFTA negotiations to start (Lustig, 1992, p. 129; Shadlen, 2017, p. 94). Unsurprisingly, after Bush and Salinas announced their plans to initiate the negotiations for a new trade agreement on June 11, 1990, Salinas promised a new pharmaceutical patent law on January 24, 1990 (Baca, 1994, p. 195), which would provide a degree of protection "similar to that available in industrialized countries" (SECOFI, 1990, p. 173 as cited in Shadlen, 2017, p. 94). In return for Mexico's willingness to satisfy their demands, the US removed Mexico from the Priority Watch List that year (Baca, 1994, p. 195; Shadlen, 2017, p. 94; Silbermann, 1996, p. 619-20; USTR, 1990).

In many ways, Salinas' acquiescence to the new pharmaceutical patent law was an acknowledgment that the new realities about stronger intellectual property rights are now to be faced and satisfied if the broader goal of internationalizing the national economy is to be pursued. Indeed, when Salinas presented his patent law proposal to Congress in December 1990, he made remarks that were radically at odds with his previous position as the chief policymaker in President de la Madrid's (1982-1988) government (Shadlen, 2017, p. 95). For President Salinas, the goal of the new intellectual property law was "to profit from international flows of trade, investment, and technology" (Cámara de Senadores, 1990, p. 4 as cited in Shadlen, 2017, p. 95). Yet, more than accepting patent protection for pharmaceuticals, the most dramatic shift in Salinas' attitude toward pharmaceutical patents was his eventual assent for pipeline protection. Indeed, when the USTR implied that omitting pipeline patents would jeopardize NAFTA negotiations, the government included pipeline provisions in the patent law draft (Shadlen, 2017, p. 95).

The patent law proposal that Salinas submitted to Congress in December 1990 started to be discussed after six months yet passed into law within a single day. According to Nadal (1995, p. 117), the LFPPI was "rushed through an ignorant Congress in 1991 as a gesture to the American government in order to obtain the fast-track authorization for the negotiation of NAFTA". Indeed, Shadlen's (2017, p. 104-7) observations corroborate this claim, noting that debates over the patent proposal in Congress were remarkable for their lack of content. Importantly, Shadlen (2017, p. 104-7) states that the main opposition to the patent law that belonged to the Institutional Revolution Party (Partido Revolucionario Institucional, PRI) came from the center-left Party of the Democratic Revolution (Partido de la Revolución Democrática, PRD), which nonetheless failed to formulate a concrete critique of the

patent draft. At best, the opposition focused on broader issues such as globalization and imperialism or criticized the speedy legislation process, omitting to discuss the impact of patents on the pharmaceutical industry and national healthcare system.

Mexico's new patent law, the Law for the Development and Protection of Industrial Property (Ley de Fomento y Protección de la Propiedad Industrial, LFPPI), came into effect on June 28, 1991, and radically reversed Mexico's long-standing approach to pharmaceutical intellectual property (Sandoval & Leung, 1993, p. 150).[30] Indeed, Mexico's new LFPPI exemplifies extremism in nearly all facets of pharmaceutical patent law, leading LFPPI to "serve as a standard against which the United States gauges intellectual property regimes of other countries" (Hugbauer & Schott, 1992, p. 174, as cited in Silbermann, 1996, p. 620). For one thing, as a member of NAFTA, Mexico introduced pharmaceutical patents much earlier than many other developing countries with a broad patentability criteria that allowed for multiple patenting (Guzmán, 2011). Relatedly, Mexico allowed for patent protection for pharmaceuticals to be started immediately in 1991, forgoing any possibility of preparing the domestic industry for the possible detriments of pharmaceutical patenting. Moreover, Mexico adopted a national exhaustion of rights regime that prohibited parallel importation, effectively eliminating any possibility of obtaining cheaper medications from other countries.

However, the most radical change came with LFPPI's adoption of pipeline protection. By virtue of being a member of NAFTA, Mexico was required to allow recognition for patents that are already granted and applications already filed outside of Mexico. Even though LFPPI stated that pipeline protection would end when the patent term in the first country of application expired, the fact that the twenty-

[30] For a detailed overview of Mexico's 1991 Industrial Property Law, see Baca (1994), Farolan (2001), (Pemberton & Soni, 1992) Sandoval & Leung (1993), and Silbermann (1996).

year patent term is calculated from the date of filing in Mexico, which was later than the original international filing date, meant that any extensions of patent terms granted in the original filing country would also be adopted in Mexico without risk of exceeding the twenty-year period (Shadlen, 2017, p. 96).

As for compulsory licensing provisions, it appears that Mexico chose to over-comply despite the leeway afforded by NAFTA (Baca, 1994; Shadlen, 2009, 2010, p. 828).[31] In other words, although NAFTA did not impose as restrictive conditions for compulsory licensing as it did for retroactive protection and parallel importation, Mexico devised its compulsory licensing provisions in an unnecessarily complicated way that significantly impaired its ability to negotiate lower prices with transnational pharmaceutical companies (Baca, 1994, p. 183; Guzmán, 2011; Shadlen, 2017, p. 96). Indeed, the new law's compulsory licensing provisions, which established a series of steps and requirements to be satisfied, created the impression that only "flagrant patent abuse" would be subject to compulsory licensing (Baca, 1994, p. 200). Besides that, the LFPPI defines "local working" to include importation, implying that owners of the pharmaceutical patents are not required to manufacture the patented product within the country (Guzmán, 2011; Shadlen, 2017, p. 96).

In Turkey, things proceeded a little differently. Importantly, unlike the relatively new context that NAFTA established in Mexico, the idea of a customs union between the European Community and Turkey has long been in the making. The 1963 Ankara Agreement envisioned the Customs Union as the third and final stage of the gradual process leading to Turkey's full membership in the EC, whereby the Additional Protocol signed in 1970 defined the terms of its implementation (İlkin,

[31] Shadlen (2009, 2010) notes that NAFTA's provisions over compulsory licensing were identical to those in WTO's TRIPS Agreement, which gave national governments considerable discretion in determining the grounds for their compulsory licensing provisions. For an in-depth examination of Mexico's compulsory licensing provisions, see: Baca (1994).

1990; Hug, 2008; Kabaalioğlu, 1998). Due to this prospect of eventual membership, the process towards the Customs Union has always been predicated on a progressive alignment of the economic and commercial policies, as well as technical standards, between the EC and Turkey.

However, because frequent freezes had been the norm that characterized Turkey's relationship with Europe for decades, the revitalization of the relationships in the early 1990s heightened the urgency of the old commitment to harmonize, not only because the Customs Unions was approaching but also because previously unknown demands were now being made. Reflecting the growing prominence that the EU was now placing on the issue (Muzaka, 2013), stronger intellectual property rights emerged as a pressing conditionality that Turkey rapidly needed to satisfy (SPO, 1995).[32]

Unsurprisingly, in a number of meetings prior to the decision to initiate the Customs Union, the EC officials made it clear to both the Turkish government and business community that a new patent law was required if the Customs Union was to be finalized. In these meetings, pharmaceutical patents often received special attention, which is unsurprising given that the share of pharmo-chemicals imported from the Community countries increased from 53% in 1983 to 80% in 1987 in Turkey's total pharmo-chemicals imports (Çınar, 1993, p. 104). Indeed, the importance placed on pharmaceutical patents was made abundantly by EC Vice President Martin Bangemann during his early 1992 visit to Turkey. Attending a meeting held by Turkish-German Pharmaceutical Industries Cooperation, Bangemann stated that "the changes that Turkey will make in the pharmaceutical

[32] Such obligations to devise a new patent and other intellectual property laws more in line with the European norms were not unique to Turkey. The same conditions were also set for the EFTA countries in 1992. See: State Planning Organization. (1995). Seventh Five Year Development Plan Special Committee Report on Intellectual and Industrial Rights.

industry in line with the EC will be a step towards integration with the EC" and demands as such constitute a clear "invitation from Europe" ("Bangemann: Türkiyesiz Bir AT Düşünülemez", 1992).

The impact of this conditionality in shifting the preferences of the Demirel government is equally dramatic as in Mexico. The new patent law proposal, prepared jointly by the Ministry of Industry and Trade and the State Planning Organization, that allowed for patent protection in pharmaceuticals represented a significant policy shift for a country that not only refrained from offering protection in its national legislation but also avoided becoming parties to a number of the international conventions and organizations that would have implications for pharmaceutical patents (Eren-Vural, 2007a, 2007b; SPO, 1995, p. 57-8; Suluk, 2018, p. 92; Togan, 2012, p. 12). It is also noteworthy that the draft law proposed only a five-year transition period for both product and process patents, despite the fact that ongoing Uruguay Round negotiations had already reached a consensus on longer transition periods for developing countries (Sell, 2003; Matthews, 2002; Muzaka, 2011).

While the shifts in Executive preferences and the arguments for upholding new drafts were fairly similar, the legislative process by which Mexico and Turkey passed patent laws was dramatically different. In stark contrast to Mexico, Turkey's legislative branch met the Executive's patent law draft with much greater resistance. Demirel's proposed patent law could never pass the legislature in two and a half years. For one thing, the patent law draft could never elevate to the main agenda of the Turkish Grand National Assembly's (Türkiye Büyük Millet Meclisi, TBMM) General Council. Instead, the patent law draft received intermittent but scattered attention from all political parties, which maintained a largely consistent stance throughout the 19th Legislative Term (1991-1995). The evidence on parliamentary

discussions suggests that parliamentary opposition to intellectual property rights was stronger than opposition to any other Customs Union-related harmonization legislation, such as the consumer protection and competition laws. Furthermore, contrary to what transpired in Mexico, the evidence indicates that debates over the proposed patent law almost always revolved around pharmaceutical patents in Turkey. Indeed, in Turkey, pharmaceutical patents were never regarded as an arcane matter but as a profoundly stigmatizing political issue that pitted three broad groups against one another: defenders of "natural rights," proponents of global economic integration, and critics of the Customs Union. Throughout the 19th legislative term, this tripartite division within Parliament persisted.

The deputies of the center-right True Path Party (Doğru Yol Partisi, DYP), the governing party of the coalition government, maintained the position established by Prime Minister Tansu Çiller (1993-1995) in her reading of the government program on June 30, 1993. Çiller promised to expedite the process of harmonization in order to finalize the Customs Union. For Çiller, who believed that the steady inflow of FDI into Turkey necessitated incentivizing policies, a new patent law was imperative. In line with Çiller's objectives, DYP deputies, joined by their coalition partner center-left Social Democratic Populist Party (Sosyaldemokrat Halkçı Parti, SHP), framed intellectual property rights and other EU-related legislation as prices to be paid in Turkey's pursuit of global integration and international competitiveness. While they frequently asserted that Turkey's poor track record in protecting intellectual property rights exposed them to frequent criticism and was something the "EU required immediately," they acknowledged the need for a lengthy transition period for patent protection in pharmaceuticals.

The main opposition to the patent law proposal came from the Islamist Welfare Party (Refah Partisi, RP). For RP deputies, the Customs Union amounted to a virtual surrender of Turkey's economy to the EU, while the patent law was an unnecessarily high concession that would never result in technology transfer. Among all deputies, the majority of criticism directed at pharmaceuticals patents came from RP deputies, who contended that this Western-imposed patent law was part of the big game aiming to "kill the only standing pharmaceutical industry", which would only lead to skyrocketing drug prices and collapse of the social security system. In between these two extremes was the pro-liberalization, center-right Motherland Party (Anavatan Partisi, ANAP), which agreed with RP that the patent law was an EU-imposed obligation but nonetheless believed that these laws needed to pass.

Thus, rather than being thoroughly discussed in the General Council, the patent law draft traveled across various parliamentary committees.[33] The committee discussions, which took place against the backdrop of a changing political and economic landscape shaped by the 1994 economic crisis and the accelerating Customs Union process, attest how the scope and terms of debates increasingly narrowed down over time. Importantly, while discussions before 1993 witnessed contestations over whether to introduce pharmaceutical patents, the subsequent debates centered on when and how to introduce pharmaceutical patents.

Interestingly, the different ministries' preferences were mixed and did not conform to the expectations that their party leanings would predict. The Ministry of Industry and Trade, which was affiliated with the center-left SHP, and later the center-left Republican People's Party (Cumhuriyet Halk Partisi, CHP), prioritized economic benefits and advocated for a timeline that would not jeopardize Turkey's

[33] For a review of these parliamentary discussions, see also: Eren-Vural (2007b, p. 368-70).

relationship with the US and the EU. In contrast, the Ministry of Health, which was affiliated with the center-right DYP, argued for the longest possible transition period permitted under TRIPS. This internal conflict within the Executive branch continued in subsequent years, reaching its peak in the 1995 committee discussions. In response to the radical proposal by the Trade and Industry Committee to reduce the five-year transition period to four years and include a pipeline protection mechanism, the Health Committee participants rejected the proposal outright, increased the transition period to ten years, and eliminated pipeline patents. At the time, Health Committee's proposal appeared to be the final comprise (Eren-Vural, 2007b, p. 370).

By 1995, the transnational pharmaceutical companies, the US, and the EU had grown frustrated with Turkey's protraction. The USTR had escalated pressure on Turkey, placing it on the Priority Watch List in 1992 and threatening to remove Turkey from the GSP system (Geray, 1993; Kozluklu, 1994, 1995; USTR, 1992). Similarly, the EU's response took on a harsher tone. In responding to these growing external pressures, the government pledged to pass the patent law swiftly (Erel, 1994).

Nonetheless, by the early days of 1995, promises without action had become untenable. Turkey joined the WTO on January 26, 1995, promising to amend its intellectual property laws to conform to TRIPS. However, more importantly, on March 6, 1995, the EU and Turkey signed Association Council Decision No. 1/95, which established January 1, 1996, as the start date for the Customs Union. Decision No. 1/95 mandated that all necessary legislative harmonization be completed by October 1995. (Eren-Vural, 2007).

Arguably, the critical context established by Decision No: 1/95 compelled Prime Minister Çiller to exercise executive authority in the process. Perhaps, the

significant event that prompted Çiller to request the Parliament to issue an executive decree was the tumultuous debate over the amendment of the Law on Intellectual and Artistic Works. Tellingly, the Law on Intellectual and Artistic Works that came to the General Council on February 10, 1995, could not pass until June 7, 1995. Interestingly, deputies debated the law with a greater emphasis on patents than on copyrights, and each party took a much harsher tone than before. Indeed, frequent clashes over the law even motivated one MP to throw a glass at the President of the General Council. Unsurprisingly, Çiller's request for an enabling act also sparked intense debates over the constitutionality of relying on executive decrees and the expedited legislative process, which, however, did not prevent the enabling act from passing the Parliament on June 8, 1995.

On June 24, 1995, the 551 Decree Law on the Protection of Patent Rights (Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname) was issued alongside several other executive decrees on other types of intellectual property rights. The patent decree law included a five-year transition period for process patents (beginning on January 1, 2000) and a ten-year transition period for product patents (beginning on January 1, 2005), in accordance with the Health Committee's proposal. However, when the European Commission declared that the ten-year transition period violated Association Council Decision No: 1/95, the Çiller government issued a second executive decree on September 22, 1995, reducing the transition period for both product and process patents to a mere three years (Eren-Vural, 2007b, p. 372).

Similar to Mexico, Turkey's new patent law marked a sea change in the country's long-standing opposition to pharmaceutical patents. The Patent Decree Law allowed for patent protection to pharmaceuticals for the duration of twenty years, to

be started in 1999. Moreover, Turkey adopted the “mailbox application” system as a form of retroactive protection, which meant that the patent applications filed in Turkey would be deposited until the country’s transition period expires. Despite these differences between Mexico and Turkey’s new patent laws, their policy choices in patentability criteria, exhaustion of rights regime, and compulsory provisions were strikingly similar. In Turkey, too, the broad scope of patentability criteria allowed for multiple patenting on a single drug, prohibited parallel importation, defined importation as “local working,” and set a series of long steps for compulsory licensing.

