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# Coalitions and Compliance

*The Political Economy of Pharmaceutical  
Patents in Latin America*

KENNETH C. SHADLEN

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# Part I

## Context, Theory, Explanatory Framework

# 1

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## Global Change, Political Coalitions, and National Responses

Intellectual property policies affect the processes by which knowledge and information become privately owned, and the terms under which privately owned knowledge and information are used. Because these arrangements influence how citizens and governments access essential knowledge- and information-intensive goods, such as educational materials, medicines, seeds, and software, national policies in this area affect peoples' lives, and countries' trajectories of development in the global economy.

Traditionally, countries around the world enjoyed significant freedom in determining what types of knowledge and information benefited from intellectual property protection, and how much protection rights-owners enjoyed. Intellectual Property (IP) policies were driven by national characteristics, such as levels of income, industrial structure, scientific, and technological capabilities. In general, poorer countries with less technological development tended to adopt more lax IP policies to facilitate the use of knowledge and information, and over the course of acquiring more technological capabilities the amounts of IP protection they made available would increase as a reflection of these changes. Indeed, the close relationship between national conditions and IP policies has long been a staple of case study, comparative historical, and econometric research.<sup>1</sup>

That world is a thing of the past. The late twentieth century was marked by a fundamental transformation in the global politics of IP. In the 1980s and 1990s, as IP became defined as “trade-related,” countries wishing to participate in international trade became obligated to undertake significant revisions of

<sup>1</sup> See, for example, Chen and Puttitanun (2005), Dutfield and Suthersanen (2005), Hudson and Minea (2013), Kawaura and La Croix (1995), Kim et al. (2012), Kumar (2002), Maskus (2000; 2012), Marron and Steel (2000), May (2000; 2007a; 2013), May and Sell (2006), Odagiri et al. (2010), Ordover (1991), Schiff (1971).

their policies toward patents, copyrights, trademarks, and other forms of IP.<sup>2</sup> The drivers of national IP policy were now international, too.

The cornerstone event in this global sea change was the inclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the World Trade Organization (WTO), which was founded in 1995.<sup>3</sup> But TRIPS is just part of the story. At the same time as new multilateral rules were being established, the international IP regime was also shaped directly by the actions of larger developed countries that gave the promotion of IP increasingly prominent places in their foreign policy and aid agendas. Similarly, international organizations such as the World Intellectual Property Organization (WIPO) have acted as enthusiastic advocates of increased protection. These shifts replaced a world marked by differentiation, where national IP policies were allowed to correspond to local conditions, with a world of harmonization, where all countries' IP policies are expected to correspond to new international standards.

The global sea change ushered in new IP policies throughout the world, as country after country altered laws and created new state agencies, all toward increasing levels of IP protection. Countries made patent protection available in technological areas where it had previously not been allowed, for example, they strengthened the rights of exclusion that patent owners enjoyed, and they created new administrative agencies and courts to establish and protect these new private property rights. The new approach toward IP is part and parcel of yet another shift, as the focus on privately owned knowledge has been complemented by a focus on “knowledge-based” development. Governments and international organizations have come to embrace, at least rhetorically, the role of IP as a stimulus for innovation, and the importance of innovation as key to increasing firms' competitiveness and national welfare (OECD 2013; Powell and Snellman 2004).

Not surprisingly, as countries reacted to the global sea change, cross-national indices of IP rights have come to reveal across-the-board increases. The mean for ninety-nine developing countries in the most frequently cited index of patent protection, which scores countries from zero to five, increased from 1.6 in 1990 to 2.7 in 2000, reaching 3.1 by 2005 (Park 2008). Similarly, the mean score of “legal transplantation,” an index of 121 developing and post-communist countries' similarity with policies of the United States (US), rose by 150 percent from 1995 to 2008 (Morin and Gold 2014).

<sup>2</sup> IP is the umbrella term for a range of instruments that confer rights of exclusion to the owners of intangible goods. Patents protect inventions, copyrights, and trademarks protect forms of expression. What they have in common is that they convert knowledge and information into private property.

<sup>3</sup> On TRIPS and, more generally, the establishment of the IP-trade linkage, see, among others, Braithwaite and Drahos (2000), Deere (2008), Drahos (1995), Matthews (2002), Maskus (2012; 2014), May (2000), Muzaka (2011a; 2011b), Orsi and Coriat (2006), Pugatch (2004), Ryan (1998), Sell (2003; 2010a).



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Yet even in this context of overarching increases in IP rights, we continue to witness cross-national diversity. Countries reacted differently to the pressures emerging from the global sea change, and then subsequently took different steps in revising these policies and practices. The result of this iterative policymaking process is that countries with new IP systems introduced in response to the new external environment still differ on key characteristics of how they establish and protect privately owned knowledge.

This book analyses this diversity, both cross-national variation in countries' responses to the global sea change and longitudinal patterns of change within countries, in the context of pharmaceutical patents. As of the late 1980s, patents on pharmaceutical products were rarely available in developing countries. Many countries offered patents on pharmaceutical processes, i.e. the manufacturing techniques for making drugs, but few did so for the chemical compounds and medicines themselves. Firms could receive patents for these inventions in most developed countries, but they would not even bother to seek patents on pharmaceutical products in most developing countries because, simply, drugs could not be patented.<sup>4</sup> A key feature—arguably the single most important feature—of the global sea change is to bar countries from retaining the statutory prohibitions that most had until this time: *countries must allow pharmaceutical products to be patented*. By the mid-1990s, virtually all developing countries had committed to introducing pharmaceutical patents, and by the mid-2000s this process was complete in all but the poorest countries.

The shift from pharmaceuticals being largely non-patentable to being nearly universally patentable is striking in terms of the global scope and pace that this occurred—but it is far from the end of the story. Pharmaceutical patents are new, and transitioning from a world where the knowledge associated with medicines was a public good to a world where such knowledge is privately owned and controlled, generated new challenges for state and non-state actors. In response to these challenges, many countries subsequently set out to modify their new patent systems. While the initial policy choices in the 1990s regarded decisions over introducing pharmaceutical patents, policy choices in the 2000s regarded making revisions to the new pharmaceutical patent systems to adjust how they function. The end result of these two episodes of change is that policies continue to vary in important ways. Or, to put it differently, forms and styles of compliance with the new global order of private knowledge in pharmaceuticals differs from country to country.

How to account for variation in national patent systems? This book addresses that question with a two-stage approach. Countries' initial responses to the global sea change varied as a consequence of how industrial legacies interacted with export profiles to affect the possibilities for building coalitions

<sup>4</sup> Prior to the late 1970s, pharmaceutical patenting was not available in many developed countries either, as discussed in Chapter 2.

around the issues of when and how pharmaceutical patents should be introduced. How these initial conflicts regarding the introduction of patents were resolved, in turn, conditioned policy choices in the 2000s, around how the new pharmaceutical patent systems function. The two periods of change are linked in that the first set of choices generated distinct challenges to be addressed, and the initial choices also inspired different changes to social structure which, in turn, affected subsequent possibilities for coalition building.

