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The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Activism

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Abstract

This paper analyzes the politics of intellectual property (IP) and public health in Brazil and Mexico. Both countries introduced pharmaceutical patents in the 1990s, to comply with their international obligations. Indeed, both countries' IP systems were markedly similar in being favorable to the interests of the transnational, innovation-based pharmaceutical sector. Yet since the late 1990s the two countries have diverged in dramatic fashion. In Brazil the response to the high price of drugs and societal demands to reform the IP system has been to make obtaining private ownership over knowledge more difficult and to increase the rights of third parties to access and use knowledge. In Mexico, the response to similar demands has been to raise impediments to third parties' rights of access and use and effectively extend the periods of protection granted to patent-owners.

To explain these differences the paper adopts a political economy approach, analyzing the nature of actors pushing for IP reform and subsequent patterns of alliance formation and political mobilization. In both countries, drug patents, escalating prices, and limited access led to backlash against the IP system, but the two countries demonstrate marked variation in the presence of powerful alliance partners to lend their support to activists clamoring for change. In Brazil, the combination of a strong, interested, and active Ministry of Health and a more autonomous local pharmaceutical sector created a propitious environment for initiatives to reform the IP system. In Mexico, the subordination of the Secretariat of Health and fundamental transformations of the local industrial sector meant that calls to reform the IP system were not well-received. Instead, the reform project in Mexico became commandeered by IP owners and ultimately had the perverse effect of reinforcing and strengthening the system that was being challenged.

The paper concludes by underscoring the importance of pharmaceutical industries for development. The findings suggest that the existence of independent pharmaceutical sectors may not just be beneficial for industrial development, but also for promoting public health and pursuing humanitarian goals. The basis of this conclusion is that the key variable in explaining efforts to reform patent systems to increase access to drugs is the presence of an autonomous, national pharmaceutical industry that is available as an alliance partner for those pushing for such reforms. Thus, the key to IP-for-humanitarianism is maintenance of some degree of IP-for-industrialization.

The Politics of Patents and Drugs in Brazil and Mexico:
The Industrial Bases of Health Activism[*]

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Introduction

National strategies for managing intellectual property (IP) influence trajectories of industrial development and capacities to address humanitarian concerns. As pillars of national systems of innovation, IP regimes drive the direction and pace of technological change; they affect the pace by which knowledge is created and diffused. And by affecting access to technologically-intensive goods, such as pharmaceuticals, IP regimes contribute to national strategies for protecting public health. How IP systems change, then, has broad significance for analysts of development and international political economy.

In this paper I bridge these two dimensions. In analyzing the politics of drug patents and healthcare in Brazil and Mexico, I show that how IP affects the industrial sector – particularly the pharmaceutical industry – establishes the political parameters that affect countries' abilities to use IP to promote public health.

Prior to the 1990s, neither Brazil nor Mexico (nor many other countries in the developing world) granted patents on pharmaceutical products.[1] As a result, local firms could produce imitation, "generic" versions of new drugs – drugs that typically were under patent in the OECD.[2] In the 1990s, both countries introduced pharmaceutical patents to comply with new international rules barring the previous practice of making pharmaceuticals non-patentable. Providing market exclusivity to owners of new drugs raises prices and concerns with access to medicines, a topic that has been the subject of an ever-growing body of literature.[3]

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[1] In fact, until the 1970s and 1980s some developed countries (e.g. Italy) did not issue pharmaceutical patents either. See WHO (2002).

[2] Although in this paper I use the term "generic" to refer to drugs that are not protected by patents, a more comprehensive definition would also stipulate that the drug not be protected by trademark. Many unpatented drugs continue are marketed under brand-names, especially when they are sold directly to the public as over-the-counter products.