The different processes by which patent laws passed through Mexico's Congress and Turkey's Parliament reveal much about the nature of legislative politics in Mexico and Turkey. Importantly, due to the highly technical nature of intellectual property rights, which necessitate expertise not only in law but also in industry dynamics, Senators and deputies relied heavily on information provided by non-state actors. Therefore, discussions at both the general and committee levels shed light on the extent to which these non-state actors have had access to representatives. Indeed, as I will show next, the differences in the legislative processes largely reflected the relative powers of different social groups contesting over pharmaceutical patents and their political mobilization capacity. From this vantage point, the opposition’s inability to articulate substantive criticism of Salinas’ patent law draft stemmed partly from the failure of the opposing local actors to provide the PRD with adequate information and arguments to refute the LFPPI supporters' claims (Shadlen, 2017, p. 104-7). In contrast to the opposing groups’ failure to effectively mobilize their allies in the legislative branch, proponents of pharmaceutical patents and their attorneys provided extensive information to Senators and deputies (Shadlen, 2017, p. 104-7).

In the case of Turkey, too, the consensus reached at the Health Committee, as well as the conflicts at the General Council, indicate that local actors opposing pharmaceutical patents were more effective at mobilizing and gaining access to deputies. Indeed, accusations were even leveled against the RP deputies during the parliamentary debates for their alleged close ties to domestic pharmaceutical companies.

However, the different legislative processes over pharmaceutical patents in Mexico and Turkey did not result in dramatically different policy outcomes. While domestic actors opposed to pharmaceutical patents were better represented in Turkey's Parliament than in Mexico's Congress, this did not prevent the Turkish Executive from bypassing the legislative branch through two executive decrees. Indeed, absent Çiller's second executive decree, a comparison of Mexico and Turkey's experiences could easily have been a study of variation in pharmaceutical patent laws. This perplexing result speaks to the role of political institutions in economic policymaking, as it simultaneously confirms and refutes several predictions made in the literature. That is, with a long history of one-party rule and a presidential system in which the dominant right-wing party commands the legislature, it is unsurprising to the existing literature that Salinas achieved what he desired with such ease (Casar, 2002; Haggard & Webb, 1993; Shadlen, 2017; Weldon, 1997).

What transpired in Turkey, however, is rather puzzling as the literature falters in accounting for how and why, in a relatively more democratic country with a fragmented coalition government whereby a right- and left-wing party shared authority, the Executive had such an ability to act unilaterally in ways that circumvented the authority of the very institution charged with creating and enacting

the country's laws. How this is accomplished in the case of pharmaceutical patents requires consideration of the overlap between the Executive's preference for regional integration and the domestic interests that facilitated achieving this outcome.

4.2 Reluctant acquiescence: Transnational and domestic pharmaceutical companies

In both Mexico and Turkey, the driving force behind the push for stronger patent protection in pharmaceuticals was the transnational pharmaceutical companies. Importantly, given their long-standing presence in the Mexican and Turkish markets, transnational pharmaceutical corporations shared the common concern about the complete lack of patent protection for pharmaceuticals in both countries. Indeed, their push for the maximum possible protection for pharmaceutical products and processes at the earliest possible time reflected their globally consistent preference, which they often sought to achieve by assisting in the very formulation of domestic laws. Very broadly, in both countries, what the transnational pharmaceutical companies preferred were the immediate patentability for their pharmaceutical innovations, extensive retroactive protection for their innovations through pipeline patent protection that allow recognition for drugs already patented elsewhere, weak compulsory licensing provisions that would make it impossible to override their private rights of exclusion in their innovation, and any other provision that would serve to increase the strength of their rights.

The transnational pharmaceutical companies found ample opportunities to voice their demands in both countries. For instance, in Mexico, the transnational companies were well-represented locally by the Mexican Pharmaceutical Industry Association (Asociación Mexicana de la Industria Farmacéutica, AMIF) and the Mexican Intellectual Property Association (Asociación Mexicana para la Protección

de la Propiedad Intelectual, AMPPI). Both AMIF and AMPPI have been vocal about their dissatisfaction with Mexico's insufficient patent system since at least 1976 (Shadlen, 2017). Indeed, in response to the 1986-7 LIM reform, AMIF reacted harshly and demanded immediate patentability, retroactive protection through pipeline provisions, and stricter provisions for compulsory licensing (Shadlen, 2017). It's unsurprising that these demands were largely reflected in Salinas' 1990 proposal to Congress, given that AMIF not only mobilized its member firms and allies in the intellectual property law community to assist in the writing of the draft but also built strong relationships with government officials and deputies to ensure the smooth passage of the patent law draft (Shadlen, 2017).

Unlike in Mexico, transnational pharmaceutical companies operating in Turkey did not have a separate industry association until 2003. Transnationals, along with a few domestic producers, were members of the Turkish Pharmaceutical Manufacturers' Association of Turkey (İlaç Endüstrisi İşverenleri Sendikas, İEİS), which was founded in 1964. As a result, transnational corporations operating in Turkey primarily communicated their demands through individual press releases or their home country's officials. This did not, however, prevent them from participating in policy debates. With a long history in the Turkish pharmaceutical market, transnational pharmaceutical companies also developed strong relationships with government officials, which helped sway the Ministry of Industry and Trade to include pharmaceutical patents in the 1992 patent law proposal (Eren-Vural, 2007b, p. 365).

In both Mexico and Turkey, pro-patent coalitions led by transnational pharmaceutical companies eventually prevailed over the anti-patent coalitions led by domestic pharmaceutical companies. Throughout the 1990s, transnational

pharmaceutical companies' unmatched economic and political dominance significantly weakened domestic actors' ability to resist, compelling them to concede not only to patent protection in pharmaceuticals but also to strong exclusionary rights in pharmaceuticals. What explains the Mexican and Turkish pharmaceutical companies' profound inability to mobilize a strong political opposition at the time of policy change?

The immediate answer lies in the peculiar circumstances of the 1990s, which saw a profound inability on the part of domestic companies to cope with the increasing market competition unleashed by the intensifying economic liberalization. In effect, the prospects of further liberalization under the regional trade agreements served only to asymmetrically weaken the domestic pharmaceutical companies vis-à-vis transnational corporations, further increasing domestic pharmaceutical firms' fears for their own survival. In this critical period marked by a wide disparity in the economic, political, and technological power between domestic and transnational companies, the domestic pharmaceutical companies were forced to reluctantly acquiesce to pharmaceutical patents in order to ensure their own survival. At a deeper level, however, the answer lies in the historical dynamics that perpetuated these profound asymmetries between domestic and transnational firms in Mexico and Turkey, which only came to the fore in the 1990s with full force to the detriment of domestic companies. Therefore, a complete explanation of how the transnational pharmaceutical companies held sway over domestic pharmaceutical companies in debates over pharmaceutical patents necessitates understanding the Mexican and Turkish industrial legacies that put them in such a difficult position in the 1990s. Before looking at the dynamics of evolution in the Mexican and Turkish domestic pharmaceutical industries, it is essential to understand the nature of innovation and

production in the pharmaceutical industry and where patent protection is situated in these processes. The pharmaceutical industry consists of two different segments: the upstream pharmo-chemical sector and the downstream formulation sector. The upstream pharmo-chemical sector focuses on developing and producing active pharmaceutical ingredients (APIs), which serve as inputs to the formulation sector that assembles various other inputs to manufacture the final drug forms.

Both segments of the pharmaceutical industry are immensely technology-intensive. While the formulation of finished drugs necessitates knowledge about manufacturing processes, the development of new APIs requires extensive accumulated knowledge and process technology to engage in the highly inventive activity of creating new chemical molecules. Patent protection in pharmaceuticals comprises both segments of innovative and productive activity in the industry. While process patents help protect the inventor's commercial interest in his or her innovation in the manufacturing processes, patent protection in products generates an effective commercial return for the finished APIs that may enter into various drugs.

For any country, therefore, achieving complete self-sufficiency in pharmaceutical production necessitates a well-developed upstream pharmo-chemical sector that could support the downstream formulation sector by eliminating the need for the imports of patented pharmo-chemicals used in drug manufacturing. However, as is the case in many other developing countries, Mexican and Turkish pharmaceutical companies lacked the technological prowess necessary to simultaneously develop upstream and downstream sectors, instead preferring to concentrate on the industry's technologically less intensive formulation sector. In that sense, while the elimination of pharmaceutical patents in both Mexico and Turkey has contributed to the development of local manufacturing capabilities, it is hardly

that non-patentability alone led to self-sufficient domestic industries (Kırım, 1985, p. 231; Guzmán, 2011). The ensuing reliance on externally-derived technology has profound implications for domestic producers, not only because how they choose to acquire foreign technology determines the terms of their relationships with their foreign counterparts but also because how they manufacture drugs determines their ability to market them.

In Turkey, the major reason behind the weakening of local resistance was the dual structure of the domestic pharmaceutical industry, whereby the differing types and degrees of dependence on foreign sources of technology led to a split among the domestic firms that prevented an effective resistance against pharmaceutical patents (Eren-Vural, 2007b, p. 350).

Admittedly, all groups of domestic firms in Turkey relied heavily on various forms of foreign technology, as Turkey lacked self-sufficiency both in API innovation and drug production (Çınar, 1993, p. 2; Eren-Vural, 2007a, 2007b). In the case of the upstream sector of the industry, for instance, it was hardly the case that either the Turkish government directly intervened in the industry in the form of planning and undertaking major investments or the Turkish firms sought direct forms of state intervention in the industry to help initiate and improve innovative capabilities in the technology-intensive upstream sector (Eren-Vural, 2007a, p. 116-7; 2007b, p. 353-4).

While certain forms of state regulation in the upstream sector of the industry, such as protection from import competition, investment subsidies, and a series of restrictions imposed on the transnationals to enter into the industry, eventually incentivized some larger firms to integrate backward into the pharmo-chemicals sector in the 1970s and 1980s, the elimination of investment subsidies and tariffs in

the 1990s largely eradicated these companies from the market (Çınar, 1993, p. 30-3, 41; Eren-Vural, 2007a, p. 118). As a result, the total number of firms operating in the upstream pharmo-chemical sector of the industry declined from twenty-five in 1987 to eleven in 1998 due to the increasing foreign competition through cheaper imports of pharmo-chemicals (Eren-Vural, 2007b, p. 352). Therefore, despite this fleeting success, all domestic pharmaceutical companies remained reliant on the importation of pharmo-chemicals to continue their manufacturing processes, importing around 70% of the domestic demand (Çınar, 1993, p. 126; Kırım, 1985, p. 231).

Besides the dependency on foreign sources of pharmo-chemicals, all domestic companies also relied heavily on foreign technology to acquire knowledge about manufacturing processes, that is, detailed information about how to proceed in the formulation of final drugs. Yet, despite these common insufficiencies in production, the strategies used by various groups of domestic firms to handle these dependencies varied significantly, ultimately determining their collective capacity to resist pressures for patent protection in pharmaceuticals.

The first group of domestic manufacturers chose to acquire necessary technical knowledge about manufacturing processes through technology transfer and licensing agreements with transnational firms (Çınar, 1993, p. 28; Eren-Vural, 2007a, p. 117). Close collaborations with transnationals were deemed advantageous for these companies not only because licensing provided constant and low-cost access to the licensor company but also because detailed information about drugs acquired through licensing facilitated subsequent marketing and registration processes (Eren-Vural, 2007a, p. 117, 2007b, p. 351-2). The foreign pharmaceutical corporations also preferred the licensing route as a viable business model to market their products under conditions of non-patentability (Eren-Vural, 2007b, p. 352). Additionally,

because of these licensing arrangements, domestic firms were obliged to import pharmaceutical chemicals from their licensor companies (Eren-Vural, 2007a, p. 118, 2007b, p. 353). Concentrating on manufacturing licensed and imitated products, this group of companies has grown to be the most powerful player in the domestic industry (Eren-Vural, 2007a, p. 117, 2007b, 352; Kırım, 1985, p. 231).

By contrast, the other group of domestic firms chose both to import their input pharmo-chemicals and the necessary manufacturing technology from unpatented sources in other countries, most notable being Eastern European countries. This strategy for acquiring foreign technology helped these firms to lessen their reliance on transnational pharmaceutical companies (Eren-Vural, 2007b, p. 350-1). Importantly, the documents that accompanied the purchasing of production rights from these countries included detailed descriptions of the manufacturing processes and other information required for the registration processes (Eren-Vural, 2007b, p. 351). Accordingly, with differences in size and type of activity, this group of domestic companies concentrated mainly on producing copy products under their own brand names (Kırım, 1986; Eren-Vural, 2007a, p. 117, 2007b, p. 351).

Largely benefiting from the favorable restrictions on the entry of foreign capital into the formulation sector, these two groups of domestic firms dominated the local pharmaceutical market well until the 1990s (Eren-Vural, 2007a, p. 118). Indeed, available evidence indicates that in the 1980s, domestic producers accounted for more than 60% of total domestic market sales and that four of the top ten companies are locally owned, with the market leader being a Turkish firm (Çınar, 1993, p. 108; Eren-Vural, 2007a, p. 114, 2007b, p. 350; Kırım, 1985, p. 231).

The market dominance of the Turkish pharmaceutical companies was primarily underpinned by a collective skepticism toward pharmaceutical patents

(Eren-Vural, 2007b; SPO, 1991). Importantly, both groups of domestic companies initially strongly opposed the introduction of pharmaceutical patents. However, once they understood that non-patentability was no longer an option, they pressured the government to take advantage of the longest transition period permitted under international agreements to better weather the impending shock. Indeed, the domestic actors' preference for lengthy transition periods is largely to their benefit as a longer time frame could enable local industries i) to adapt the impending competitive conditions by diversifying their production methods, ii) to establish new commercial networks to survive under conditions of increasing competition, and, if possible, iii) to upgrade their R&D capabilities to become players in the industry in the long-term.

However, in the early 1990s, this unified resistance of domestic producers to pharmaceutical patents began to erode. Two factors in the 1990s played a significant role in undermining this collective stance in the Turkish pharmaceutical industry. Firstly, the liberalization of the foreign investment regime in 1986 effectively opened the way for the entry of transnational pharmaceutical companies into the domestic industry (Eren-Vural, 2007b, p. 366; Fırat, 2006, p. 11). Indeed, between 1986 and 1995, twenty-one transnational pharmaceutical companies entered Turkey (Eren-Vural, 2007a, p. 380). Given that the majority of transnationals entering the Turkish market originated in the EU, this appended to the EU's pressure for a new pharmaceutical patent law (Eren-Vural, 2007b, p. 366). Secondly, the looming Customs Union meant that pharmaceutical import tariffs would be reduced to zero on January 1, 1996, signaling the arrival of further foreign competition in the industry (Acar & Yeğenoğlu, 2004; Çınar, 1993).

Together, these two developments in the early 1990s permitted transnational companies to operate in the Turkish market independently, eliminating their reliance

on local manufacturers to market their products. This was a frightening prospect for the group of firms that had long-standing collaborative relationships with transnationals, directly threatening their market survival. Indeed, after transnational pharmaceutical companies threatened to withhold licensing agreements if they refused to concede pharmaceutical patents, this strongest segment of the Turkish pharmaceutical industry acquiesced reluctantly (Eren-Vural, 2007b, p. 367). These firms' concession to pharmaceutical patents appears not irrational as they saw their future through the continuation of licensing arrangements that would provide access to new technologies and products that could ease the costs of adjustment (Eren-Vural, 2007b, p. 367). The fact that these firms conceded to pharmaceutical patents does not appear irrational: they saw their future in the continuation of licensing agreements that would provide access to new technologies and products, which could also help mitigate adjustment costs (Eren-Vural, 2007b, p. 367).