The empirics are drawn from the cases of Argentina, Brazil, and Mexico. None of these countries offered pharmaceutical patents as of the late 1980s, when they were signaled out for their resistance and came under considerable pressure to make pharmaceuticals patentable (Gadbaw and Richards 1988b, 7–8). When they acquiesced to international pressures and agreed to introduce pharmaceutical patents, they did so differently; and when they subsequently revised their new pharmaceutical patent systems they did so differently again. Over the course of these two periods of change, Argentina produced a “market-preserving” patent regime, featuring minimalist, by-the-books adherence to the country’s new international obligations, complemented by regulatory changes designed to help local firms adjust to the new status quo and retain a dominant position with respect to international competition. Brazil yielded a “neo-developmental” system, with the country adopting global norms in a way that puts IP and innovation at the heart of development policy, but at the same time introducing a range of measures designed to ameliorate the effects of stronger protection. And Mexico produced an “internationalist” patent regime, marked by an expanding embrace of global norms and adoption of “best practices,” all with an eye toward attracting foreign investment into the pharmaceutical sector.

The objective of this book is to explain these differences in a way that allows us, more generally, to understand cross-national and longitudinal variation in national policies. While there is an abundance of scholarship on the global politics of IP, explaining for example the integration of IP into international trade rules and conflicts over IP at multilateral and regional levels, as well as a proliferation of case studies of IP policymaking,<sup>5</sup> our understanding of the drivers of national responses to the new external environment remains underdeveloped. This book offers a systematic approach toward studying cross-national and longitudinal variation, one that allows us to understand how the major changes in the global politics of IP migrate to the national level and affect domestic policies and practices over time.

<sup>5</sup> See, among others, the contributions to Coriat (2008), Dreyfuss and Rodriguez-Garavito (2014), Haunss and Shadlen (2009), Löfgren and Williams (2013), Mani and Nelson (2013), Shadlen et al. (2011). Important comparative studies (cross-national or within-country longitudinal) also include Deere (2008), Eimer and Lutz (2010), Eren-Vural (2007), Filomeno (2014), Flynn (2011; 2013; 2015), Godoy (2013), Guzmán (2014), Haggart (2014), Matthews (2011), Ramanna (2005), Rodríguez-Franco (2012), Shadlen (2009b; 2012).

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Persistent differences in how countries go about establishing the ownership of knowledge, and setting the terms on which privately owned knowledge is used, have important implications for human welfare and economic development. Patents confer exclusive rights over manufacture, distribution, and sales; in a market where a drug is covered by a patent, there will likely be just one supplier of the drug. We expect drugs with single suppliers to be more expensive than drugs with multiple suppliers, so the introduction of pharmaceutical patents can, potentially, create barriers to access of essential drugs. Also, as pharmaceuticals were often a strategic area for industrial promotion and a source of manufacturing employment, new patent systems that endow single firms with control have implications for economic development. Thus, it matters how countries react to the global sea change in IP and position themselves in the new international order.

Before proceeding, it is important to underscore that the relationships between pharmaceutical patents, drug prices, and health outcomes are exceptionally complex. The extent to which patents yield high prices, for example, depends on degrees of competition in given therapeutic segments, the availability of substitutes, the marketing strategies of firms that control patented drugs, and the purchasing practices of public and private healthcare providers. And access to medicines depends on more than the price of drugs: in some countries, poverty and the state of healthcare systems mean that access to medicines and adherence to treatment are problems even when drugs are free. Yet, for all that, when drugs have a single supplier that can set the price, if that price is high, some may suffer from reduced access, and the effects of reduced access can be detrimental for individuals and public health.

And not only are the relationships between patents, prices, and health complex, they are often difficult to observe. Reduced access to key drugs may produce a wide range of setbacks, deprivations, and hardships. Obviously, lack of access to life-saving medicines can be fatal, a scenario that is exemplified in the case of HIV/AIDS, which in the absence of drugs is a death sentence. Not all situations are so stark, but the challenges posed by patents and prices are serious nevertheless. Lack of access to a particular drug might mean that patients rely on inferior treatments and endure more pain and suffering, or perhaps have to live with more discomforting side effects or become more susceptible to other related illnesses. Lack of access to some medicines may compel people to make multiple trips to clinics, for example, perhaps spending more of their family income on transportation, or be unable to continue in their employment. And so on. The effects on health and livelihoods, short of life or death scenarios, are serious too, but these can be hidden and thus difficult for analysts to track and record.<sup>6</sup> And of course the

<sup>6</sup> It is often difficult, as Godoy cogently writes, to provide a “body count” (Godoy 2013, 46–7).

allocation of funds to secure access to drugs for one disease or condition, where treatments are more expensive because of patents, may result in diminished access for other patients with other conditions.

The remainder of this chapter consists of three sections. The next section situates the analysis in the context of broader scholarship in comparative and international political economy. In doing so the key building blocks of the coalitional argument are presented. The following section then reviews scholarship on the politics of IP, with an eye toward integrating international and domestic factors. The final section discusses the logic of case selection, the method of data collection and comparative analysis, and the organization of the chapters that follow.

## HARMONIZATION, DIFFERENTIATION, AND COALITIONAL POLITICS

The trends witnessed in IP, of big changes sweeping the globe and reflected in currents of national convergence, alongside striking differences between countries, are anything but exceptional. To the contrary, the late twentieth and early twenty-first centuries constituted a period of persistent diversity in the context of overarching convergence in many areas. Democratization swept the world, economic liberalization became the norm, and anti-poverty programs gained a central place on the development agenda, to give just three examples of global trends, but countries continued to exhibit important differences in their democratic political institutions and practices, the extent to which economic actors are subject to market competition, and the characteristics of social protection. Indeed, diversity in the context of convergence is the norm. As countless scholars of comparative and international political economy have shown, broad tendencies toward convergence, be they rooted in international rules, technological change, or the diffusion of new ideas, manifest themselves differently in distinct national contexts.<sup>7</sup>

<sup>7</sup> Examples, by no means a comprehensive list, include Brooks (2008) on diversity within the shift toward privatized pension systems, Etchemendy (2011) on diversity in trade and industrial policies in liberalizing countries, Mosley (2003) and Brooks and Kurtz (2012) on diversity of financial regulations in the context of financial globalization and open capital accounts, Murillo (2009) on diversity in national strategies toward privatizing and regulating public utilities, Rudra (2008) on diversity of developing countries' social welfare regimes in the context of globalization and privatization, and Wellhausen (2014) on countries' diverse policies toward foreign investors. Among scholars working on the politics of intellectual property, Haggart's (2014) analysis of digital copyright in Canada, Mexico, and the US is explicitly framed in terms of persistent national diversity as well.

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In explaining cross-national and within-country diversity, the focus in this book is placed on the ways that changes to social structure affect political actors' abilities to construct and sustain supportive coalitions. Executives are key players throughout the analysis, as presidents bore the burden of responding to global pressures to adopt new IP systems in the 1990s, and Health Ministries bore the brunt of dealing with the effects of new pharmaceutical patent systems in the 2000s. These events altered Executives' preferences, often in unexpected ways. Yet Executives need room to act. Be they presidents embracing the global sea change and seeking to introduce new IP regimes in conformity with foreign governments' and foreign investors' wishes or Ministers of Health reacting to the effects of pharmaceutical patents and seeking to revise their countries' new patent systems, Executives need to build coalitions to overcome opposition and secure their desired outcomes, i.e., to see that their policies can be enacted and sustained.