The changes in the 1990s posed a greater threat to these companies; the entry of transnational companies could wipe them out of the market, as well as the patent protection for pharmaceuticals. Unsurprisingly, in response to the turnaround by their local allies, the group of firms that relied less on transnationals, as represented by the Turkish Pharmaceutical Industry Association (Türkiye İlaç Sanayi Derneği, TİSD), became more abrasive in their opposition against pharmaceutical patents (Acar & Yeğenoğlu, 2004; Miser, 1994; "'Türkiye İlaç Patentine Hazır Değil,'" 1993). Indeed, this division within the domestic pharmaceutical industry became visible in the public statements of İEİS as of 1992 and was amplified in parliamentary committee deliberations (Eren-Vural, 2007a; Geray, 1992c; İmşir, 1992a, 1992b; Kızanlık, 1992). Importantly, the major civil society allies of this group of producers were the Turkish Pharmacists' Association (Türk Eczacıları Birliği, TEB) and the

Turkish Chamber of Pharmacists (Türkiye Eczacılar Odası), which also fiercely opposed pharmaceutical patents (Acar & Yeğenoğlu, 2004; İmşir, 1994). As evidenced by the parliamentary debates and the Health Committee's proposal, this group of local manufacturers and pharmacists had made significant contributions to these discussions (Eren-Vural, 2007b; Temelkuran, 1995).

In the end, however, this internal split within the industry against the mounting offensive from the pro-patent coalition led by the transnationals only weakened the voices of patent skeptics. Indeed, due to this division among local actors, the scope of pharmaceutical intellectual property debates narrowed significantly, with discussions focusing exclusively on transitions, although, unlike NAFTA, the Customs Union did not include specific requirements for other areas of patent law (Eren-Vural, 2007a). The rest is, as we know, the passage of stronger rights of exclusion in Turkey's pharmaceutical intellectual property law, all to finalize the Customs Union process.

Different from Turkey, the primary reason for the weakening of local resistance in Mexico was the dual structure of the domestic pharmaceutical market, which compelled domestic pharmaceutical companies to concede pharmaceutical patents in exchange for the government's promises to maintain existing purchasing arrangements (Shadlen, 2017; Zúñiga & Combe, 2002). How and why the Mexican pharmaceutical industry eventually acquiesced to pharmaceutical patents is equally striking as the Turkish case.

The rise and fall of the Mexican pharmo-chemical industry is a dramatic instance on every account. In the 1960s, the Mexican domestic firms largely benefited from various state supports such as import protection, direct subsidies, and tax incentives and achieved tremendous capabilities in the production of APIs.

Indeed, Mexico’s reputation in the steroid hormone industry is often hailed as a success story in the modern “wonder drugs” industry, achieved under conditions of dependency (Gereffi, 1983, p. 48). Therefore, by the late 1980s, the ninety Mexican firms operating in the upstream pharmo-chemical industry provided approximately 60% of the domestic demand for pharmo-chemicals (Shadlen, 2017, p. 98).

However, just like in Turkey, the extensive liberalization policies and the removal of licensing requirements in Mexico vanished more than half of the Mexican firms operating in the upstream pharmo-chemical sector of the industry (Guzmán, 2011; Shadlen, 2017, p. 98; Zúñiga & Combe, 2002, p. 203). The result is the increasing dependency of the local manufacturers on patented sources of pharmo-chemicals and the reduction in the number of firms that could effectively resist patents in pharmaceuticals (Guzmán, 2011; Shadlen, 2010, p. 828, 2017; Zúñiga & Combe, 2002).

Despite the decaying success of the industry's upstream sector, Mexican producers retained their stronghold in the downstream formulation sector of the industry, selling primarily to the public market. Since the industry's beginnings in the early postwar decades, Mexico's manufacturers' strength in drug formulation has been largely dependent on government purchasing practices (Shadlen, 2017, p. 98; Zúñiga & Combe, 2002). Benefiting largely from the broad coverage of the national health insurance provided to formal sector workers, Mexico's final drug producers controlled approximately 70% of the public sector market in 1987 (Shadlen, 2017, p. 98; Zúñiga & Combe, 2002).

However, in the early 1990s, the Mexican manufacturers' high reliance on the government's preferential purchasing practices proved highly detrimental. Because NAFTA negotiations also necessitated a reassessment of discriminatory government

purchasing practices (Shadlen, 2017, p. 99; Zúñiga & Combe, 2002, p. 203), the domestic manufacturers found themselves simultaneously constrained on two fronts: both the immediate introduction of pharmaceutical patents and the prospect of losing supportive government purchasing regulations threatened the local producers' survival. Indeed, the stakes were too high for Mexican manufacturers, as their historical reliance on government purchasing made them less concerned with upgrading their marketing skills and commercialization strategies, rendering their prospects for success in the transnational-dominated private market extremely bleak (Shadlen, 2017, p. 99).

At a meeting between the Salinas government and national firms represented by the National Association of Drug Manufacturers (Asociación Nacional de Fabricantes de Medicamentos, ANAFAM) and the National Chamber of the Pharmaceutical Industry (Cámara Nacional de la Industria Farmacéutica, CANIFARMA), the government pledged to maintain the current government procurement arrangement if the local industry abandoned its opposition to the introduction of pharmaceutical patents (Guzmán, 2011, Shadlen 2017, p. 100). Unsurprisingly, the Mexican firms, profoundly dependent on selling to the government, saw their survival in the continuity of the government benefits and acquiesced to the introduction of pharmaceutical patents. Admittedly, it is dubious whether the Mexican companies could hold sway over Salinas' pro-NAFTA government. However, as in Turkey, effective political mobilization by domestic manufacturers could broaden the scope of debates over pharmaceuticals and negotiate favorable terms in other areas of pharmaceutical patent law that have not been restricted by NAFTA (Shadlen, 2017, p. 100).

As such, NAFTA and Customs Union processes asymmetrically influenced transnational and domestic pharmaceutical companies in Mexico and Turkey. On the one hand, NAFTA and Customs Union processes intersected with the harmful effects of economic liberalization on the industry's upstream pharmo-chemical sector. The elimination of pharmo-chemical firms from the market reduced the number of firms capable of resisting pharmaceutical patents and increased the vulnerability of local firms in the downstream formulation sector of the industry to transnational pharmaceutical corporations' demands. On the other hand, these regional arrangements weakened domestic pharmaceutical firms further by compelling them to choose between patent protection and market survival. In the end, both NAFTA and the Customs Union weakened the ability of domestic manufacturers to resist pharmaceutical patents.

4.3 NAFTA and the Customs Union supporters: Exporters and the business community

In both Mexico and Turkey, regional trade agreements increased the membership and power of pro-patent coalitions led by transnational corporations and Executives. Due to the fact that both NAFTA and the Customs Union were contingent on the introduction of pharmaceutical patents, or the promise to do so, those who stand to benefit the most from stable, permanent, and expanding access to the US and EU markets joined the pro-patent coalitions in Mexico and Turkey.

In Mexico, the promise of NAFTA to mitigate the risk of unilateral removal of preferential benefits by the US, as well as the prospect of lost export opportunities if the agreement failed to materialize, were the key factors that turned exporters into ardent patent supporters of pharmaceutical patents. The fact that around 70% of

Mexico's total exports went to the US (around 30% of which were under GSP status) made Mexico particularly vulnerable to the US Trade and Tariff Amendment Act of 1984, which linked adequate intellectual property protection as an eligibility criterion for GSP benefits (Shadlen, 2017, p. 49).

NAFTA's promise to reduce Mexico's vulnerability to the sudden removal of GSP benefits by institutionalizing a stable and permanent relationship with the US prompted Mexican exporters to mobilize for the pharmaceutical patent cause. Represented by their key associations, the National Association of Importers and Exporters (Asociación Nacional de Importadores y Exportadores de la República Méxicana, ANIERM) and Mexican Business Council for Foreign Affairs (Consejo Empresarial Mexicano para Asuntos Internacionales, CEMAI), exporters in Mexico actively lobbied in support of pharmaceutical patents to secure the signing of NAFTA (Shadlen, 2017).

In Turkey, too, the potential winners of the Customs Union actively engaged in debates over pharmaceutical patents. As the Customs Union was planned to eliminate all quotas facing the Turkish textile and clothing exporters, the textile industry emerged as an outspoken advocate for not only the Customs Union but also the pharmaceutical patents (Eren-Vural, 2007a, 2007b; Pamuk, 2018; Yılmaz, 2011). Indeed, as the deadline for signing Association Council Decision No. 1/95 approached, the Turkish Clothing Manufacturers' Association (Türkiye Giyim Sanayicileri Derneği, TGSD) increased pressure on the government to pass the necessary laws, stating that they "will not pay the price of being late" if the domestic pharmaceutical industry continued to oppose pharmaceutical patents ("'Gecikmenin Faturasını Ödemeyiz,'" 1993).

The allies of pro-patent coalitions in the broader political economy were not confined to exporters only. In both Mexico and Turkey, pro-patent coalitions benefited significantly from the support of the most powerful segments of business organizations, which also often represented the exporters. For instance, in Mexico, a new organization called the Coordinator of Foreign Trade Business Organizations (Coordinadora de Organismos Empresariales de Comercio Exterior, COECE) was formed in 1990 to convey business' demands to the government and has been instrumental in advancing NAFTA negotiations (Schneider, 2004, 2015; Shadlen, 2017). With COECE's prominent role in coordinating NAFTA process, much dissent towards the agreement has been stifled (Shadlen, 2017; Schneider, 2015, p. 37). Additionally, Mexico's largest business association, the Business Coordinating Council (Consejo Coordinador Empresarial, CCE), also lobbied strongly in favor of the new patent law to progress NAFTA negotiations. Consequently, the opposition to pharmaceutical patents faced a formidable and more resourceful pro-NAFTA group.

Turkey's business community, likewise, has been active throughout the period ("Özel Sektörden Hükümete AB Desteği," 1995; "TABA'nın Patent Sorunu," 1992). The peak business association in Turkey, the Turkish Industrialists and Businessmen's Association" (Türk Sanayicileri ve İş Adamları Derneği, TÜSİAD), has been a vocal supporter of the Customs Union.[34] The majority of TÜSİAD's members were large and resourceful companies that either had long-standing collaborative relationships with European firms or were capable of weathering and benefiting from the Customs Union's impending competition (Eder, 2001).

[34] It is also important to note that, at the time the Customs Union negotiations were on the way, the President of TÜSİAD was the owner of a prominent Turkish pharmaceutical company, which was a long-standing licensee of the transnational pharmaceutical companies (Eren-Vural, 2007b, p. 351).

While the Independent Industrialists and Businessmen's Association's (Müstakil Sanayici ve İş Adamları Derneği, MÜSİAD) anti-Western rhetoric and increasing competition argument created an internal schism within the Turkish business community toward the Customs Union, these defiant voices have been successfully eliminated not only because of their relatively weaker economic significance but also of the ideological reframing of the Customs Union as progress towards Turkey's long-awaited "Westernization" (Eder 2001, p. 48-9; Öniş & Türem, 2001, p. 101; Yılmaz, 2011). In that sense, the prevailing pro-EU sentiments in the business community have viewed the political and economic costs of the Customs Union as necessary sacrifices, where pharmaceutical patents were merely one (Eren-Vural, 2007b).

The mobilization of exporters to the push for patent protection of pharmaceuticals attests how Mexico and Turkey's experiences in pharmaceutical intellectual property rights was a question of regionalization. Indeed, these regional trade agreements have fundamentally transformed the broader political economy, profoundly altered the interests and preferences of each stakeholder, and strengthened the pro-patent coalitions at the expense of anti-patent coalitions. In the face of a formidable alliance between the transnational pharmaceutical companies, Executives, and exporters, the domestic pharmaceutical companies had little influence. The end result is an enthusiastic over-compliance, borne out by a zealous commitment to regional economic integration.

CHAPTER 5

EXTERNAL RELATIONS, DOMESTIC CALCULATIONS, AND DIVERGING PATHWAYS: MODIFICATION OF PHARMACEUTICAL INTELLECTUAL PROPERTY RIGHTS IN MEXICO AND TURKEY

In the 1990s, Mexico and Turkey's patterns of compliance with the new global rules on intellectual property were marked by a similarity. In response to the changing global dynamics in the 1990s, Mexico and Turkey responded enthusiastically by enacting pharmaceutical intellectual property laws that conferred strong rights of exclusion to the patent holders, with little or no use of public-regarding policy options. However, the similarity between Mexico and Turkey largely waned in the 2000s. In this second stage of pharmaceutical intellectual property policymaking, Mexico and Turkey's pharmaceutical intellectual property regimes evolved in opposite directions.

In the 2000s, Mexico experienced three phases of pharmaceutical intellectual property reforms that further consolidated owners' exclusionary rights over their pharmaceutical intellectual property. While the efforts in the early 2000s to amend compulsory licensing provisions started with only "good intentions," these efforts backfired and made it even more difficult to issue compulsory licenses. A series of litigations triggered by the newly installed patent linkage system led to several court decisions in the mid-2000s, which perversely resulted in the expansion of the patentability criteria, extension of the patent terms, and the introduction of the data exclusivity period. Mexico's reform efforts suffered yet another setback in the 2010s when the country's pre-grant opposition system veered off course. In Mexico,

therefore, the end result was a further strengthening of the country's already strong pharmaceutical patent system.

In contrast, what transpired in Turkey was a gradual reversal of initial over-compliance, a progressive weakening of the exclusionary patent rights in pharmaceuticals. While Turkey reluctantly conceded to offer a data exclusivity period to satisfy the EU directives minimally, the introduction of the Bolar exception and staunch opposition to offer patent term extensions in the 2000s only foreshadowed what was to come in the 2010s. Indeed, the long-awaited Industrial Property Law of 2016 fundamentally altered the policy choices made in the 1990s, although not without contestation. Compulsory licensing provisions were altered to make it easier to use the intellectual property without the owner's consent, with a series of provisions compelling the owner to work the patent in Turkey. The country's exhaustion of rights regime is also transformed, making it now legal to parallel import products from where they are cheaper. And, at the risk of raising eyebrows in the EU, patentability criteria remained unchanged, refusing to explicitly identify biotechnology and secondary innovations as patentable subject matter.

What accounts for Mexico and Turkey's divergent policy paths in the 2000s? Why was Turkey able to weaken the exclusionary rights of pharmaceutical patents but not Mexico? Was Mexico simply unconcerned about the public health consequences of pharmaceutical patents?

Admittedly, Mexico's northern neighbor is not only the prime mover in the global fight for stronger intellectual property rights but remains to be its leading trade partner. Moreover, given the US-friendly orientations of PAN Presidents Vicente Fox (2000-2006) and Felipe Calderón (2006–2012), it is hard to expect Mexico to take big risks in pharmaceutical intellectual property that would upset the US.

Alternatively, Turkey's growing detachment from the EU is undeniably a part of its new paradigm in pharmaceutical intellectual property. Statements by the AKP government that underline Turkey is under no obligation to abide by the EU's demands for stronger pharmaceutical intellectual property rights abound, illustrating how distancing from the EU was a risk that Turkey afforded to take. So, would a less US-friendly or less conservative Mexican government could succeed in introducing more health-friendly pharmaceutical intellectual property policies like Turkey?

Evidence suggests that what led Mexico and Turkey's experiences to diverge was hardly because of differences in intentions. Indeed, even in US-friendly Mexico, efforts to modify the pharmaceutical intellectual property regime in a more health-friendly way were not absent. As the public health expenditures soared and the unaffordability of medicines spiked, Mexican health officials, too, felt compelled to take action.

At this point, it is worth asking whether the broader political changes in Mexico and Turkey play a role in explaining the divergent evolution of their pharmaceutical patent regimes. Importantly, throughout the 2000s, the relationship between the Executive and Legislative branches in Mexico and Turkey also evolved in largely opposite directions. While the legislative branch was growingly empowered vis-a-vis the Executive in Mexico, the Eecutive's power grew relative to other branches of government in Turkey (Özel, 2021; Zamora & Cossío, 2006). This is an important observation to take into account as the changing relationship between the Executive and Legislative had far-reaching implications on the broader political economy, including the transformation of government-business relations (Özel, 2021).

Unquestionably, the expanding authority of the Turkish Executive was a significant factor that influenced the pharmaceutical intellectual property policymaking processes in Turkey. Indeed, evidence reveals the ability of the AKP government to insist on its desired policy changes, despite opposition from other domestic actors. Yet, it is doubtful had the AKP government would be able to or even willing to introduce these changes if the domestic pharmaceutical companies lacked the potential to support and provide a viable solution to the AKP government's aspirations for the country's overall pharmaceutical policy, which had a clear penchant for prioritizing electorally-beneficial health-oriented policies.[35]

In that regard, there is evidence that domestic manufacturers have sought government support at least since the early 2010s and that the AKP government has introduced various incentive packages since then (İEİS, 2011; TOBB, 2012; Ünal, 2017, p. 145-6). However, what is more striking is the fact that Turkey's new Industrial Property Law coincides with the AKP government's announcement of a nationalization program in pharmaceutical production. The purpose of the new program was to incentivize the domestic production of generic drugs that Turkey imports but that can be produced by Turkish manufacturers. To "compel" the companies to participate in the program, the AKP government stipulated that failure to domestically produce generic versions of these drugs would result in exclusion from the government reimbursement list (TİTCK, 2016). While this new program was well-received by Turkish manufacturers, it was met with hostility by transnational pharmaceutical corporations (Kaya, 2017; PWC, 2019).

[35] This constructive relationship between the government and pharmaceutical manufacturers echoes what was observed in Brazil. Indeed, one of the defining characteristics of Brazil's public HIV/AIDS program was its reliance on domestic manufacturers to produce drugs under compulsory licensing (Eimer & Lütz, 2010; Flynn, 2013; Shadlen, 2009).

Therefore, the question of why, in contrast to Turkey, Mexico failed to modify its pharmaceutical intellectual property regime in a way more attuned to respond to health challenges is not a matter of differences in intentions but differences in capabilities. The divergent pathways of Mexico and Turkey in the 2000s resulted from the different abilities of competing coalitions for change, which were shaped by the legacies of the previous policy choices. This chapter explains how the magnitude of the shock caused by the policy choices in the 1990s and the temporal proximity between the introduction and modification efforts of pharmaceutical intellectual property are two key factors in understanding the divergent pathways of Mexico and Turkey in the 2000s.

This chapter is divided into five sections. In the following section, I present the available evidence on the impact of pharmaceutical patents in Mexico and Turkey. In the second section, I examine the modification efforts in Mexico and describe how in each instance health-oriented policy initiatives failed to achieve their intended objectives. In the third section, I turn to the experiences of Turkey and show how in each instance health-friendly policy initiatives succeeded in achieving their intended objectives.

5.1 The costs of pharmaceutical patents in Mexico and Turkey

The new global order in which pharmaceutical innovation became a privately protected property fundamentally transformed the domestic dynamics in Mexico and Turkey. In the 2000s, both countries experienced hardships borne out by their decisions in the 1990s. Changes in three interconnected areas growingly revealed that Mexico and Turkey's pharmaceutical patent regimes significantly mismatched their domestic realities. However, because Mexico and Turkey differed in the extent

to which they conferred exclusive rights and the time in which they introduced new patent laws, they faced similar problems to differing degrees.

Firstly, in both Mexico and Turkey, the period following the adoption of new patent laws saw a dramatic increase in the number of pharmaceutical patent applications filed, especially by foreigners in comparison to nationals. According to Yalçıner (2002, p. 25), for instance, between 1995 and 2002, only 53 pharmaceutical patent applications were filed by Turkish nationals, compared to 3527 by foreign nationals. As Eren-Vural (2013, p. 239) notes, this trend in Turkey has continued in the subsequent years: between 2004 and 2010, of all the 6637 pharmaceutical patent applications made to the Turkish Patent Institute, only 344 were made by Turkish nationals, compared to 6293 by foreigners. As for Mexico, Shadlen (2017, p. 171) observes a similar trend: between 1991 and 2000, the number of pharmaceutical and pharmo-chemical patent applications in Mexico increased sixfold, from 500 to 3000 in the early 2000s, before increasing further to 4500 in the early 2010s.

The most important reason that accounts for the disparity between Mexico and Turkey in terms of patenting activity is that, while Mexico granted immediate patentability to pharmaceuticals, Turkey implemented a "mailbox application" system that delayed examination until 1995. Indeed, Mexico's choice not only to allow immediate pharmaceutical patenting in 1991 but also to offer pipeline patents as a method of retroactive protection meant that the impacts of pharmaceutical patenting would be felt much sooner and greater than in other developing countries because a greater number of pharmaceuticals would be patentable in Mexico. Importantly, as Shadlen (2017, p. 171) notes, more than 1600 patents were granted via the pipeline mechanism in the early 1990s, and 89% of the 159 new drugs that were approved for launch in the US between 1996 and 2004 received patents in

Mexico. Therefore, what we witness is a much more dramatic impact of pharmaceutical patents on patenting activity in Mexico than in Turkey.

Secondly, in both countries, the period following the introduction of pharmaceutical patents witnessed rising prices of medicines that increasingly burdened national health systems. Importantly, the relationship between patents and prices is complex, as prices are a function of multiple factors. Moreover, prices of different medicines may vary across countries, whereby overall prices of medicines may remain relatively low. Yet, the fact that both Mexico and Turkey experienced serious hardships in containing rising pharmaceutical expenditures after the introduction of pharmaceutical patents is telling.

The problems that early and extreme patenting caused in Mexico are largely acknowledged. In the early 2000s, for instance, prices for medicines in Mexico were higher than in many developing countries (Danzon & Furukawa, 2008; Kanavos & Vandoros, 2011; Moïse & Docteur, 2007, p. 30-1). Moreover, although the competition from Indian suppliers helped reduce the prices of HIV/AIDS drugs globally, the prices of patented antiretrovirals in Mexico remained higher than in many other developing countries (Adesina, Wirtz, & Dratler, 2013; Bautista-Arredondo, Mane, & Bertozzi, 2006; Shadlen, 2017, p. 174). Indeed, in the early 2000s, Mexico had the highest rates of pharmaceutical spending among OECD countries, measured as a share of total health spending. Mexico's pharmaceutical spending as a share of total health spending jumped from 19% in 1999 to 36% in 2003. (OECD, 2022).

In the case of Turkey, there are few studies examining the direct impact of patents on pharmaceuticals or comparing medicine prices in Turkey to those in other countries (Atikeler & Özçelikay, 2016; Gürsoy, 2017; Kockaya, Atikeler, Esen, &

Tuna, 2013; Monitor Group, p. 11). However, it has been noted that, given the lengthy development of new pharmaceutical products, Turkey's mailbox application system will increase the prevalence of patented drugs in 2005 and 2007 (Monitor Group, p. 13; SPO, 2004, p. 45). However, Turkey also experienced significant growth in pharmaceutical spending. However, Turkey also saw a significant increase in pharmaceutical expenditures. For instance, between 2002 and 2010, the growth rate of public pharmaceutical expenditures as a percentage of total health expenditures increased by 15% annually, reaching 42% of total health expenditures in 2010. (Eren-Vural, 2013).

Thirdly, the decisions made by Mexico and Turkey in the 1990s fundamentally altered their domestic pharmaceutical industries. Importantly, commonly experienced economic liberalization policies in the 1990s, further intensified by the lowering of tariff rates due to NAFTA and the Customs Union, commonly led to the elimination of companies operating in both upstream pharmo-chemical and downstream formulation in Mexico and Turkey (Eren-Vural, 2007a, 2007b, 2013; Moïse & Docteur, 2007; Shadlen, 2017; Zúñiga & Combe, 2002). The outcome, of course, was a deepening dependency on the importation of pharmo-chemicals and increasing market competition in both countries, which led to significant declines in the market shares of domestic companies (Eren-Vural, 2013; Guzmán, 2011; Monitor Group, 2003; Shadlen, 2017; Zúñiga & Combe, 2002).

The other side of the same coin is the dramatic increase in the number of transnational pharmaceutical companies entering the domestic markets, facilitated by the further liberalization of foreign direct investment regimes in both countries. Importantly, transnational entry into both markets occurred through the direct entry and the acquisition of generic companies (Eren-Vural, 2007a; 2007b). In Turkey, for

instance, the 1990s saw the entry of twenty-four transnational companies entering into the domestic market, followed by sixteen more in the 2000s (Eren-Vural, 2007b, p. 380, 2013, p. 234). Accordingly, the market share of transnationals increased from 48% in 1999 to 53% in 2002 (Monitor Group, 2003; Fırat, 2006). In Mexico, the 200% increase in foreign direct investment between 1999 and 2006 was significantly more influential in altering the country's domestic dynamics (Guzmán, 2011). From 1997 to 2003, transnational pharmaceutical companies in Mexico accounted for approximately 90% of all domestic market sales (Hayden, 2007, p. 479).

Why do transnational pharmaceutical companies dominate the Mexican market more than in Turkey, and what repercussions does this have for domestic pharmaceutical companies? Importantly, the answer lies in the differences in policy decisions made in the 1990s, which led to varying magnitudes of initial shocks experienced by domestic firms.

The fact that Mexico introduced pharmaceutical patents early, immediately, and with a pipeline protection made the detrimental impacts of pharmaceutical patents to be felt earlier and more extreme than in Turkey, which granted a three-year transition period for the start date of pharmaceuticals and accepted to process patent applications after 1995. While the introduction of pharmaceutical patents reoriented the focus of both the Mexican and Turkish companies largely toward the production of generics, the differences in these policy choices led to different adjustment patterns and, therefore, different relative capabilities vis-à-vis transnational companies.

In Mexico, the market dominance of the transnational pharmaceutical companies meant that one option for domestic companies was to enter into licensing agreements with transnational companies to introduce new drugs to the market.

However, due to the dramatic economic and technological disparity between the transnational and domestic pharmaceutical companies, the Mexican firms entered into such relationships as weak partners (Shadlen, 2017; Zúñiga, Guzmán, & Brown Grossman, 2007). Another option for domestic companies was to focus on upgrading their generic manufacturing capacity, which, in turn, shifted their attention to the factors determining the duration of exclusivity periods for the patented drugs (Shadlen, 2017).In either case, the changes brought about by policy decisions in the 1990s transformed the Mexican pharmaceutical industry into a significant export hub to other nations, with the majority of manufacturing operations taking place under the supervision of transnational corporations (Guzmán, 2011).

Like Mexico, licensing agreements with transnational companies continued in Turkey (Eren-Vural, 2013). Moreover, the Turkish pharmaceutical industry also became an important export hub to other countries, most notably to markets in the Middle East, the ex-Soviet Republics, and North Africa (Eren-Vural, 2013). However, in the case of Turkey, the companies engaged in export operations were primarily Turkish generic manufacturers. Indeed, after introducing pharmaceutical patents, Turkish companies intensified their focus on developing generic versions of patented drugs, which became their stronghold (Eren-Vural, 2013). Furthermore, as a response to changing market dynamics, Turkish manufacturers have also increasingly focused on developing new production methods and modifying existing chemical entities (Eren-Vural, 2013). Rather than aiming for high levels of inventive activity, the Turkish generic companies' focus was to engage in incremental innovation, which sought to achieve market exclusivities and product differentiation through obtaining secondary patents (Eren-Vural, 2013).

Overall, there is clear evidence that the policy choices made in the 1990s were followed by rising public health expenditures and a significant transformation of the Mexican and Turkish pharmaceutical industries. How did Mexico and Turkey attempt to respond to the challenges and opportunities borne out by their policy choices in the 1990s? Did these different impacts of pharmaceutical patents inspire different policy attempts, and if so, to what extent?

5.2 Over-compliance goes extreme: Mexico

5.2. 1 Don’t dare to threat: Revision of compulsory licensing provisions

In 2002, the Mexican Chamber of Deputies received a proposal to reduce the patent protection period for essential medicines from twenty to ten years in order to effectively address the challenges posed by a potential "serious illness" (Hayden, 2007, p. 480; Shadlen, 2017, p. 175). While the proposal appeared to be motivated by concerns about high drug prices in Mexico, its success was highly improbable due to three fatal flaws.

Firstly, the proposal presented legal difficulties. Any attempt to reduce the duration of pharmaceutical patents would contravene Mexico's obligations under both NAFTA and TRIPS. Unless Mexico suddenly decides to withdraw from these treaties, disputing the twenty-year mandatory duration of protection is a mere impossibility.

Secondly, the proposal raised political problems. The deputy who made the proposal was from an opposition party, the Ecologist Green Party of Mexico (Partido Verde Ecologista de México, PVEM), that initially sided with PAN during the Alliance for Change to support Fox's candidacy on July 2, 2000, general elections but later moved to staunch opposition (Shadlen, 2017; Spoon & Gómez, 2017).

Thirdly, the proposal presented a political threat. The deputy who made the proposal was the nephew of Victor González Torres, a divisive political figure at the time (Shadlen, 2017, p. 176). González Torres was the owner and president of Farmacias Similares, a chain of pharmacies that gained popularity in the 1990s as its slogan "The Same, But Cheaper!" coincided with the Ministry of Health's search for cost-cutting measures (Hayden, 2007, p. 479). However, González Torres' promotion of Farmacias Similares as a means to "pharmaceutical sovereignty" later morphed into a campaign against the entire medical establishment, as well as all the country's leading economic and political figures, whom he perceived as perpetuating the corrupted health system (Hayden, 2007, p. 480-4; Shadlen, 2017, p. 176). Importantly, González Torres' increasing attacks on the key figures of Mexico were not in vain, as he had his own political aspirations, including a bid for the presidency in 2006 (Hayden, 2007, p. 485; Shadlen, 2017, p. 176).

Although the proposal failed to advance in the Chamber, the issues it raised persisted. Despite Mexico's incipient commitment to increase access to HIV/AIDS medications to broader segments of the population, the fact that it faced higher prices than many other developing countries increased concerns (Bautista-Arredondo, Dmytraczenko, Kombe, & Bertozzi, 2008). Recall that the high prices of HIV/AIDS medicines were a problem shared by many developing countries that eventually led to the Doha Declaration in 2001, which provided an explicit legal ground for developing countries to use compulsory licensing as a tool to address public health challenges. Indeed, certain developing countries exemplified outstanding leadership in using compulsory licensing for public health purposes, with Brazil being the most assertive actor. Therefore, inspired particularly by the Brazilian example, the President of the Science and Technology Commission, a PAN deputy, assumed

ownership of the proposal and set about modifying it (Cohen & Lybecker, 2005, p. 226; Shadlen, 2017, p. 176-7).