The analytic approach adopted here thus takes seriously Executives' shifting preferences, though placing them in the context of the changing constraints within which Executives act. Political scientists and sociologists that emphasize the constraints on agency often focus on political institutions, such as how constitutions, legislatures, and party systems circumscribe Executive autonomy.<sup>8</sup> I emphasize social structural constraints; how changing constellations of interests create or foreclose opportunities for coalition building and, subsequently, political action.

Attention is placed on two ways that constellations of societal interests are transformed so as to alter the panorama of coalition-building possibilities. First, international politics can reconfigure domestic political processes by differentially empowering and mobilizing rival actors in state and society.<sup>9</sup> The specific focus in this book is on the efforts of the United States Government to make access to the US market conditional upon increasing the level of IP protection. As many researchers have shown, external pressures can encourage exporters to push for policy changes.<sup>10</sup> I build on this research by linking exporters' mobilization to a specific aspect of trade structure: dependence on removable, discretionary trade preferences. Exporters typically have little reason to participate in debates over IP, but threats of diminished market access can change that. In situations where higher shares of exports enter the US market under preferential and removable trading arrangements, exporters, fearing loss of market access, can be mobilized by the advocates of IP protection. I label this process, of otherwise indifferent exporters becoming

<sup>8</sup> Calvo (2014); Carey and Shugart (1998); Corrales (2002); Flores-Macias (2012); Lichbach and Zuckerman (1997); Mainwaring and Shugart (1997); Shugart and Carey (1992).

<sup>9</sup> Brooks and Kurtz (2012); Farrell and Newman (2014); Frieden (1991); Gourevitch (1978; 1986); Katzenstein (1977); Keohane and Milner (1996); Rogowski (1990); Solingen (2009).

<sup>10</sup> Baldwin (1985); Bastos (1994); Bayard and Elliott (1994); Gilligan (1997); Kaempfer et al. (1987).

preoccupied with a new issue and thus wanting their governments to acquiesce to external demands, “activating agnostics.”

That changes in the external environment, such as new international agreements or shifting global economic conditions, can alter domestic political processes, is the cornerstone of much of contemporary political economy. Scholars of “open economy politics” (Frieden 1991; Keohane and Milner 1996; Lake 2009) typically identify the actors with a stake in a particular set of policy choices, observe how these actors’ preferences and resources are altered by the relevant international stimuli, and then consider subsequent domestic political processes. Yet external pressures can mobilize *new* actors too (Jacoby 2006). The actors identified *ex ante* as those with a stake in a given policy debate may not constitute the universe of relevant parties. External pressures can also affect domestic politics by creating new constituencies—not just strengthening or weakening already-interested actors, but expanding these actors’ range of allies by bringing otherwise uninterested players into policy debates. The mobilization of exporters as advocates of IP protection, i.e. activating agnostics, is an illustration of this phenomenon.

The second way that coalitional possibilities change is that new policies can alter subsequent trajectories of political mobilization (Falleti 2010; Pierson 1993; Thelen 1999; 2003; Weir 2006). Once policies are introduced, however fraught the conflicts over their introduction, actors may subsequently adjust to the new status quo. In such a context, phenomena of increasing and decreasing returns affect successive policymaking episodes (Pierson 2000; 2004). Increasing returns allows those engaged in favored activities to accumulate resources, a process that entrenches constituencies for continuity. In contrast, decreasing returns can dilute opposition to new policies once they are implemented. New policies may also change the character of the state, by spurring the creation of new agencies, institutions, and organizations, or by giving new prominence and authority to existing bodies. Decisions on major policy issues can shape subsequent trajectories of change and, importantly, the strategies of actors that then work within the parameters established by the new status quo (Farrell and Newman 2014; Immergut 2008; Shaffer 2014).

The asymmetric effects of policy choices on patterns of political mobilization and subsequent episodes of coalition building invoke notions of path dependence, where policymaking at  $T_2$  is not subject to a “roll of the die” (Weir 2006) but conditioned by choices made at  $T_1$ . Initial choices constrain what follows, but, importantly, explanations that take into account the legacies of policy choices need not mechanically demand continuity. Rather, the key is to identify tractable effects of outcomes in one period on outcomes in a subsequent period.<sup>11</sup> Just as new policies may entrench “winners” and encourage

<sup>11</sup> Boas (2007); Capoccia and Kelemen (2007); Chorev (2015); Collier and Collier (1991); Falleti and Mahoney (2015); Mahoney (2000, 2001).

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continuity, they may also trigger reactions by actors that seek to modify the new status quo. In both scenarios, policies are producing patterns of political mobilization that, in turn, condition subsequent episodes of policymaking. Nor does an approach that takes seriously the path-dependent effects of policy choices preclude the possibility that politicians may, simply, try to alter policy trajectories. Even once countries have adopted one set of policies, elections can return a new government that seeks change, or more simply political leaders may seek to alter course on account of new ideas or new evidence. Yet actors' range of freedom to alter course is limited: policies adopted in one period, by transforming social structure and the state, cast a shadow over policymaking in subsequent periods.

Together, changes to the international environment and path-dependent policy effects can alter constellations of interests within national political economies. The extent to which external pressures encourage exporters to care about new policy areas affects opportunities for political action on the part of Executives seeking to steer a given course. Likewise, reactions to policies inspire new patterns of mobilization and thus reconfigure constellations of interests, again shifting the social terrain upon which coalitions are constructed. These changes open or foreclose opportunities for political agency. Politicians that seek a particular course of action, in response to external pressures, partisan biases, or new social challenges, need to build coalitions—and their abilities to do so are affected by changes to underlying constellations of interests and social structure.

This approach to changed social structure and thus shifting coalitional possibilities allows us to understand patterns of cross-national and longitudinal variation in IP policies. The global sea change converted Executives into enthusiasts of patent protection in the 1990s. Yet presidents faced opposition to altering their countries' patent systems, and the extent to which they were able to build coalitions to overcome this opposition depended on the ways that the external shocks affected social structure. Then, in the 2000s, when Health Ministers sought to revise their new patent systems, their opportunities for action were constrained by the transformations of social structure induced by the first set of changes. The following section places the coalitional approach in the context of previous research on the drivers of national IP policies.

## THE DRIVERS OF COMPLIANCE AND OVER-COMPLIANCE

Coalitional change helps us understand variation in the forms of compliance with international rules and norms. The politics of patents is an iterated process, with key policy choices occurring over two distinct periods. In the 1990s, countries established new patent systems in response to the global

sea change; all countries complied with TRIPS, but they did so differently. Then, in the 2000s, many countries sought to reform their new patent systems; again, they did so differently. Just as post-Communist countries of Central and Eastern Europe first introduced private property rights and then subsequently reformed their new private property systems (Bohle and Greskovits 2012; Hancke 2008; Jacoby 2006; Szelényi 2015), or as countries privatized pension systems and utilities and then subsequently introduced regulations to these newly privatized sectors (Brooks 2008; Murillo 2009), countries introduced pharmaceutical patents and then subsequently revised their new patent systems.

How can we account for cross-national and within-country, longitudinal variation in patent policies? As noted, theory and empirics both suggest that IP policies are driven by domestic conditions. As countries acquire more innovative capabilities and their scientific and industrial sectors move closer to the technological frontier, for example, demands for increased IP protection are expected to follow (Acemoglu et al. 2006; Chen and Puttitanun 2005; Kalaycı and Pamukçu 2014). So universal was acceptance of the relationship between national conditions and IP policies that one prominent scholar, in reviewing the literature, characterized the link as “obvious” (Maskus 2000, 102).