The Commission substantially altered the PVEM deputy's proposal by shifting the emphasis from patent terms to compulsory licensing, an area in which Mexico possessed autonomy both under NAFTA and TRIPS (Shadlen, 2009, 2017, p. 177). The text approved by the Science and Technology Commission in March 2003 included three critical objectives: establishing that a state of "serious illness" declared by health authorities serves as a basis for compulsory licenses, shortening and simplifying the processes for declaring "serious illness," and ensuring that compulsory licenses are issued quickly and with low royalty rates (Cohen & Lybecker, 2005, p. 226; Shadlen, 2009, 2017, p. 177).

Not surprisingly, the transnational pharmaceutical corporations operating in Mexico objected strongly to these changes that would enhance the government's ability to use their patents without their consent. The AMIIF not only galvanized its member companies to oppose these changes but also rallied allies in the broader domestic and international community, including the USTR, PhRMA, the US, and European patent offices, foreign embassies, and Mexico's leading business association, CCE (Hayden, 2007, p. 480; Shadlen, 2017, p. 177-8). However, not confining itself only to resist these changes, the AMIIF also went on the counter-offensive with its formidable allies to secure a version of compulsory licensing provisions that would make granting of compulsory licensing even more difficult than before (Shadlen, 2017, p. 177-8).

The counter-offensive coalition of the AMIIF ultimately prevailed for two main reasons. Firstly, the Fox administration never endorsed the proposal in the first place, though the new proposal originated from a PAN deputy-led Science and

Technology Commission (Shadlen, 2017). For one thing, although Mexico has struggled to contain the rising costs of medicines since the 1990s, the government's sensitivity to such changes has been comparatively less pronounced than, say, Brazil. The Mexican health care system was not universal, and the vast majority of HIV/AIDS medications were distributed largely outside of Mexico's Ministry of Health and Assistance's (Secretaría de Salubridad y Asistencia, SSA) oversight (Shadlen, 2009). This public sector demand structure for medicines rendered SSA largely oblivious to the ongoing affordability crisis (Shadlen, 2009, 2017).

Importantly, the Fox administration's aspiration to extend immigration clauses in NAFTA also contributed to the Executive's remoteness to the bill. In fact, according to Shadlen (2017, p. 178), a letter from the US Embassy directly warned Mexico of the "grave complications that might arise" if the Science and Technology Commission's proposed provisions on compulsory licensing were enacted.

Furthermore, and perhaps even more significantly, there was no countervailing coalition to oppose the extremist demands of the counter-offensive coalition. For the domestic pharmaceutical companies, mainly represented by ANAFAM, increasing the government's ability to issue compulsory licenses contributed little to their market prospects. Because the drugs that were likely to be the objects of compulsory licenses were HIV/AIDS drugs generically manufactured and imported by Indian producers, the issue of compulsory licensing was largely irrelevant to their interests (Shadlen, 2017, p. 179). Instead, the Mexican producers were now interested in provisions that would increase their early entry into the market, the strength, and terms of market exclusivities that the transnational pharmaceutical companies possessed.

Unsurprisingly, the law approved by President Fox in 2004 was the polar opposite of what the Science and Technology Commissions intended: the new text increased the barriers to issuing compulsory licenses by complicating the steps for declaring a "serious illness," eliminating "serious illness" as a sole basis for a compulsory licensing and instituting high minimum royalty rates to be paid to transnationals in return for compulsory licenses (Shadlen, 2017, p. 179). Simply put, after the 2004 compulsory licensing reforms, the Mexican government's ability to threaten the transnational pharmaceutical companies to reduce prices further diminished.

The 2004 compulsory licensing reform demonstrates that Mexico's early and aggressive implementation of pharmaceutical patents bolstered the transnationals' hand to the detriment of domestic producers, making health-friendly coalition-building more difficult due to local sectors' diminished capabilities and shifting preferences. At a broader level, too, the Executive's dependence on the United States to achieve its objectives in other areas of interest through a quid pro quo replicated the patterns of the 1990s in the early 2000s. Therefore, the end result is a further buttressing of the power of transnational pharmaceutical companies in Mexico and a weakening of the government's ability to respond to public health challenges.

As for the Farmacias Similares, its resistance was not left unpunished. The new health regulations by the health surveillance agency in 2010 effectively ended the "similares" market, as the new regulatory requirements were elevated to the degree that "Similares" would fail to satisfy (Guzmán, 2011).

5.2.2 Triumph through litigation: Patent linkage system, expansion of patentability criteria and patent terms, and introduction of data exclusivity

In 2003, the Fox administration introduced a patent linkage system in Mexico. Patent linkage refers to the practice of tying the marketing approval of new drugs with the patent status of existing drugs and refusing to grant market authorization until the patent term expires (Raju, 2022). Therefore, under this new arrangement, Mexico's health surveillance agency, the Federal Commission for Protection against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS), was made obligated to inquire about the patent status of existing drugs from Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Industrial, IMPI), prior to approving new drugs for market release, and to withhold approval if a patent is in effect for the drug in question (Moïse & Docteur, 2007; Shadlen, 2017).

Accordingly, the IMPI was responsible for publishing a supplementary gazette of pharmaceutical patents in force in Mexico to guide COFEPRIS' decisions in market approval. Therefore, the objective of the overall system is to prevent infringement of existing patents as listed in the supplementary gazette in the process of market approval for new drugs.

While Mexico's decision to institute a patent linkage system seemed largely unnecessary, as neither NAFTA nor TRIPS required such an arrangement, it was part and parcel of the new wave of pressures from the US to ratchet up intellectual property protection in pharmaceuticals (Shadlen, 2009, 2017; Shadlen, Sampat, & Kapczynski, 2020, p. 87). Guzmán (2011) notes that in the case of Mexico, the introduction of a patent linkage system was a courtesy, yet again, to PhRMA's request in 2003.

However, unlike what was witnessed in the case of compulsory licensing, the patent linkage system provoked fierce debates in the country. Specifically, two main problems with Mexico's patent linkage system fueled contestations.

Firstly, Mexico's patent linkage system is an unbalanced arrangement as it asymmetrically benefits the owners of pharmaceutical patents at the expense of generic competitors. This is essentially because, in relatively more balanced patent linkage systems like in the US, although the linkage prevents generic firms from receiving market authorization while patents on a given drug are in effect, the system counterbalances this by granting a 180-day shared market exclusivity to all firms that successfully invalidate patents through litigation (Hemphill & Sampat, 2012; Raju, 2022; Shadlen, 2017). The fundamental concept underlying the patent linkage system in the United States is the simultaneous prevention of patent infringement and encouragement of challenging patents that should not have been granted in the first place (Shadlen, 2017, p. 181).

In the case of Mexico, however, the absence of a shared market exclusivity clause creates a collective action problem. In the absence of shared market exclusivity, generic challengers are dissuaded from contesting the validity of valid patents, as they must share the benefits with other firms while bearing the costs and risks of litigation alone (Hemphill & Sampat, 2012; Shadlen, 2017, p. 182).

Secondly, Mexico's patent linkage system further benefits the originator companies in the sense that it also protects "weak" patents from infringements in the market approval process. In general, secondary patents are more vulnerable to patent challenges as they are patents on incremental innovations such as alternative molecular forms, compositions, formulations, or uses. Yet, Mexico's patent linkage system provides strong legal protection to these patents as well. The supplementary

linkage gazette published by IMPI includes not only primary patents but also secondary patents, which makes their existence a basis for denying market authorization to new drugs (Guzmán, 2011; Shadlen, 2017, p. 182).

These provisions were met with intense opposition from domestic pharmaceutical companies. Since Mexico's new patent linkage system not only diminished their incentives to challenge in-force patents but also placed secondary "weak" patents as an impediment to their market entry, much seemed to be at stake for the domestic pharmaceutical companies (Guzmán, 2011). Consequently, unlike its indifference to the issue of compulsory licensing, ANAFAM opposed the introduction of a linkage system and, more so, the inclusion of secondary patents in IMPI's supplementary gazette (Shadlen, 2017, p. 182-3).

The domestic pharmaceutical companies' opposition was joined by the health officials, which also harshly criticized both the institutionalizing of the patent linkage system and the inclusion of secondary patents. For one, they never imagined the patent linkage system to turn out such perversely, as they believed it would only serve to clarify the patents in force and their expiration dates to facilitate the market approval process (Shadlen, 2017, p. 183). Moreover, they never endorsed the inclusion of secondary patents in the gazette on the grounds that it could "artificially extend" the exclusivities of patent protection and result in higher drug prices (Shadlen, 2017, p. 183).

Therefore, the debates on the patent linkage system became one in which the transnational pharmaceutical companies supported the inclusion of secondary patents in IMPI's supplementary gazette, whereas the domestic pharmaceutical companies, the Health Secretariat, and COFEPRIS resisted the inclusion of secondary patents in the gazette. These fierce debates on secondary patents triggered extensive litigation,

whereby the transnational pharmaceutical companies ultimately triumphed: the Mexican Supreme Court ruled that IMPI must publish all pharmaceutical patents, both primary and secondary, in the linkage gazette (Guzmán, 2011; Shadlen, 2009, 2017). These decisions that were "made with absolute ignorance" significantly hindered the facilitation of generic competition after the expiration of patent terms, effectively serving the interests of transnational corporations (Guzmán, 2011, p. 123).

However, this second victory for transnational companies in the 2000s merely foreboded what was to come. Following the decision regarding the status of secondary patents, two additional court decisions strengthened the exclusionary rights of patent holders.

The first occurred when, despite resistance from domestic pharmaceutical companies and the Executive, the courts decided that the terms of patents granted under the pipeline protection could be extended (Shadlen, 2017, p. 183). The push for the extension of patent terms by the transnational companies was a globally witnessed novel trend, and they largely succeeded in Mexico with the assistance of the courts. The disappointment was to the domestic companies and health officials, who expected to benefit from the generic entry following the otherwise impending expiration of patents.

The second court decision that benefited transnational corporations was the introduction of the data exclusivity period for pharmaceuticals (Shadlen, 2017, p. 185-6). Again, data exclusivity was part of the global push for increasing the strength of pharmaceutical intellectual property rights in the 2000s, and the Mexican courts helped the transnationals achieve their preferred policy changes. Even though neither NAFTA nor TRIPS required additional exclusivity status for test data, the

transnational companies' complaints about "inadequate" data protection succeeded in reaping a five-year data exclusivity period through the courts. The fact that all of this occurred despite intense opposition from domestic pharmaceutical companies and health officials is indicative of the immense power of transnational corporations in Mexico and their ability to pursue their objectives in a variety of institutional settings (Shadlen, 2017, p. 186).

The cumulative effect of these court rulings in the 2000s was a drastic reduction in the Executive's capacity to address public health issues. This further restriction in the permissible policy options was frequently bemoaned by the Mexican officials, who characterized the problem as a complete lack of policy instruments to effectively negotiate price reductions (Shadlen, 2017, p. 175).

Importantly, during these years, the Mexican government's awareness of the close relationship between patents and health increased, not only because the 2009 "swine flu" pandemic revealed their inability to provide adequate medicines but also because the expansion of the new health insurance program, Seguro Popular, since 2004 made the stakes higher than ever before (Dion, 2008; Shadlen, 2017; Sparkes, Bump, Özçelik, Kutzin, & Reich, 2019). In addition to hosting the International AIDS Conference in 2008, Mexican officials have made two other decisions that demonstrate their dedication to addressing public health issues.

The first was when, in 2008, a new entity titled the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (for Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud, CCPNM) was established via a presidential decree to eliminate inefficiencies in the public procurement of patented medicines and to negotiate price

reductions (Adesina, Wirtz, & Dratler, 2013, p. 2; Gómez-Dantés, Wirtz, Reich, Terrazas, & Ortiz, 2012; Moye-Holz, van Dijk, Reijneveld, & Hogerzeil, 2017).

In addition, COFEPRIS' decision to cancel the plant request in 2009 could also be regarded as an acute manifestation of these growing concerns. What was once viewed as a policy instrument to compel transnationals to physically invest in the country has now been repealed to incentivize them to introduce less expensive medicines in the country (Guzmán, 2011). Again, the fact that it largely failed to achieve its aims but further contributed to the deindustrialization of the country speaks to the domineering power of the transnationals in Mexico.

5.2.3 Not opposition but mere observation: Pre-grant opposition system

Mexico's last reform attempt came in 2010. Despite their hard failures in the preceding years, the domestic pharmaceutical companies persuaded Mexico's two leading parties, PRI and PRD, to introduce the Congress a proposal to introduce a pre-grant opposition system in Mexico (Shadlen, 2017, p. 185). Importantly, just like the reform attempts on compulsory licensing provisions were influenced by Brazil's activism, the pre-grant opposition reforms received inspiration from India, which has not only an effective pre-grant opposition system but also an overall patent law that is generally skeptical of private property rights in pharmaceuticals (Amin, Rajkumar, Radhakrishnan, & Kesselheim, 2009).

The objective of an opposition system is to enable "third parties" to participate in the patent examination procedure by providing input on whether the submitted application meets the country's patentability criteria (Amin, Rajkumar, Radhakrishnan, & Kesselheim, 2009). In the pre-grant opposition system, this input occurs prior to the patent being granted and is intended to assist the patent office in

evaluating the patent application's consistency with the rules. Importantly, because potential challengers participate in the patent administration process and act as a corrective to granting of erroneous patents, opposition systems are expected to produce "stronger" patents with greater legal validity (Amin, Rajkumar, Radhakrishnan, & Kesselheim, 2009; World Health Organization, World Intellectual Property Organization, & World Trade Organization, 2021, p. 66). Therefore, opposition systems can be viewed as tools for serving the public interest, but only if the patent office is made obligated to respond to societal inputs by incorporating them into the patent examination process.

Because the pre-grant opposition system provides a channel of access to third parties in the patent examination process, the Mexican pharmaceutical companies regarded this option as a crucial opportunity to advance their interests. Because the IMPI's patent examination process was often speedy and frequently flawed, and because patents are generally difficult to remove once granted, domestic pharmaceutical companies saw pre-grant opposition as a means to prevent IMPI from issuing erroneous patents in the first place (Amin, Rajkumar, Radhakrishnan, & Kesselheim, 2009; Shadlen, 2017). The Mexican health officials have also expressed support for the pre-grant opposition system for similar reasons (Shadlen, 2017). In many ways, the pre-grant system was one of Mexico's few remaining options to combat the exclusionary rights of patent holders since the reform efforts in the preceding decade had only gone against them.

However, similar to previous health-oriented modification efforts, the pre-grant opposition system also failed to achieve its intended objectives. The primary antagonists were, once again, transnational pharmaceutical corporations, which fought vehemently against any attempt to reduce their private intellectual property

rights, even slightly. Indeed, by once more mobilizing its allies in the broader global and domestic political economy, the AMIIF reiterated the general platitudes: that a pre-grant opposition would only slow patent examination, reduce the rate of innovation, and prevent new drugs from reaching the Mexican market (Amin, Rajkumar, Radhakrishnan, & Kesselheim, 2009; Shadlen, 2017).

Despite the unified stance of the Executive, health officials, and the domestic pharmaceutical companies to modify Mexico's pharmaceutical patent regime in a more health-friendly way, these "good intentions" only backfired once again. President Calderón signed in 2010 a significantly weakened version of the initial proposal, ripped off from its public-regarding nature. Although the law permitted third-party input in the examination process, it was merely on paper: IMPI was in no way not obligated to consider the input in the examination process nor respond to it (De La Sierra, 2017; Shadlen, 2017). Consequently, although the pre-grant opposition process did not effectively strengthen the exclusionary private rights of patent holders, this was the objective of the pre-grant opposition system, which was thwarted by the transnational pharmaceutical companies' dominating influence.