As obvious as the relationship may have been, it is also obvious that domestic factors, alone, can no longer adequately account for what has transpired in the current era, when patent regimes of virtually all countries, with varying circumstances, have undergone profound changes. It is hardly conceivable that the relevant national-level variables changed and reached similar thresholds to establish the conditions for increased patent protection in so many countries at the same time. Indeed, historically IP systems have tended to exhibit resistance to abrupt change (David 1993; Lamoreaux et al. 1999; Lerner 2000). The observation of profound transformations in a short period of time poses a puzzle and necessitates taking seriously the international drivers of patent policy change (Shadlen et al. 2005).

But how to think about the international drivers of policy change is not entirely straightforward, either. The obligations imposed by the WTO and TRIPS themselves do not suffice as explanatory factors. All members of the WTO are also parties to TRIPS. Because the Uruguay Round, the multilateral trade negotiations that produced the WTO and the various agreements within the WTO, was completed with a “single undertaking,” countries could not pick and choose their agreements, but rather had to become parties to all of the agreements included in the Final Act of 1994.<sup>12</sup> However, while all countries that are members of the WTO needed to comply with TRIPS, they had leeway in determining how to do so, a point driven home emphatically by the

<sup>12</sup> There are a few exceptions to this statement, for example, the WTO’s Government Procurement Agreement is a “plurilateral” accord that countries can opt in or out of.



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abundant legal and policy literature documenting the significant array of TRIPS-acceptable policy options available.<sup>13</sup>

The relevant question is not if countries comply with TRIPS but rather *how* they do so. Some countries may stick strictly to what the international rules require, doing what needs to be done to remain safe from dispute settlement at the WTO, but little more. Some countries may go beyond TRIPS, offering more IP protection than the agreement requires. Forms of compliance—or, more specifically, degrees of “over-compliance”—needs to be the focus of attention.<sup>14</sup> If we conceptualize the outcome as degrees of over-compliance, then to understand variation we need to look beyond the WTO itself. After all, the entire range of variation under study, from minimalist compliance to extreme levels of over-compliance, is compatible with WTO membership. Chapter 2 discusses specific policy choices that were contested in each country. For now, staying at a more general level, the objective is to elucidate the drivers of the different ways that countries comply with the global sea change in IP.

The emergence of regional and bilateral trade agreements with IP provisions that exceed TRIPS is commonly regarded as a driver of over-compliance. The US, European Union (EU), and Japan have all negotiated a large number of trade agreements with developing countries that include IP provisions exceeding those in the WTO.<sup>15</sup> To be sure, countries that enter into bilateral trade agreements of this sort will end up with over-compliant patent systems. Yet attributing IP policy outcomes to bilateral trade agreements may be misleading. Countries might over-comply because they have bilateral trade agreements with major trading partners, but just as well countries might have these agreements because they have over-complied or are prepared to do so. The latter scenario is highly plausible. The US Government, for example, makes it clear that securing levels of IP protection beyond what is required by TRIPS is an objective of negotiating trade agreements with developing countries, and political leaders that enter into negotiations for such agreements do so knowing that they will be expected to alter their IP policies accordingly.

<sup>13</sup> Bermudez and Oliveira (2004); Commission on Intellectual Property Rights (2002); Correa (2000b); Hilty and Liu (2014); Kapczynski (2009); Musungu and Oh (2006); Reichman (1996; 2009a; 2009b); Scherer and Watal (2002); Shadlen (2009a); UNCTAD-ICTSD (2005); Watal (1999; 2001).

<sup>14</sup> I borrow the concept of “over-compliance” from Walter (2008; 2014). Gold and Morin (2014), seeking to explain a similar phenomenon, refer to this as different levels of “legal transplantation.” Many observers also refer to countries introducing “TRIPS Plus” policies.

<sup>15</sup> The immense literature on IP in bilateral trade agreements includes El-Said (2005; 2007), Fink and Reichenmiller (2005), Krikorian and Szymkowiak (2007), Kuanpoth (2008), Mercurio (2006), Morin (2006; 2009), Roffe and Spennemann (2006), Sell (2007; 2010b), Seuba (2013), von Braun (2012).

Nor can trade agreements comfortably explain countries' subsequent policy choices, those introduced after all relevant steps required by the agreements were taken. Consider the case of Mexico, the one country examined in this book that has a bilateral trade agreement with the US, the North American Free Trade Agreement (NAFTA).<sup>16</sup> Understanding Mexico's patent policy choices in the 1990s necessitates understanding Mexico's pursuit of NAFTA, but the trade agreement's explanatory power for Mexico's subsequent policies is weaker. Because NAFTA's IP provisions are permissive, compared to more recent trade agreements, they left Mexico with ample opportunities to modify the patent system in the 2000s.<sup>17</sup> That Mexico did not do so, and even accentuated the degree of over-compliance, cannot be attributed to obligations that the country incurred as a party to NAFTA. Indeed, the policy changes of the 2000s occurred not because of restrictions imposed by the IP provisions in NAFTA, but rather *despite* the opportunities for policy innovation allowed by NAFTA.

Technical assistance, whereby local officials and policymakers are aided in adopting "best practices" in IP policy by donor governments and international organizations, is also regarded as a driver of over-compliance. The US, EU, and Japan have extensive technical assistance and capacity-building programs, as do international organizations such as the World Intellectual Property Organization.<sup>18</sup> In the mid-1980s, for example, the United States Patent and Trademark Office launched the Global Intellectual Property Academy, to "help countries around the world improve their IP programs and services."<sup>19</sup> Such initiatives, which provide assistance in drafting legislation or training officials, can encourage countries to adopt IP policies and practices that exceed the WTO's requirements.<sup>20</sup> Here again, as with trade agreements, the causal links need to be considered with caution. Countries typically approach foreign governments and international organizations and request technical assistance; the observed outcomes may not be attributable to technical assistance, so much as the conditions that prompted the country to request technical

<sup>16</sup> Mexico has trade agreements with the EU and Japan too.

<sup>17</sup> The literature on IP in regional and bilateral trade agreements tends to neglect NAFTA, largely for the reasons discussed in the text. NAFTA was negotiated in the early 1990s, prior to the completion of the TRIPS negotiations and establishment of the WTO, and the IP provisions in NAFTA are more similar to the IP provisions in the WTO than is the case with trade agreements negotiated in the 2000s.

<sup>18</sup> Ghafele and Engel (2012); Matthews and Muñoz-Tellez (2006); May (2004); Morin and Gold (2014); Peterson (2012); Roffe et al. (2007).

<sup>19</sup> See 'History of the Global Intellectual Property Academy', at [goo.gl/sFql2h](http://goo.gl/sFql2h).

<sup>20</sup> In addition to these studies that examine the role of technical assistance in shaping countries' policies, other work focuses on how technical assistance affects implementation. Drahos (2008; 2010), for example, acknowledges cross-national differences in policies, but argues that technical assistance may yield similarities in patent offices' administrative and interpretive practices, a process he refers to as "invisible harmonization."

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assistance. Simply put, we are rarely observing countries that were undecided on IP policy and over-complied on account of technical assistance, but, typically, countries that decided to over-comply and requested technical assistance to help them do so.

While neither trade agreements nor technical assistance provide sufficient explanations for countries' initial choices to over-comply, both of these can certainly affect IP policy outcomes, indirectly, over time. As trade agreements cover many policy areas, these can have myriad effects on the economy and society, which in turn can alter coalitional possibilities. Policy options that were available but foregone at one point may no longer be feasible, politically, at a later point, on account of changes to social structure induced by trade agreements. If the broader changes to social structure that trade agreements can bring about are more consequential than the agreements' binding IP provisions per se, trade agreements may be more significant in a political economy sense than strictly legal sense. Technical assistance and capacity-building programs can also affect social structure and the state. Even if the existence of a technical assistance program may reflect (rather than drive) a country's decision to over-comply, it can embolden constituencies within the receiving country. This may happen via the strengthening within the state, in both material and reputational senses, of patent offices, and by increasing national officials' integration into global networks (Drahos 2010). The effects of technical assistance delivered as a consequence of policy choice in one period can alter the state and social structure and thereby constrain policy choice in a subsequent period.

External pressures, in the form of trade sanctions, are another external factor that are commonly cited as drivers of over-compliance.<sup>21</sup> The most visible actor here has been the United States Trade Representative (USTR), which engages in a global monitoring practice, evaluating all countries' IP regimes. Since 1989 the USTR has issued the annual Special 301 Report, essentially a global report card. Each country identified in the Special 301 reports is placed on a "Watch List" or "Priority Watch List," or, more severely, labeled as a "Priority Foreign Country." As countries are placed on the Watch List and then escalated to the Priority Watch List, the threat and likelihood of bilateral trade sanctions increase, and when a country is identified as a Priority Foreign Country, which Drahos (1995, 423) labeled "trade's death row," the USTR is obligated to initiate proceedings to apply trade sanctions.<sup>22</sup> Any assessment system has

<sup>21</sup> Deere (2008); Drahos (1995; 2001); Flynn (2015); Morin and Gold (2014); Okedjii (2004); Pechman (1998); Sell (2003; 2010a); Stacy (2004).

<sup>22</sup> Although Priority Foreign Country is meant to trigger the process leading to trade sanctions, countries can be sanctioned without ever being labeled as such. It is worth noting that the 1988 Omnibus Trade Act, which is the law that required the USTR to conduct the Special 301 reviews, did not specify the Watch List or Priority Watch List. Congress instructed the USTR to identify "Priority Foreign Countries," a status that would trigger an immediate

benchmarks against which subjects are being measured, and the benchmark for the USTR's assessments has never been the TRIPS agreement, which of course did not exist yet when the system was introduced in 1989, but rather a vision of "best practices" that go beyond anything required by international agreements. And this continued after the WTO was created and TRIPS came into effect in 1995. According to the "Uruguay Round Agreements Act," failure to provide adequate and effective protection of intellectual property can trigger trade sanctions "notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the TRIPS Agreement."<sup>23</sup> Countries are pressured to over-comply, and threatened with trade sanctions if they do not do so.

Here too the effects of Special 301 need to be considered with caution. To be sure, the USTR keeps a watchful eye on IP practices around the globe and is exceptionally active in pushing countries to adopt over-compliant patent regimes. As Table 1.1 indicates, the number of countries identified has increased greatly since the Special 301 process began, starting at twenty-five countries, consistently twice that number for a period in the 2000s, and even when declining after 2005 always considerably above the 1989 level. Many of the countries targeted by the USTR have indeed over-complied with their TRIPS obligations, but not all countries fall into line; national responses to these bilateral pressures differ greatly. Indeed, notwithstanding the USTR's own touting of Special 301's effectiveness in altering national practices and the considerable attention it attracts, research on the effects of the USTR and Special 301 (and of US trade sanctions more generally) are decidedly ambiguous.<sup>24</sup> Neither small-n comparative case studies nor large-n econometric analyses have been able to demonstrate systematic effects of Special 301 on countries' IP policies.

The challenge is thinking about the conditions under which trade pressures might be effective in altering countries' policies. To elicit a response, threats to punish countries need to be credible, in that the USTR has to be able to take

investigation and lead, potentially, to the imposition of retaliatory trade sanctions. In the first year, the USTR exploited ambiguity in the law's phrasing to modify the system and supplement the category of Priority Foreign Country with the Watch List and Priority Watch List. According to the USTR, establishing these incremental levels constituted "an enhancement that we [the USTR] have added to the statute to make it more effective" (Q/A, ~~at end of Fact Sheet, 1989 Report~~ annexed to the initial Special 301 Report, USTR 1989a). To make the process yet more supple, in 1993 President Bill Clinton's first USTR, Micky Kantor, added "out of cycle reviews" as an additional lever.

<sup>23</sup> I am grateful to Duncan Matthews for bringing this passage of US trade law to my attention.

<sup>24</sup> Studies demonstrating the ambiguous effects of USTR pressures include Bayard and Elliott (1994), Bentolila (2002), Buscaglia and Long (1997), Deere (2008), Elliott and Richardson (1996), Hirst (1998), Knapp (2000), Morin and Gold (2014), Noland (1997), Sell (1995), Shadlen et al. (2005), Zeng (2002).

**Table 1.1.** USTR’s Special 301 Reports: Number of Countries Listed

Year	Number*
1989	25
1990	23
1991	29
1992	34
1993	30
1994	27
1995	32
1996	34
1997	47
1998	49
1999	55
2000	57
2001	51
2002	51
2003	50
2004	52
2005	52
2006	48
2007	43
2008	46
2009	45
2010	41
2011	40
2012	40
2013	41
2014	37
2015	37
2016	34

\* Number includes countries included on the Watch List, Priority Watch List, or identified as Priority Foreign Country.

Source: Author’s elaboration from USTR’s Special 301 Reports

the steps it is threatening to take, and worrisome, in that whatever it is that might be removed as punishment must matter enough to stimulate a reaction. Obviously if two countries engage in little trade than threats to remove market access are unlikely to have much effect. Yet even in the case of countries that engage in extensive trade, the ability to impose restrictions on another country’s exports are limited to some degree by the WTO. Because WTO members must grant all other members equivalent market access, known as most-favored nation (MFN) treatment, the US ordinarily cannot raise tariffs on one country’s exports of a given good without raising tariffs on all countries’ exports of that good, and threats to raise tariffs across the board and thus affecting all exporters, on account of a single country’s actions, may lack credibility.

Not all trade takes place on MFN terms, however, and threats to raise tariffs that are not subject to MFN can have more credibility. The WTO allows countries to positively discriminate and grant some countries preferential (“better-than-MFN”) market access. The bilateral trade agreements discussed above constitute one example of this, another is through a set of programs known as the Generalized System of Preferences (GSP) that permits preferences outside of reciprocal trade agreements. The United States (along with many other countries) has an array of GSP and GSP-related schemes that offer preferential access on a discretionary basis. Whereas the preferences between partners in bilateral trade agreements are bound by international commitments, preferences granted under the GSP, also above and beyond the MFN concessions of the WTO, are granted at the pleasure of the importing country, and can be removed at the pleasure of the importing country as well. Moreover, and in contrast to MFN-based market access that, if adjusted for one country needs to be adjusted for all countries, the US can *selectively* extend and withdraw preferential market access.