5.3 Gradual path to minimal compliance: Turkey

5.3.1 The generic solution: Bolar exception and data exclusivity

In the early 2000s, debates over pharmaceutical intellectual property in Turkey remained centered on the European integration process. Importantly, while the introduction of pharmaceutical patents was a significant component of Turkey's obligations under the EU's legislative harmonization process, subsequent debates saw disputes over "gray areas" that lacked clear requirements regarding the substance and timing of provisions to be adopted. For example, pursuant to Association Council

Decision No: 2/97, Turkey was to grant pharmaceutical products a six-year data exclusivity period beginning January 1, 2001. However, after the EU agreed to grant pharmaceuticals a ten-year plus-one exclusivity period in 2004, it became unclear whether Turkey should grant pharmaceutical test data a six-year exclusivity period or a ten-year plus-one exclusivity period. Nonetheless, the European Commission continued to press Turkey to quickly adopt a data exclusivity clause to maintain negotiations ("Müzakere Öncesi Dört Sıkıntı," 2005; Poyrazlar, 2005). Similarly, the EU raised the issue of patent term extensions more frequently in the 2000s. Indeed, in 1992, the EU began granting patent holders patent term extensions via supplementary protection certificates and hoped to expand it to all countries with which it is affiliated. Consequently, in the early 2000s, two major points of contention in Turkey were data exclusivity and supplementary protection certificates.

Data exclusivity was a major priority for multinational pharmaceutical companies (Monitor Group, 2003, p. 15). For these companies, the lack of data exclusivity was not only a clear impediment to commercial viability but also a clear violation of Turkey's obligations under the Customs Union. They also attempted to persuade Turkish policymakers by arguing that granting data exclusivity would benefit Turkey not only by bringing new treatments to market but also by attracting foreign direct investment into the pharmaceutical industry (Monitor Group, 2003, p. 45-6). However, their calls for data exclusivity were largely ignored during the turbulent context of the 2001 economic crisis. In return, a group of EU-originated transnational pharmaceutical companies filed a complaint with the European Commission in October 2003 via the European Federation of Pharmaceutical Industries Associations (EFPIA) (Eren-Vural, 2013, p. 227).

Domestic pharmaceutical companies fought hard against data exclusivity proposals. In stark contrast to the 1990s, domestic manufacturers coalesced under a single political voice in the early 2000s. This was primarily because data exclusivity and extended patent term protection meant a delayed market entry of generics, a market segment dominated by Turkish pharmaceutical producers. For example, in June 2003, İEİS released a report examining the impact of data exclusivity on the Turkish pharmaceutical industry and public health economy (Monitor Group, 2003). The report's findings were gruesome for Turkish manufacturers: a transfer of profit from generic producers to originators with a disproportionate impact on small businesses (Monitor Group, p. 6). The report demonstrated specifically that, while data exclusivity may aid Turkey's path to the EU, it may result in increased reliance on imported drugs (Monitor Group, p. 8). With much at stake, therefore, both İEİS and TİSD advocated for data exclusivity to begin only upon Turkey's accession to the EU (İEİS, 2005; "' İlaçta 1 Ocak Milat Olsun,'" 2005; Monitor Group, 2003, p. 15; Uslu, 2005). Indeed, the conflict was so deep that the İEİS' strong opposition to data exclusivity exacerbated intra-association conflicts, leading transnational pharmaceutical firms to separate from the İEİS to form the Association of Research-Based Pharmaceutical Companies (Araştırmacı İlaç Firmaları Derneği, AİFD) in 2003 (Acar & Yeğenoğlu, 2004; Eren-Vural, 2013).

The subsequent debates over data exclusivity and patent term extensions revealed that the dispute over pharmaceutical intellectual property in Turkey was far more complex. Importantly, the economic and political significance of the EU's anchor role in the early 2000s, as well as the prospects offered by eventual membership, are extensively documented (Öniş, 2003; Pamuk, 2018). Indeed, the newly-elected AKP government appeared to favor smooth relations with the EU as

well (Acemoglu & Ucer, 2015; Arat & Pamuk, 2018, p. 97; Eren-Vural, 2013; "Gözler Yabancı Sermayede," 2002). In that sense, it would be unlikely to see the AKP government cross paths with the EU over pharmaceuticals, and, thus, satisfactory compliance was a must.

However, the same AKP government also placed a premium on expanding access to health care to large segments of the population, which inevitably led to cost-cutting measures to control the mounting expenditures (Arat & Pamuk, 2018, p. 50; Eren-Vural, 2013; Sparkes, Bump, Özçelik, Kutzin, & Reich, 2019). Indeed, in 2004, albeit remained largely ineffective, an external reference pricing system was established as an early method of cost-containment (Dorlarch, 2016; İEİS, 2005; Mısırlıoğlu, Esatoğlu, & Arslan, 2016). In effect, the Turkish government saw the shift to generic medications as a component of its cost-cutting efforts and would not wish to disrupt the competitive dynamics of generic producers (Monitor Group, 2003, p. 15). Therefore, the AKP government could also not cross paths with the local generic producers by undermining the presence and future of their operations.

Interestingly, the transnationals sought to obtain data exclusivity through the judiciary. In 2004, for example, a multinational pharmaceutical company filed a lawsuit with the Council of State seeking to have Article 9 of the Medical Pharmaceutical Products Licensing Regulation (Tıbbi Farmasötik Ürünler Ruhsatlandrma Yönetmeliği) revoked on the grounds that it violated Article 39 of the TRIPS Agreement and created an unfair competitive environment for their intellectual property rights (Sezgin Huysal, 2009, p. 38-40). Tellingly, the transnational company that brought the suit interpreted the matter as a breach of data exclusivity (which Turkey has never offered) rather than a violation of data protection (which Turkey satisfied). The Council of State's decision, however, was

equally telling; not only that Turkey has met its international obligations under Article 36 of the Regulation in that regard, but the state also has a constitutional obligation to ensure the population's access to medicines (Sezgin Huysal, 2009, p. 39).

Furthermore, reflecting this pro-health ethos of the day, the Bolar exception was also adopted in Turkey on June 22, 2004, as an amendment to the patent law decree 551 (Sezgin Huysal, 2009, p. 179-182; Yıldırım, 2007, p. 142). The adoption of the Bolar exception was a triumph for local generics producers; they can now use an original producer's test data in their application for market approval of their generic drug without the original producer's consent (Munoz-Tellez, 2022). Put differently, the adoption of the Bolar exception in Turkey meant the facilitation of market competition by allowing for the quick entry of generic drugs into the market.

When it eventually came to deciding on data exclusivity, the Executive's stance was clearly an attempt to strike a workable balance. On January 19, 2005, the Regulation on the Marketing Authorization of Medicinal Products for Human Use established data exclusivity for pharmaceutical products. Although in line with the demands of the pharmaceutical transnationals and the EU, the Regulation provided retroactive protection to products registered in any country of the EU between January 1, 2001, and December 31, 2004, the Regulation accomplished four things that constituted a minimum level of compliance with the EU standards: i) the Regulation set the term of data exclusivity to six years, the shortest minimum possible, beginning on the first day of marketing authorization in any country of the European Customs Union (ECU), ii) excluded from coverage those molecules for which generics applications were filed in Turkey prior to December 31, 2004, iii) restricted the term of data exclusivity period to be expired with the end of patent

protection in Turkey, and iv) in exceptional cases that seriously threaten public health, an exception could be made to data exclusivity to facilitate the granting of compulsory licensing (Sezgin Huysal, 2009, p. 40-3).

Unsurprisingly, Turkey's reluctant compliance with the data exclusivity obligation drew ire from both the EU and transnational corporations. Indeed, with the start of the EU accession negotiations in 2005, Turkey's minimum offering of data exclusivity and lack of patent term extensions have frequently been cited as a source of concern. However, neither of the subsequent appeals succeeded in convincing Turkey to extend the term of exclusivity period or patent protection. By contrast, Turkey refused to accept supplementary protection certificates, arguing that they are not a mandatory component of any international treaty and that Turkey is not yet a member of the EU (Sezgin Huysal, 2009).

The political processes that witnessed the AKP government's decisions regarding the Bolar exception, data exclusivity, and patent term extension are critical to understanding not only Turkey's early turnabout from its enthusiastic adoption of strong rights of exclusion in pharmaceutical intellectual property but also because they foreshadow the tone of subsequent debates in pharmaceutical intellectual property. Importantly, until the early 2010s, the main axis of debate between transnational and domestic pharmaceutical companies continued to be centered on the purported benefits of R&D in creating new drugs for treatment versus the critical role of generic drugs in ensuring broad access to treatment. In a number of meetings organized by İEİS, for instance, the leading figures in the industry underlined the "generic drug industry's importance in terms of public health and public finance" and the potential of Turkish manufacturers to become global players in the long-term (İEİS, 2005, p. 4).

Understanding these debates are also important in the sense that they delineate the AKP's overall stance on the issue of pharmaceutical policy. Importantly, the distance that the AKP government put between itself and those that threatened its objective to ensure the viability of healthcare finances was not only in the area of pharmaceutical intellectual property. As Dorlach (2016) successfully illustrates, the AKP government's commitment to stable public health finances is evident, even more so, in the case of the "earthquake-like" switch to the global budget in 2009. According to Dorlach (2016), in the context of ongoing negotiations for a stand-by agreement with the IMF that constituted a critical juncture for addressing rising pharmaceutical expenditure, the AKP government's choice for price cuts (populist solution) rather than out-of-pocket payments (neoliberal solution) was due to the electoral payoffs Erdoğan saw in not "cutting from people's medicines." Importantly, this decision was facilitated by the diminished political clout of the foreign transnational corporations and the lack of an industrial policy at the time that would benefit from high prices (Dorlach, 2016).

5.3.2 From conflict to consensus? The Industrial Property Law

In the 2010s, a new and more extensive episode of contestation in Turkey's pharmaceutical intellectual property law took place. Significantly, at least three significant factors contributed to the motivations for reform during this era.

Firstly, because Turkey's first modern intellectual property law was enacted through executive decrees, there was no comprehensive framework of intellectual property law in place. The excessive number of articles in the previous decrees made it difficult to achieve internal consistency across texts. Secondly, because the Constitutional Court subsequently repealed several of the articles contained in the

executive decrees, there were legal voids that required filling. Thirdly, as in many other developing nations, the patent laws enacted in the 1990s no longer aligned with Turkey's socio-economic needs and goals and its industrial developmental aspirations in the 2000s.

The mid-2000s marked the beginning of efforts to draft a new patent law, but it was not until 2013 that the Turkish Patent Institute's (Türk Patent Enstitüsü, TPE) proposed patent law became the subject of parliamentary debates. Eventually reaching the Parliament in March 2013, the draft's stated objectives were to i) harmonize Turkish intellectual property law with EU directives, ii) restructure the TPE in a way to address growing administrative burdens, iii) address the legal gaps, and iv) tailor the domestic law to respond Turkey's changing needs. Despite the optimism of the Executive regarding the patent law proposal's fate in Parliament, the 2013 proposal neither effectively merged the previous executive decrees into a single law nor garnered sufficient political support to pass into law.

However, it did not die. The TPE developed and expanded the 2013 draft and proposed a more comprehensive and ambitious patent law draft in 2016. Reflecting the overall widespread support for the proposal from both the ruling and opposition parties, the patent law draft passed the Parliament on December 22, 2016, and took effect on January 10, 2017, as Turkey's new Industrial Property Law (Sınai Mülkiyet Kanunu, SMK). What occurred over the three-year period to resolve previous conflicts? Arguably, the evolution of debates in three key areas of contention points to the underlying cause: the Executive's growing assertiveness, aided by the growingly well-resourced local pharmaceutical industry's assistance.

The first area of contestation in both the 2013 and 2016 law-making processes was the issue of patentability criteria, specifically in two areas: secondary

patents and biotechnology patents. Indeed, the issue received considerable attention specifically in 2013 and was fiercely debated in three committees: Committee on EU Harmonization, Industry, Trade, Energy, Natural Resources, Information, and Technology Commission, and Health, Family, Labor, and Social Affairs Commission.

At issue was the clarification of definitions. Importantly, the patentability criteria as defined in Patent Decree Law 551 were already extremely broad (Eren-Vural, 2013). There were no specifically restrictive definitions of novelty or inventiveness nor specific provisions that excluded secondary or biotechnology patents from the patentability criteria (Eren-Vural, 2013). Indeed, in practice, the Turkish Patent Institute has already processed secondary and biotechnology patent applications from both foreign and domestic applicants, especially since 2000, when Turkey joined the European Patent Convention (EPC).

In both 2013 and 2016, the TPE officials defended that because these patents were already being processed by the Institute and the provisions in the decree law were already EU-compliant, there was simply no reason to explicitly define secondary and biotechnology innovations patentable subject matter in law. Moreover, in 2013 the TPE officials defended their proposal as one reflecting the sensitivities of the Ministry of Health and other relevant institutions and organizations.

However, for the transnational pharmaceutical companies, an explicit definition of the patentability criteria to include secondary and biotechnology patents were necessary to achieve "legal clarification." In numerous committee debates, attorneys of transnational corporations argued that the proposal should be amended to conform to the European Patent Convention (EPC) concerning secondary and

biotechnology patents. If not, they said, it could be perceived as a deficiency by the EU.

The position of domestic companies was the opposite of that of transnational companies, particularly in the case of biotechnology patents. Indeed, the domestic companies were firmly on the defensive regarding biotechnology patents in 2013, arguing that there is no need to be proactive about such matters, especially when the EU also does not have a clear stance on the issue. However, concerning secondary patents, there is scant explicit commentary from local manufacturers in 2013 and 2016 parliamentary debates and the media. As noted by Eren-Vural (2013), the increasing incremental innovation activities of domestic manufacturers increase their demand for patent protection on these minor modifications, so their absence from discussions on secondary patents appears logical.

In 2013, the Health, Family, Labor, and Social Affairs Commission was the site of the most heated debates over secondary patents, with the most evident skepticism. Importantly, this Commission was not initially designated as a forum for deliberation on the new patent law. In large part, the opening of debates in this Commission appears to be precipitated largely by the insistence of a CHP deputy, who was previously a pharmacist, that the effects of the new rules on pharmaceuticals warranted a closer examination and discussion. This Committee's position on secondary patents was unambiguously prudent: secondary patents should not be included in the law because they could harm generic competition, which, in turn, would only be detrimental to the country.

The outcome of these debates over patentability criteria was determined mainly in 2013. In fact, similar to the terms of discussions in 2013, the Industry, Trade, Energy, Natural Resources, Information, and Technology Commission

reached a consensus in the mid-2016s that there is no need to separately regulate secondary and biotechnology patents in law, as the provisions in the existing law state explicitly that "inventions in all areas of technology will be patented, provided they meet the patentability requirements," which also includes patents for new molecules, formulations, secondary use, and biotechnology inventions. On a broader scale, however, this stance paralleled the period's prevalent distancing from the EU, as frequent remarks were made that underlined there is no need to satisfy the EU's demands as Turkey is not yet a full member.

The exhaustion of rights regime was the second main area of contestation both in 2013 and 2016. In 2013, the TPE proposed to renounce the national exhaustion of rights principle in favor of international exhaustion of rights to allow for parallel importation. Significantly, the issue received relatively less attention in 2013 than in 2016, reflecting the inability to reach a consensus (Eren-Vural, 2013). However, in 2016, the issue returned with full force. In 2016, the debates over the exhaustion of rights regime began with a motion from a MHP deputy to remove the proposed article establishing international exhaustion of rights in Turkey because it was inconsistent with the EU directives and lacked domestic support.