The discretionary and removable attributes of GSP make it an important factor to consider in thinking about the effectiveness of trade sanctions. Pushing countries into altering their IP practices by withdrawing regular, MFN market access can invite retaliation in ways that attempts to do so by withdrawing better-than-MFN preferential market access does not. If the US Government wishes to remove MFN trade benefits from a WTO member, it is constrained in doing so and any measures must be enacted in a non-discriminatory manner; a developing country, even one that is highly dependent on the US market for exports, can challenge the US under the WTO’s dispute settlement rules for denying it MFN treatment. Likewise, if the US wishes to remove preferences granted to a partner of a bilateral trade agreement, it is constrained by the terms of the agreement. But importing countries have more discretion with regard to the better-than-MFN trade benefits they make available under GSP schemes.

These characteristics of trade are useful for understanding the conditions under which external pressures may achieve their goals. In their study of legal transplantation in IP, for example, Morin and Gold (2014) find that that USTR pressures were associated with over-compliance in the 1990s but less so in the 2000s, and they attribute this to the inability of the USTR to wield the instrument of removing preferences. The authors refer to a 1999 WTO legal ruling, which called into question importing countries’ abilities to unilaterally remove preferences, and suggest that this gave developing countries comfort to ignore the USTR’s threats. Trade structure prompts us to think of this differently. It very well might be that countries ignore the USTR because they regard threats to remove preferences as illegal and lacking credibility, but it also may be that countries regard the threats and possibilities of sanctions as genuine, but disregard them anyway because the effects of being punished are

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minimal. After all, the USTR's pressures were not uniformly effective prior to the 1999 WTO ruling either. As much as an issue of international law, the effectiveness of the USTR's pressures may vary on account of conditions within the targeted countries.

The structure of a country's trading relationship with the US can make the USTR's threats to remove preferential market-access concessions more or less credible, and more or less worrisome. If exporters have minimal dependence on US preferences, either because they export relatively little to the US, or because what they export enters the US under ordinary MFN tariffs or preferences that constitute commitments in bilateral trade agreements, then we would not expect threats—even credible threats—of preferences to be withdrawn to generate much concern. Yet if removable, preferential exports to the US constitute a higher share of overall exports, we might expect the USTR's threats to be more alarming.<sup>25</sup>

The share of a country's exports that enter the US on preferential and removable terms, and thus its sensitivity to the removal of concessionary market access, constitutes its "political trade dependence" (PTD). The adjective "political" is used to emphasize that market access is extended and withdrawn according to political winds in the importing country.<sup>26</sup> The distinctiveness of this measure of trade dependence is critical. A standard measure of bilateral trade dependence is one country's exports to another (e.g. the US) as a share of its total exports. This can be supplemented with a measure of asymmetrical export dependence, which considers country X's exports to the US as a share of total exports, relative to US exports to X as a share of total US exports (Zeng 2002). Neither of these measures captures the level of exporting countries' dependence on market access that is concessionary and subject to withdrawal. All countries that export highly to the US are sensitive to fluctuations in demand derived from changes in the US economy, but they do not experience the same sort of vulnerability as a country with high PTD.

Threats of diminished market access can alter political coalitions and affect IP policy by mobilizing exporters. Most manufacturing firms in basic, labor-intensive industries are generally unconcerned with patents; they neither seek patents for their own inventions nor regard patents as relevant for their access to others' inventions. But when their continued access to the US market depends on revising national practices, these otherwise indifferent and uncommitted firms and their sectoral organizations may be converted into enthusiastic lobbyists for patent protection. Again, this is referred to as

<sup>25</sup> Morin and Gold (2014) do not consider countries' trade structure in their analyses, neither of the 1990s when they regard the USTR as important, nor of the 2000s, when the USTR's demands are regarded as less consequential.

<sup>26</sup> The concept of political trade dependence is developed and explored in Manger and Shadlen (2014) and Shadlen (2008).

“activating agnostics” because we would not expect these actors to care one way or the other about patent policy, but they may be made to care on account of their dependence on—and demand for retaining—preferential access to the US market. A country’s PTD level should not be regarded as a generator of spontaneous mobilization and predictor of patent policy, but rather a conditional factor that simplifies or complicates coalition building. As presidents and Ministers of Health seek to build coalitions for their desired policy outcomes, they need to cultivate and mobilize bases of support. PTD provides a reading of the social terrain upon which coalitions can be constructed; it is a way that social structure enables or constrains Executive agency.

In addition to mobilizing exporters, another way that external shocks can reconfigure constellations of actors and interests, and thus alter coalitional possibilities, is through the policies themselves. As discussed, even if bilateral trade agreements and technical assistance are not the drivers of initial policy choices, they can alter state and society in such ways as to shape subsequent policymaking episodes. New agencies, institutions, and organizations—sometimes even new ministries—may be created, for example, or new lines of funding put into place. As new challenges emerge, the character of the state confronting these challenges may be fundamentally different from when initial policy decisions were made, and transformed by the earlier choices.

Policy choices can also affect social structure. The introduction of new laws and regulations deters some activities, through outright prohibition or by raising the associated costs. As actors who face decreasing returns adjust to the new status quo, either by adapting to the new regulations or shifting their activities into other areas, they become less available to participate in political coalitions. Some actors that might have participated in political coalitions in one time period, prior to a policy change, may no longer be available in a subsequent period, after the change. Importantly, these patterns of reaction and adjustment do not transpire immediately, so, as shall be discussed further in Chapter 2, a key factor is how long the new policies are in effect and have a chance to settle and alter social structure.

How coalitional possibilities are affected by adjustment to the introduction of pharmaceutical patents is one of the key analytic issues in this book; it is the counterpart to how coalitional possibilities are affected by trade pressures and activation of agnostics.<sup>27</sup> As most pharmaceutical patenting is done by a handful of leading global firms, with industries in developing countries operating far from the technological frontier in this sector, allowing pharmaceutical products to be protected by patents is likely to increase transnational

<sup>27</sup> The process of actors’ patterns of adjustment affecting industrial structure is similar to what evolutionary economists refer to as “selection” and “structured feedback” (Malerba and Orsenigo 2015).



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firms' presence in local markets. In the next chapter we will examine the relevant issues in more detail, for now it suffices to note simply that patents allow firms to keep out competitors. Where new products might have had multiple producers in the past, each with shares of the associated revenues, in a system with pharmaceutical patent protection the returns to new products are captured by single patent-owning firms.

How do local firms adjust to this new status quo? Most obviously, traditional business models of copying new drugs cease being viable as these become patented locally. Some firms attempt to adjust by trying to become more innovative, investing more in research and development of new drugs. Adjustment along this path can convert these firms into advocates of patent protection. Some firms disappear; barred from continuing with past practices and unable to adopt new viable practices, many industries close.<sup>28</sup> For all their differences, the various forms of adjustment can have similar effects on efforts to revise pharmaceutical patent systems. These firms may have resisted the introduction of pharmaceutical patents in the first place, but, once the country has a patent system, they have adjusted in ways that dampen their opposition. Neither those investing more in R&D nor those that cease to exist constitute useful allies for health officials seeking to build coalitions to ameliorate the effects of pharmaceutical patents. Adjustment can thus cause defensive coalitions, i.e. the sets of actors that opposed the global sea change in the 1980s and 1990s, to wither.