In both 2013 and 2016, transnational pharmaceutical corporations and their legal allies, as represented by AİFD, International Investors Association (Yabancı Yatırımcıları Koruma Derneği, YASED), vehemently opposed the proposal to switch from a national to international exhaustion of rights regime. Their opposition to the international exhaustion regime is understandable, given that it represented a restriction on the geographical scope of their intellectual property rights and a threat to their ability to freely determine product prices in each country where they market their products. Their position in the committee-level discussions was based on

arguments that if parallel importation were permitted, Turkey would attract only the cheapest goods in the world, exports would increase in quantity but not quality, and investor confidence would suffer.

Moreover, the transnational corporations were joined by the exporters in their opposition to the change in the exhaustion of rights regime. The Union of Chambers and Commodity Exchanges of Turkey (Türkiye Odalar ve Borsalar Birliği, TOBB) also resisted the international exhaustion of rights on the grounds that Turkey is not only an importer country but growingly an exporter country in industrial goods. According to TOBB, if parallel importation was allowed, a cheaper-priced product could return to Turkey, which would be detrimental to the country's export ambitions. TÜSİAD, on the other hand, expressed no significant concern over the exhaustion of rights issue. As reflected in its opinions, its primary concerns centered largely on criminal procedures and trademarks (TÜSİAD, 2013, 2014).

As for domestic pharmaceutical companies, there is scant evidence of their participation in 2013 and 2016 parliamentary debates on the exhaustion of rights regime. Eren-(2013) Vural's argument, based on interviews with officials and manufacturers, sheds light on their absence from these debates. She argues that the position of Turkish generic manufacturers on the issue of rights exhaustion in 2013 debates was comparable to that of transnationals. For Turkish manufacturers, the international exhaustion of rights regime posed a threat to their market prospects, as they feared that cheaper drugs manufactured by Indian and Chinese generic companies could flood into the country and limit the sales of identical or similar goods they produced under licensing agreements (Eren-Vural, 2013, p. 229-30). Seen from this perspective, their "indifference" to the issue in the 2016 debates may reflect an uneasy agreement reached with the Executive.

Indeed, what prevailed ultimately was the Executive branch's proposal on the issue. The broad coalition consisting of TPE officials, the Ministry of Health, and the Turkish Competition Authority argued that the international exhaustion of rights would not negatively impact Turkey not only because the prices of products are lower in Turkey than in other countries but also because the ensuing competition would lead to price competition and serve to consumer and national interests. Their collective insistence on the international exhaustion of rights, in turn, effectively prevented any changes in the draft law's provisions.

The last issue that received scant attention in 2013 parliamentary debates but constituted one of the most charged subjects in 2016 SMK debates was compulsory licensing. Importantly, one reason for this is the relatively less dramatic changes in the 2013 draft law than in the 2016 SMK. Indeed, the SMK significantly transformed the provisions in the 1995 patent law decree, aiming to simplify compulsory licensing in Turkey by i) setting stricter time limits for the court to decide whether or not to issue a compulsory license (one month); (ii) redefining the working requirements of the patent should be sufficient to domestic market need and (iii) and compulsory licenses could be given in cases where it could result in significant economic or technological loss to the country.

AİFD and YASED, joined by TÜSİAD, vehemently opposed the changes in the compulsory licensing provisions. Collectively, they argued that the "domestic need" is a legally ambiguous term that may unnecessarily burden the right owners as the clause may restrict their decision to supply the market with whatever quantity they want. Moreover, they argued that because public health-related articles in law already exist, these additional restrictions are unnecessary and may deter inventive activity. Overall, their opposition to these changes was based on seeing them as a

"dangerous" move that threatens the constitutionally protected right of the owner over his or her property.

İEİS and TİSD supported these changes. Their arguments largely mirror-imaged that of the transnationals, underlining the need to punish patent holders that do not use their innovation in the country. Moreover, they argued that as medicines are largely non-substitutable, the fact that transnational pharmaceutical companies choose not to license their products result in the importation of much-needed medicines from abroad with double costs, putting an immense burden on the public finances.

Throughout the discussions, the TPE officials remained steadfast in their defense of the necessity of these modifications. Insofar as reflected in the committee-level discussions, the primary intention of TPE officials in drafting these provisions appears to be to limit the monopoly rights of patent holders in order to allow society to flourish through the use of their innovations. For instance, they frequently defended their intention to simplify compulsory licensing was to compel patent holders to use their invention in the country, which they framed as being in the national interest because it would prevent abusive practices and unfair competition. They argued that if a pandemic erupted and the company did not supply enough medicines, this would raise medicine prices and disrupt market competition. They upheld their position with examples from European countries and emphasized that the amendments are consistent with TRIPS. They ultimately prevailed in committee debates, and the proposal was forwarded to the General Council.

The general-level discussions in the parliament broadly reflected the common understanding of all parties to the necessity of a new industrial property law. While opposition parties criticized the AKP government's insistence on not changing the

specific provisions of the law and showed skepticism towards the ability of the new law to jumpstart industrial development with an innovation component, they nevertheless commonly argued that their approach was broadly positive. Consequently, Turkey's new Industrial Property Law passed the parliament in three days, on December 22, 2016, and entered into force on January 10, 2017.

The end result of these contestations is the weakening of the exclusionary nature of patent holders' rights in Turkey. The final text that passed into law did not expand patentability criteria to explicitly include secondary and biotechnology patents, permitted parallel importation, and simplified procedures for compulsory licensing. In addition to these provisions directly related to pharmaceuticals, the SMK also introduced certain other novelties that are striking. For instance, the SMK eliminated all criminal penalties for patent infringement (Ekici Tağa & Ozdagistanli, 2019, p. 262). It also all patents to be granted upon examination and introduced a post-grant opposition system (Ekici Tağa & Ozdagistanli, 2019, p. 262).

To summarize, Mexico and Turkey's modification efforts in the 2000s proceeded in diametrically opposed directions. While each adjustment effort in Mexico witnessed the triumph of transnational pharmaceutical companies, the progression of policymaking processes in Turkey attests to their decaying political clout in the country. In explaining these diverging policy trajectories of Mexico and Turkey, the analysis showed that the difference was not because the Mexican Executive cared more about the public health challenges than Turkey but because it was unable to realize its policy proposals due to the radically transformed social structure that impeded health-friendly reform efforts in every instance. Therefore, by revealing the dynamics of these highly complex and political policymaking processes in each country, this chapter showed how temporality affected possibilities for

coalition-building in the 2000s that contributed to the diverging pathways of Mexico and Turkey's pharmaceutical patent regimes.

CHAPTER 6

CONCLUSION

Since the late twentieth century, the global political economy has undergone radical transformations. The changing nature and intensity of international economic activity that witnessed the accelerated flow of goods, capital, people, and information generated a world characterized by greater interconnectedness and interdependence. Yet, this escalating complexity did not come without complications, as it raised the issue of the governability of cross-border economic activity. To respond to these challenges unleashed by these massive transformations, new international have proliferated in various issue areas to regulate global economic activity effectively and, thereby, ensure the proper functioning of the global market economy. These emerging global governance frameworks, often called the "rules of globalization," added to the complexity of global economic relations by commanding compliance with a set of uniform minimum standards in issue areas that formerly fell under the jurisdiction of sovereign governments. As a result, greater regulatory convergence became a staple of the process of economic globalization, demanding similarity instead of differentiation.

In this process of increasing convergence in domestic laws, policies, and institutions, changes in rules over intellectual property have been no exception. Since the late 1980s, the question of governing global trade in intangible assets in a world marked by greater competition was resolved through the creation of a new form of global governance in knowledge and information that mandated global harmonization in a set of substantive minimum global standards. Centrally embodied in the TRIPS Agreement and later cemented through various international

arrangements, the emerging global intellectual property rights regime sought to eradicate geographical diversity in favor of global uniformity. Consequently, the emerging legal infrastructure for the growing knowledge-based global economy demanded similarity in national intellectual property laws and policies to ensure the global protection of private rights of ownership in intellectual property.

While it is indisputable that new global rules restrict national policy autonomy to facilitate similarity, globalization, nonetheless, is very much a process of degrees in which compliance with global rules comes in multiple forms. Indeed, the persistent diversity in national patterns of compliance with global rules in areas as diverse as financial, environmental, and labor standards, among others, is a persistent reality that shows, despite global changes that generate commonly faced policy constraints, diversity remains in how individual countries respond to these external demands. This, in turn, makes the persistence of cross-national variation despite pressures for global convergence another hallmark of economic globalization.

Compliance with the new international minimum standards in intellectual property rights share this trajectory. As an outcome of the TRIPS Agreement, countries willing to participate in the multilateral trade regime agreed to adapt their national intellectual property laws and policies as demanded by the new global standards, despite their disparate levels of economic and technological development and distinct socioeconomic needs and objectives. However, within this process of global harmonization, individual countries showed considerable diversity in the ways in which and the extent to which they complied with these new international standards. More specifically, while each country was obligated to provide stronger protection and enforcement for intellectual property rights within its borders, many

exhibited striking differences in their decisions regarding what intellectual property to privately protect, how to protect, when to protect, and to what extent to protect.

This thesis examined the issue of national diversity in the context of global convergence by focusing on the most contentious subset of intellectual property rights, namely the rules over pharmaceutical intellectual property. To understand the sources of variation in this particular area where the conflict between private interests and public interest manifests itself most clearly, this thesis sought to understand the experiences of two critical cases of Mexico and Turkey in their efforts, first, to comply with their new obligations in pharmaceutical intellectual property, and second, to adjust these rules to their domestic needs and goals. By presenting a thorough analysis of the similar beginnings but subsequently diverging pathways of Mexico and Turkey's pharmaceutical intellectual property policymaking processes, this thesis demonstrates that, despite intense pressures to converge, domestic negotiation of global rules still remains a central feature of a world characterized by greater economic and political interdependence.

This concluding chapter expands on the theoretical and normative implications that flow from the linkage between global and domestic levels in the politics of pharmaceutical intellectual property by reviewing the key analytical issues that emerged throughout the analysis. The first section of this chapter synthesizes the main theoretical connections between the politics of intellectual property rights and the major lines of debates in the political economy literature. The second section highlights the limitations of this study and suggests additional research areas that could contribute to our understanding of the similar and dissimilar dynamics that may be at work in the politics of intellectual property rights. The third and final section contemplates the future of pharmaceutical intellectual property in a new

knowledge-based global economy by revisiting the normative implications of the perennial private rights versus public benefits dilemma that characterizes rulemaking processes in intellectual property.

6.1 Linking the global and domestic in the politics of intellectual property

Understanding variation in national responses to the new global rules in intellectual property is essentially a question of understanding the projections of the global changes on the domestic political economy. Existing scholarship on the global politics of intellectual property offers convincing explanations as to why and how these changes occurred and where political and economic pressures stem from that prompt domestic policy change. As demonstrated in Chapter 2, the conventional explanation in the existing literature attributes this global change primarily to the shifting patterns of production and competition in the global economy. Indeed, the growing unease of the knowledge-intensive industries in the US as a response to these changes, as well as their active participation in the global campaign for a trade-based approach to intellectual property, are key aspects that precipitated the changes in the global politics of intellectual property. In this regard, it is impossible to comprehend the emergence of the global regime in intellectual property without examining their responses to rapid technological change and intensifying international trade that led to the creation of a new set of rules that would globally protect their intangible assets.

However, the emergence of a new global framework of rules in intellectual property is hardly the exclusive achievement of a handful of global corporations committed to globalizing the private rights of ownership to protect their assets. The emergence of the new global intellectual property rights regime is not a discrete

event that occurred in isolation but rather a consequence of the shifting dynamics of the global economy since the late 1980s. Contrary to the literature's weak linkage between intellectual property rules and the shifting course of economic liberalization at the turn of the twentieth century, this thesis views globalization of intellectual property rights as an institutionalist intervention to better govern the growing complexity of global economic activity in intellectual property by conceptualizing them as a second-stage economic policy reform.

This study demonstrates that understanding intellectual property rights as a second-stage economic policy reform is analytically lucrative for several reasons. Firstly, intellectual property rights share many attributes of second-stage economic policy reforms that help clarify the purpose of these new rules governing knowledge and information. Intellectual property rights constitute a part of the new forms of global regulations, also known as the “rules of globalization,” that emerged as a result of the growing emphasis on institutions in governing the global market economy. In that sense, as part of this new paradigm, intellectual property rights as a second-stage economic policy reform also sought to facilitate and coordinate intensifying cross-border economic activity by globalizing monopoly rights in knowledge and information to facilitate the liberalization of trade in intangible property.

Secondly, as with many other second-stage economic policy reforms, intellectual property rights were difficult and costly to implement. On the one hand, due to their "technical" nature, second-stage economic policy reforms often necessitated substantial bureaucratic and administrative effort (Krueger, 2000, p. 4). On the other hand, the primary impetus for change in most second-stage economic policy reforms came from the outside, effectively transforming them into compelled

obligations. Many of these characteristics are shared by intellectual property rights. In many developing countries, there have been intense domestic debates regarding the political viability and socioeconomic suitability of implementing new intellectual property rules, making the implementation of new intellectual property rules a test of the state's willingness to relinquish its sovereign policy autonomy in order to integrate with the global economy (Wilcox, 2005).

Importantly, this thesis also shows that the "costliness" of intellectual property reforms also depends on how they were disseminated. In that sense, this thesis distinguishes between the impact of multilateral and regional trade agreements on national intellectual property rights laws and policies by highlighting the differing degrees of trade-offs that developing nations face in multilateralism and regionalism. Specifically, whereas the WTO's TRIPS Agreement and various regional trade agreements are based on a similar bargain in which market access is contingent on compliance with specified intellectual property rules, the bargain in the case of regional trade agreements is significantly more "intense" (Manger & Shadlen, 2014; Shadlen, 2005). This is primarily because regional trade agreements provide greater and more discriminatory market access than multilateral agreements. Consequently, they frequently necessitate a greater degree of regulatory convergence than is required by multilateral arrangements (Manger & Shadlen, 2014; Shadlen, 2005).

Exposing this external push for policy change is essential for understanding why developing countries implemented intellectual property reforms swiftly and in concert. This is primarily because without the compelling influence of these international obligations, it is unlikely that the historically resistant intellectual property policies of developing countries would change (Shadlen, 2017, p. 23). However, it is crucial to distinguish between the effects of multilateralism and

regionalism to understand the experiences of countries such as Mexico and Turkey, whose intellectual property reform efforts were primarily centered on their regional integration projects. Indeed, because of NAFTA and the Customs Union, Mexico and Turkey faced requirements for greater regulatory convergence in intellectual property rights and numerous other issue areas to achieve greater and more discriminatory market access (Eder, 2001). This is a significant part of the explanation as to why Mexico and Turkey passed new pharmaceutical patent laws that offered strong forms of protection in the 1990s.

The fact that Mexico and Turkey's experiences occurred through the regional route generates significant implications on the nature of multilateralism and regionalism in influencing national intellectual property reforms. Allowing us to better understand which external pressures lead to more dramatic domestic policy change, why and how, Mexico and Turkey's responses to the new global rules in intellectual property rights provide a useful terrain for assessing the different effects of multilateralism and regionalism on the dynamics of intellectual property policymaking by highlighting the more stringent regulatory requirements that regional trade agreements demand in exchange for greater market access.

Moreover, Mexico and Turkey's unique experiences also show us the different impacts of different regionalisms. In this regard, the introduction of pharmaceutical patents in Mexico and Turkey, which centered primarily on their regional integration projects under NAFTA and the Customs Union, respectively, reveals the different roles of the United States and the European Union in inducing changes in national policies. This is an important contribution that speaks not only to the larger debates on multilateralism versus regionalism but also to the nature of the

US and the EU's "power" and the extent of their coerciveness in pressuring developing countries.