Yet these two forms of adjustment, trying to be more like “big pharma” or ceasing to exist, do not constitute the universe of responses to the introduction of pharmaceutical patents, and the withering of defensive coalitions is not inevitable. Even in countries with patents, opportunities for production and sales continue to exist in older drugs: because patents expire, pharmaceutical markets include segments featuring firms using knowledge that is no longer privately owned. Some local firms continue to exist, and new firms continue to emerge, selling older drugs where patents are no longer relevant or entering the market with follow-on versions when patents expire. In sum, rather than reacting to the new status quo by becoming originator firms or exiting the sector altogether, many firms adjust to the introduction of pharmaceutical patents by becoming different types of non-originator firms (del Campo 2016; Kale 2010; Shadlen 2007). Local pharmaceutical firms in developing countries may become more like “generic” pharmaceutical firms in developed countries, trying to avoid infringement in their new market segments, while militating against abuse of the patent system. Depending on local firms' abilities to react in this way, defensive coalitions can persist or be reconstituted for subsequent conflicts over how pharmaceutical patent systems function.

<sup>28</sup> Some firms may pursue rearguard strategies and continue to make their own versions of patented drugs, but doing so is risky and not the norm.

Differential patterns of adjustment to initial policy choices affect subsequent coalitional possibilities. Policy choices made in the 1990s cast a shadow over policymaking processes in the 2000s. The former does not determine the latter, but, by triggering distinct patterns of adjustment, the first set of choices conditions the second. The two policymaking episodes that are central to this book, introducing pharmaceutical patents and revising new patent systems, are not independent events. Differences in how patent regimes were introduced in the 1990s generate distinct challenges and inspire different patterns of adjustment in domestic pharmaceutical sectors, which in turn affect possibilities for coalition building in the 2000s.

To summarize, the focus here is on two mechanisms by which constellations of actors and interests change in response to external shocks, and as they do so shift the opportunities for coalition building. The first regards trade pressures mobilizing exporters and altering the universe of actors that care about IP policy. The second regards policies, once introduced, inspiring patterns of adjustment and reconfiguring interests around IP policy. Both of these mechanisms shift the social terrain in ways that can enable or constrain policymakers seeking to build coalitions to secure their desired outcomes. Where higher shares of exports enter the US market under preferential and removable trading arrangements, building coalitions for over-compliance in the introduction of pharmaceutical patents becomes easier. And depending on the magnitude and duration of the shock generated by initial policy choices and subsequent transformations of state and society, efforts to modify new patent systems are also constrained.

Finally, and to return to a larger theme of this book, it is important to underscore that both of these mechanisms constitute domestic politics being shifted by *international* changes. While this is easy to see with regard to trade pressures mobilizing exporters, it is also the case when we observe political coalitions reshaped over time by domestic actors' reactions to new policies. The new constellations of interests and patterns of mobilization are the products of an exogenous shock in the first place. If not for the fundamental changes in the global politics of IP, we are unlikely to have witnessed the initial policy changes that transformed the state, inspired adjustment, and subsequently reshuffled social structure. Even if the most important factors accounting for policy variation in subsequent periods are domestic, the entire political economy has been shaped by the initial exogenous shock. This is, essentially, a revised formulation of what Gourevitch (1978) labeled the "second image reversed." In the original, the question asked was how changes in the international environment affect national policies. The answer, which became foundational for decades of research in comparative and international political economy, was that the effects are mediated by national political processes. Here, adopting a longitudinal perspective, we can see how entire political economies can be transformed because of earlier external events. The

proximate causes are domestic, but the domestic conditions themselves have international roots.

## RESEARCH DESIGN, DATA SOURCES, METHODOLOGY, AND ORGANIZATION

Intellectual property provides a useful terrain to study the national consequences of international change, because without new international rules and the mass of pressures that countries faced in the 1980s and 1990s (i.e. the global sea change) there is little reason to expect developing countries to have revised their IP systems. Other areas of economic policy that also underwent substantial change in this period, such as trade, ownership of state enterprises, and regulations on foreign investment, had typically been contested internally for long periods of time, with some actors seeking the liberalization of imports, privatization of state enterprises, and greater opening to foreign investment. Though countries undeniably were subject to external pressures in these areas too, it is reasonable to expect that, even in the absence of new international rules and overtures from foreign governments, debt crises and deteriorating economic conditions would have yielded significant degrees of policy change. In the case of IP, in contrast, little if any change would have occurred in the absence of external pressures. To illustrate, even as many developing countries were fundamentally revising their development strategies in the 1980s, many continued to fight for international rules endorsing lax IP protection and fiercely resisted overtures to change national practices (Gadbaw and Richards 1988a; Sell 1998). Notwithstanding crises of development strategies and dramatic changes in countries' economic policies, IP is an area where the status quo appeared to be firmly locked in place—until uprooted by an external shock in the late 1980s and early 1990s.

Of course external shock in this period had implications not just for countries' policies and practices regarding patents, but other forms of IP too, including those regarding copyrights, trademarks, industrial secrets, and so on. Each of these fields animates different sets of interests and mobilizes different sets of actors in society and the state. And even within the realm of patents, patterns of conflict may vary by technology. Focusing on the politics of pharmaceutical patents narrows the scope of research, and in doing so allows us to tighten our analytic lens and present a parsimonious and systematic explanation for the national effects of global shifts in ways that are not possible when assessing the outcome of TRIPS implementation in all its dimensions, as previous scholars have recognized (Deere 2008; Morin and Gold 2014).

A further, substantive, reason to focus on the political economy of pharmaceutical patents is the unrivalled prominence of this particular issue area. In no other sector are patents valued so greatly as mechanisms of appropriation as they are in the drug industry, and pharmaceutical firms spearheaded the global campaign to integrate IP policy into international trade rules. Furthermore, whether or not countries should be obliged to introduce pharmaceutical patents was the singularly most contested and divisive issue during the TRIPS negotiations, and the implications of the subsequent requirement to do so have remained the central point of conflict in the decades since TRIPS entered into effect, attracting an extraordinary amount of attention from analysts, activists, and international organizations. Quite simply, in most countries, political conflicts about complying with TRIPS are, *de facto*, conflicts over pharmaceutical patenting.

Argentina, Brazil, and Mexico are appropriate cases for comparison, as these were among the countries most heavily targeted by external pressures. As of the late 1980s, none of the three allowed pharmaceutical products to be patented, yet each appeared to offer international drug firms large and potentially lucrative markets, *were* they able to obtain patent protection. In a study of IP protection in Asia and Latin America that the Pharmaceutical Manufacturers of America<sup>29</sup> presented to the US Government in 1987, Argentina, Brazil, and Mexico (along with India) featured as the most “problematic” countries and where industry most wanted the US to act: in these countries the level of protection available was the lowest and the expected gains to transnational firms of obtaining patent protection were greatest, yet these countries were also singled out for being the most reluctant to change their policies (Gadbaw and Richards 1988b; Nogués 1990). The three Latin American countries in particular thus attracted the ire of the transnational pharmaceutical sector and the attention of the US Government, *as* achieving IP policy changes in these three countries became a key objective of US foreign economic policy (Buscaglia and Long 1997; Elliott and Richardson 1996; Harrison 2004; Hirst 1998). Though each faced considerable external pressures, these three countries demonstrated differences on the key social structure variables that are advanced in this book as the factors affecting diversity in coalitions and compliance: industrial legacies in the local pharmaceutical sectors, and export profiles.

This book utilizes the approach and tools of comparative historical analysis, examining national patterns of change as the outcome of the social forces interacting and unfolding over time (Katznelson 1997; Mahoney and Rueschemeyer 2003; Mahoney and Thelen 2015; Thelen 1999). One of the key insights of the comparative historical approach is that the same factors, even when scored similarly, may affect outcomes differently depending on the

<sup>29</sup> In the 1990s this association would insert research into its title and rename itself the Pharmaceutical Research and Manufacturers of America (PhRMA).

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pace at which events unfold.<sup>30</sup> Accordingly, the structured comparisons focus on the markedly different ways that similar events occurred in three countries over time, with emphases on timing and the sequential nature of change.

Analytic emphasis is not placed on the behavior of electorates, but rather diverse forms of political action by broad social groups. Coalitions, central to this book, are conceptualized as informal alliances that manifest actors' collective expression of shared interests and objectives in the public sphere. Importantly, coalitions studied this way are identified by the analyst; they are not formal entities, such as agreements between parties in legislatures.<sup>31</sup>

The comparative case studies allow us to adjudicate between rival explanations for political outcomes. Where countries that appear similar in terms of the external pressures they are subject to and the preferences of incumbent Executives yield different responses, for example, we can question the explanatory power of those variables alone. Of course, countries always vary in multiple ways that are out of the researcher's control (i.e., we can neither keep constant nor manipulate all the relevant variables), confounding purely correlational efforts at making causal inference in small-n analyses. Case study research helps us to understand the changing relationship between variables over time, creating a forensic account of what affected what, and how. Within-case analysis and process tracing are used to assess alternative causal pathways of the outcomes of interest: the "causal process observations" obtained through process tracing enable the researcher to determine if the evidence fits one explanation better than another (Collier et al. 2010; Bennett and Checkel 2014a; Fairfield 2013; Fairfield and Charman 2017, forthcoming).

Comparative case studies based on process tracing are also essential for understanding how coalitions are constructed and change. Forms of compliance are not attributable directly to social structure; rather, forms of compliance are tied to the characteristics of political coalitions that social structure both enables and encumbers. This means that we need to build on material and more easily observable indicators, such as the market shares of rival segments of industry, and consider the way actors engage in collective action and cultivate allies, and their strategies to exploit contacts with legislators and Executive officials. We also need to see how Executives, seeking to introduce policy changes, respond to the opportunities and constraints presented by social structure. These sorts of political activities are at the heart of coalition building, and they can only be identified through case studies. Of course, linking changed characteristics of coalitions to policy outcomes is difficult, and the risk of falling into circular reasoning is ever-present. Process tracing allows

<sup>30</sup> See, among others, Collier and Collier (1991), Falleti (2005), Falleti and Lynch (2009), Falleti and Mahoney (2015), Grzymala-Busse (2011), Pierson (2003; 2004).

<sup>31</sup> Doner and Schneider (2016, 618) make this distinction as well. See also the contributions to Smith et al. (2014).

us to study the phenomena of coalitions expanding (or shrinking), mobilizing to drive policy change, and, critically, the temporal relationship between these events and the outcomes of interest (Thelen and Mahoney 2015).

The research is based on fieldwork in Argentina, Brazil, and Mexico. In addition to archival sources, press accounts, and statistical data, the research was informed by extensive interviewing. Informants in each country were identified according to functional positions, with the goal of conducting similarly structured interviews with clusters of actors from the same areas and positions in each country. For example, in each country I interviewed representatives from pharmaceutical industries, both subsidiaries of transnational firms operating locally and national firms, as well as lawyers working with these segments of the pharmaceutical sector. Likewise, in each country I interviewed officials from relevant areas of the Executive, including ministries and secretariats, patent offices and health regulatory agencies, as well as from Congress, including legislators, legislative assistants, and legislative researchers. And in each country I interviewed civil society actors, such as professionals from the medical and health fields, and individuals or organizations focused on the promotion of national science and innovation policies, as well as activists engaged in work around IP, including—but not restricted to—those working specifically on matters related to pharmaceutical patenting and access to medicines. The Fieldwork Appendix presents the location and period of fieldwork in each country, along with information on the informants in each of these functional fields.

Beyond formal, confidential interviews, the research has benefited from a substantial amount of correspondence in other forms. For example with some of the informants I have had ongoing email exchanges over course of multiple years. Though I do not identify informants in the text, where interviews and emails are cited I provide information on the functions and positions of relevant actors (and these cited interviews are listed following the references).

Using interview data presents well-known challenges for causal inference, challenges that have been amply debated (Brady and Collier 2004; Mahoney 2010; Mosley 2013; Rathbun 2008). Most obviously, the pool of subjects interviewed is not random; in fact the pool should not be random when it is essential to communicate with particular individuals about key events. And of course information relayed by informants may be incomplete, self-serving, partial, or inaccurate. One way to address these concerns was to seek “saturation,” i.e. to interview multiple people from each functional category to reach the point where additional interviews are not providing new information (Bennett and Checkel 2014b; Bleich and Pekkanen 2013; Lynch 2013). In addition, the information obtained from interviews about the role of actors in events has been cross-checked against information from the public record, newspapers, and archives (often referred to as “triangulation”), and frequently informants were asked to clarify inconsistencies in follow-up interviews

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or other forms of interaction. Saturation and triangulation thus allow the researcher to be confident that the information obtained from interviews is accurate, and, moreover, as part of a research design based on within-case analysis and process tracing, these steps allows us to use interviews as a method for collecting data to assess rival explanations.

Chapter 2 presents the substance of the policy debates. The chapter provides greater context on IP, patents, and the particular characteristics of pharmaceuticals that have always made this industry a focal point of conflict. In addition to presenting the specific policy issues that were contested as countries introduce pharmaceutical patent systems in the 1990s and then reform these new patent systems in the 2000s, the chapter presents the explanatory framework for understanding cross-national and within-case longitudinal variation in patent policy. That is, while the discussion in this chapter has discussed the relevant variables and mechanisms in more abstract form, Chapter 2 presents this more concretely, with reference to the specific debates over pharmaceutical patents.

The empirical material that follows is divided into two clusters of chapters corresponding to two periods of patent politics. Chapters 3–5 analyze how countries introduced new pharmaceutical patent systems in response to the global sea change of the 1980s and 90s, and Chapters 6–8 analyze how countries went about reforming their new patent systems in the 2000s in response to emerging challenges. In each time period the chapters are presented in the same order, starting with Argentina, followed by Mexico, then Brazil. The chapters are not presented in chronological order, but rather to highlight key aspects of the explanatory framework, namely how changing social structure and export profiles establish the conditions for Executives to build coalitions to secure their desired policy outcomes. Chapter 9 synthesizes the main findings of the book and discusses the implications of the research for the study of comparative and international political economy, and also considers the challenges that developing countries face in adjusting their development strategies to the new world of pharmaceutical patenting.