The fact that the primary impetus for intellectual property reform in Mexico and Turkey was external influences is a crucial but only a partial side of their intellectual property story. Indeed, in any developing country, understanding the final policy outcomes in pharmaceutical intellectual property policy necessitates tracing the domestic-level projections of these global pressures, that is, the political processes whereby international obligations were translated into domestic change. This is all the more crucial in the case of Mexico and Turkey since neither country's policy choices were by-the-book compliance with the rules set out by these regional trade agreements. Answering why Mexico and Turkey did not opt to fully utilize the public-regarding policy options permitted under their regional arrangements necessitates understanding the domestic politics behind these moves.

To explain Mexico and Turkey’s experiences in pharmaceutical intellectual property policymaking, this thesis advances a coalition-based argument. The analysis focuses on the political and economic capacities of domestic actors to politically mobilize and cultivate alliances in pursuit of their preferred policy preferences. In this sense, this thesis demonstrates that in both the introduction and modification phases, the final policy outcomes in pharmaceutical intellectual property resulted from the relative political capacity of competing coalitions that vied for their preferred policy choices.

According to this thesis, then, Mexico and Turkey's similar behaviors in passing strong pharmaceutical patent laws in the 1990s were an outcome of the similar domestic coalitional alignments whereby the prospects offered by NAFTA and the Customs Union asymmetrically empowered the actors in the pro-patent

coalitions, which comprised of the Executives, transnational pharmaceutical companies, and the exporters, at the expense of those in the anti-patent coalitions led by domestic pharmaceutical companies. In similar logic, Mexico and Turkey's diverging pathways in the 2000s resulted from the differing strength of the competing coalitions mobilized in support of and opposition to the Executive's more health-oriented policy proposals.

The coalitional analysis employed in this thesis allows us to better understand a number of well-established lines of inquiry in the literature on political economy, which merit further elaboration. At a deeper level, for instance, Mexico and Turkey's experiences in introducing pharmaceutical patents enable us to assess the "second image reversed" effects on policy outcomes, that is, how global changes can reconfigure domestic political processes. Specifically, this thesis shows the transformative impact of the new global politics of intellectual property rights, which advanced via the regional route, on the preferences and capabilities of three key domestic groups.

Importantly, this thesis illustrates how the broader global economic dynamics that Mexico and Turkey faced in the 1990s transformed Mexican and Turkish Executives into ardent supporters of pharmaceutical patents, effectively ending the two nations' long-standing opposition to patentability in pharmaceuticals. In summary, the thesis demonstrates that, in the context of rising protectionism and regionalism that fueled fears of marginalization, the governments of Salinas and Çiller viewed NAFTA and the Customs Union as bitter pills to swallow in order to sustain the countries' ongoing economic liberalization processes. Additionally, because these political leaders viewed the conclusion of these regional trade agreements as a mechanism for ensuring the continuation of further economic

reforms, an issue of stigmatizing foreign policy, and a matter of personal prestige at home, pharmaceutical patents were regarded as expendable concessions.

Second, the analysis demonstrates how the context created by NAFTA and the Customs Union fundamentally reshaped the relationships between transnational and domestic pharmaceutical companies in both nations. Because the patterns of industrial development in the Mexican and Turkish pharmaceutical industries did not achieve high levels of self-sufficiency in innovation, production, and marketing, the consolidation of economic liberalization policies in the 1990s and the prospect of further liberalization with regional trade agreements exposed the fragility of domestic manufacturers and weakened their political capacity to resist against pharmaceutical patents.

Lastly, and most interestingly, the analysis shows how the context created by NAFTA and the Customs Union led to the participation of actors with little direct connection to pharmaceutical patents in debates over new patent laws. Because intellectual property rights were bundled with greater and more stable market access under regional trade agreements, Mexican and Turkish exporters, who rely heavily on the US and EU markets, exerted pressure on their respective governments to make the necessary adjustments in pharmaceutical patent laws so as not to jeopardize the conclusion of these regional agreements.

In addition to revealing how external changes may differentially empower different domestic actors, the politics of introducing pharmaceutical patents in Mexico and Turkey also shows the importance of domestic political institutions in the unfolding of policymaking processes. The central analytical focus in this thesis was placed on the Legislative branches in Mexico and Turkey as they were the main sites of contestation where differing preferences of domestic actors were represented.

In doing so, this thesis looked at the relationship between the Executive and Legislative branches and examined whether and how the differences in Mexico and Turkey's political systems affected policy outcomes. This was a significant comparison because, in the 1990s, Mexico's presidential system with a strong leader was fundamentally distinct from Turkey's parliamentary system with a coalition government. Despite these differences that resulted in strikingly distinct legislative processes, this thesis demonstrates that Mexico and Turkey exhibited similar behavior in the 1990s as the Turkish Executive succeeded in passing the new patent laws through executive decrees.

Furthermore, the analysis shows that the legislative processes in Turkey not only took much longer than in Mexico but also were much more contested. In explaining this difference, the analysis points to the different nature of legislative politics in Mexico and Turkey, where the differences in the domestic political institutions of countries led to differing degrees of political representation of domestic actors in the legislative branches. However, despite the well-heard voices of domestic pharmaceutical companies resisting pharmaceutical patents in the Turkish Parliament, the outcome was the triumph of the pro-patent coalition in Turkey.

The policymaking processes in the second period of modification also demonstrate the usefulness of the coalitional framework in explaining policy outcomes. Similar to the 1990s, the policy outcomes in the 2000s were also determined by the relative strength of the competing coalitions for policy changes in both countries. However, compared to the 1990s, the politics of subsequent modification efforts were more complex in the sense that the universe of feasible policy actions was conditioned by past policy choices. In that sense, the politics of

modification reveals how temporality complicates policymaking processes by altering the domestic actors' preferences and capacities for coalition-building.

A central contention of this thesis in explaining Mexico and Turkey's differing policy outcomes in the 2000s is that the timing and substance of past policy choices leave an enduring legacy on subsequent policymaking processes by affecting the domestic actors' adjustment patterns to the new status quo. Put differently, because the introduction of pharmaceutical patents created winners and losers, how losers adapt their business models to compete in this new reality shapes their preferred policy choices in pharmaceutical intellectual property and their political capacity to effectively participate in domestic coalitions for change. Therefore, what explains Mexico's inability to undertake health-friendly pharmaceutical patent reforms as opposed to Turkey was the inability of the domestic pharmaceutical industry to provide viable support to the Executive's policy proposals, as the early and extreme introduction of pharmaceutical patents rendered them too impotent as actors for change.

Lastly, the second period of reform efforts also helps determine whether and to what extent the Executives' ideological stance affects policy outcomes in pharmaceutical patents. An important conclusion of this study was that the partisanship effects were relatively non-existent in the policymaking processes in this period of change as both the right-wing Mexican and Turkish Executives proposed health-oriented policy changes in the countries' pharmaceutical intellectual property laws due to the similar difficulties they encountered in containing rising public health costs. In other words, the analysis revealed that the divergent paths of Mexico and Turkey in the formulation of pharmaceutical patent policy were not due to differences in intentions but rather differences in capabilities, which was a function

of the way previous policy decisions were made. This is an important realization indicating that the existing literature's prediction that left-leaning governments are more prone to address problems in access to health may not always be valid, as rising costs may be sufficient to compel policy action from governments of all political stripes.

6.2 Limitations and further areas of research

Although this thesis connects the politics of intellectual property with many of the major themes in the literature on political economy, the analysis still has certain limitations that should be addressed. Firstly, this thesis suffers from an "asymmetry of information" in comparing cases. Due to the language barrier, this thesis relies extensively on secondary sources to understand Mexico's experiences. While extensive efforts were made to ensure the accuracy of the information presented in this thesis by conducting a comprehensive literature review, the analysis could be enriched by a closer examination of Mexico's primary sources. A critical venue to investigate might be the congressional debates in Mexico. As the Turkish case demonstrates, the legislative debates include detailed information about how domestic actors understand the consequences of new pharmaceutical patent rules and articulate their preferred policy positions, which are rarely available sources of information in secondary resources.

Secondly, this thesis relies heavily on written materials and does not benefit from interview data. Appealing to the perceptions of domestic manufacturers could provide an additional insight to the analysis that cannot be captured by the market shares or that is not reflected in press releases or reports. Doubtful, however, is the

extent to which such additional evidence could add a layer of analysis to this thesis beyond filling potential gaps in the empirical evidence.

The analysis in this thesis could benefit from additional high-quality data. Obtaining information on the Mexican and Turkish pharmaceutical industries was one of the obstacles I faced when conducting this research, as there is little information on market data beyond what is provided in official reports and existing literature. There are accessible data sources provided by international companies, but they are costly for individual researchers. Therefore, information provided in various data sources could be cross-checked to further ensure the reliability of the evidence presented in this study.

As for additional research areas, this thesis emphasizes the need for political scientists to pay more attention to the complexities of the political economy underlying intellectual property rights. There are important sets of questions awaiting greater attention from political scientists, which would contribute not only to our understanding of the dynamics at play in the making and changing of rules over the pharmaceutical intellectual property but also to many of the long-standing puzzles that consume attention in the literature on political economy. In what follows, I will provide three main areas for further study.

The applicability of the coalitional framework developed in this thesis to other contexts would be an essential first question. Although the focus of this thesis has been on Mexico and Turkey, two middle-income developing countries, the coalition-based framework has significant implications for understanding the experiences of other developing countries. Notably, this framework could also be used to assess the impact of the WTO's TRIPS Agreement on the pharmaceutical patent laws of developing nations. The emphasis on the industrial structure of the

local pharmaceutical industry and the responses of exporters and business groups seeking greater market access can inform analyses that wish to explain the introduction of pharmaceutical patent policies in other developing countries. Such an analysis would go beyond the literature's tendency to directly link policy outcomes with international obligations and would enhance our understanding of the domestic politics at play that produces these outcomes.

Furthermore, the coalitional framework can help us better understand the differing impacts of multilateralism and regionalism. Indeed, an important research could be one that compares the experiences of two countries, one bound by a regional trade agreement and the other only by its obligations to comply with the WTO's TRIPS Agreement. Such a study can shed light on the different effects of multilateral and regional trade agreements on the intellectual property rights policies of various nations and speak to the broader debates on the politics of multilateralism and regionalism. From this broader issue, a set of related questions could be formulated. For instance, a similar analysis undertaken in this thesis could be done that looks at similarities and differences in the role of the US and the EU in prompting domestic policy change by selecting country cases with regional trade agreements with either one of these countries.

Lastly, another potentially lucrative area of study would be to assess the utility of the coalition-based framework in other areas of intellectual property. Importantly, each type of intellectual property speaks to different interests and prompts action from different actors in the state and society (Shadlen, 2017). Indeed, even in the case of patents, for instance, disputes may vary by technology, and we may observe distinct conflicts within industry sectors than are what played out in the pharmaceutical sector (Deere, 2008; Shadlen, 2017). This is an important area of

study as it is highly likely that the question of legal ownership of knowledge and information will always remain with us in the new knowledge economy. Therefore, understanding how various actors mobilize politically for their interests in these other forms of intellectual property could significantly improve our comprehension of how national intellectual property laws are formulated and what are the distinct consequences of these policy choices for the prospects of national development and human welfare.

6.3 Pharmaceutical intellectual property rights in the knowledge economy

The private protection of pharmaceutical intellectual property is now an entrenched reality of the global political economy. While the relationship between pharmaceutical patents and drug prices continues to spark heated debates about access to medicines, these discussions are very much confined within the permissible boundaries set by this fundamental principle. Indeed, this profound transformation in the global governance of pharmaceutical knowledge that started nearly four decades ago has so fundamentally reshaped the domestic politics and policies of many developing countries that these new global rules are largely assented to and absorbed by many: today, except for a few of the world's least developed countries, pharmaceutical knowledge is a privately protected property all across the globe. Therefore, the question is no longer whether, how, and when countries should introduce pharmaceutical intellectual property rights but rather how to best thrive in this new global order in which pharmaceutical innovation is a privately protected commodity.

However, devising pharmaceutical intellectual property laws that could simultaneously incentivize pharmaceutical innovation and ensure broad access to

medicines is hardly an easy task. As reiterated numerous times throughout the analysis, responding to economic imperatives and addressing public health concerns at the same time frequently conflict acutely in the case of pharmaceutical patents. On the one hand, the changing dynamics of innovation and competition in today's global pharmaceutical industry compel originator companies to take action, which frequently serves to extend and consolidate their monopoly status. As demonstrated in the first section of Chapter 3, numerous "new" forms of intellectual property rights in the pharmaceutical industry translate into measures that reduce market competition, thereby the setting of higher prices for medicines.

On the other hand, despite ongoing international campaigns for ensuring sustained global access to essential medicines, availability and affordability of drugs continues to be a persistent problem in many parts of the globe, especially in low and middle income countries. While patents are one of the many aspects that leads to higher prices, it has been frequently noted that dense patenting landscapes are an important determinant. These inequalities in access were only further exposed with the COVID-19 pandemic, as serious problems in access to vaccines sparked yet another episode of conflict that is still very much ongoing.

The obvious question, then, is what are the options available for developing countries in devising pharmaceutical intellectual property laws and policies that would best balance this private rights versus public benefits dilemma. The first options includes the modification of domestic pharmaceutical intellectual property rights laws in a way to reduce the exclusionary nature of private rights of ownership to expand the extent of public access. As evidenced by Turkey's reform efforts in the 2000s, different aspects of the country's pharmaceutical intellectual property rights regime could be adjusted to reach that end: measures that facilitate generic

competition by limiting monopoly power of innovator pharmaceutical companies, credible tools of threat that would allow for the negotiation of cheaper prices, and opposition systems that allow for contestability of erroneous patents, among many others. In short, the main idea behind this option is to shrink the power of private rights that would better suit the country's socioeconomic needs and goals.

Yet, as exemplified by the experiences of Mexico and Turkey, this method to tackle the problems has its distinct political problems, as well as consequences. Taking the route to weaken the private rights of ownership in pharmaceutical intellectual property risks the rebuke not only from transnational pharmaceutical companies but also of the US and the EU. This may be enough of a concern for some countries that may lead to the failure of adjustment aspirations. Moreover, it is dubious to what extent this would contribute to long-term prosperity as it also risks disincentivizing the undertaking of costly long-term investments in R&D that would help achieve self-sufficiency in domestic pharmaceutical industry.

The other option that might help achieve these two goals would be the opposite extreme, that is modification of domestic pharmaceutical intellectual property rights laws in a way to increase the exclusionary nature of private rights of ownership. The rationale behind this option is that secure private rights in knowledge and information would eventually encourage cultivation of domestic innovation and production capabilities, the benefits of which would ultimately trickle down to the society.

However, this route also has its own political and economic challenges. For one thing, upgrading scientific, technological, and innovative capabilities are often complex, costly, and lengthy investments. Achieving these objectives requires not only adjusting existing laws to new aspirations but also the strengthening of

cooperation between public and private actors, as well as the regulatory capacity of the state to manage these undertakings. Moreover, these projects are costly that necessitate diverting resources from other areas. Lastly, these projects are lengthy that often bring little benefit in the short-term. Therefore, while efforts to converge the technological frontier is often a common aspiration of many developing countries, few are able to succeed.

Regardless of which way forward, it should be remembered that pharmaceuticals is a unique industry. Although it is undeniable that in our current world constrained access to an automobile, a computer, or a smartphone may make human life harder, it is only in pharmaceuticals that lack of access could result in extreme human suffering and death. In that sense, while pharmaceutical innovation is vital to cure old and new diseases, it is also equally important that these ground-breaking innovations are within reach of people suffering from these diseases.

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