[3]The question of how the introduction of pharmaceutical patents may affect drug prices and access to medicines has been addressed by social scientists from the fields of politics, economics, and law, along with health professionals and activists. A sampling of the literature includes, among others, Abbott (2005), Attaran (2004), Attaran and Gillespie-White (2001), Chaudhuri (2005), CIPR (2002), Correa (2000), Granville (2002), Heins (2008, forthcoming), Katrak (2004), Matthews (2004 and 2006); May (2002), Moatti, Coriat, Souteyrand, Barnett, Dumoulin, and Flori (2003) MSF-WHO-UNAIDS (2003), Nogués

In virtually all countries, the introduction of drug patents was met with backlash and policymakers faced subsequent pressures to modify their new IP systems. Yet policy in Brazil and Mexico took fundamentally different courses in response to this backlash. Brazil adjusted the IP system to ameliorate the effects that drug patents can have on access; Mexico introduced few adjustments, and where changes were introduced they tended to reinforce and intensify the effects of drug patents. Variation in IP can be considered along three dimensions: what knowledge can be owned as property, the rights of owners vs. users of property, and the effective duration of property owners' rights. In Brazil, obtaining private ownership over knowledge in the realm of pharmaceuticals has been made more difficult, and the rights of third parties to use knowledge has been simplified. In Mexico, in contrast, impediments have been raised to third parties' rights to use knowledge; and the effective length of protection extended.

One seemingly obvious explanation for these differences is that Mexico is a party to the North American Free Trade Agreement (NAFTA), which includes stringent IP provisions, while Brazil has no external obligations beyond the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Indeed, as we shall see below, NAFTA contains IP provisions (Chapter 17) that place greater restrictions on IP management in Mexico. Yet reliance on NAFTA as an explanatory factor can only take us so far, for the differences in the laws themselves cannot explain the subsequent divergence. If it were the case that the reforms introduced by Brazil would, were they transferred to Mexico, violate NAFTA, then NAFTA could partially account for the divergence – it could tell us why Mexico has not taken the same path as Brazil. But such is not the case: the reforms introduced by Brazil would not have violated NAFTA -- legally speaking Mexico could have done the same things. But it did not. The answer to that cannot be simply invoking NAFTA. Moreover, a strict emphasis on NAFTA cannot explain why Mexico reformed its IP system in the way it did. For as we shall see, Mexico did not simply fail to emulate Brazil's move from away from TRIPS Plus and toward TRIPS Just, but rather moved on its own to an extended version of TRIPS Plus.

Rather than focus on international legal obligations, my explanation for these different trajectories, and more generally to address the puzzle of distinct responses to similar challenges, is based on a political economy approach. I focus on the nature of actors pushing for changes (civil society, state, industry), and subsequent patterns of alliance formation and political mobilization. In both countries, drug patents, escalating prices, and limited access led to backlash; that much is constant. What varies across countries is the variation of powerful alliance partners to lend their support to activists clamoring for modification of the new IP systems.

(1993); Roffe, Tansey, and Vivas-Eugui (2006), Sell (2002 and 2006), Shadlen (2004a and 2004b and 2007), WHO (1998, 2002, and 2005). See also the abundant studies (and links to further research) at the portals of Médecins Sans Frontières (http://www.accessmed-msf.org) and the Consumer Project on Technology (http://www.cptech.org/ip/health). WHO (2001) provides an extensive (though dated) annotated bibliography of the literature.

In identifying the availability of alliance partners, the key analytic issue I shall focus on is how the introduction of new IP systems engenders transformation of interests in state and industry. In Brazil, the combination of a strong, interested, and "activist" (Biehl 2004) Ministry of Health and a more autonomous local pharmaceutical sector created a propitious environment for initiatives to reform the IP system. In Mexico, the subordination of the Secretariat of Health and fundamental transformations of the local industrial sector meant that calls to reform the IP system were not well-received. Indeed, the reform project in Mexico became commandeered by IP owners and ultimately had the perverse effect of reinforcing and strengthening the system that was being challenged.

The analysis in this paper also presents a challenge to social scientists relying on models of policy diffusion. In recent years, diffusion models have gained popularity among political scientists. Some analysts have applied such logic (if not the similar econometric techniques) to the case of IP and drugs. For example, Nunn et al (2007) suggest that Brazilian officials learned from Thailand's example of challenging transnational pharmaceutical firms. And Cohen and Lybecker (2005) suggest that the Brazilian example of reforming IP laws and practices for public health purposes can lead other countries down the same path. They even cite Mexico as a country inspired by Brazil to introduce such health-oriented IP reforms (Cohen and Lybecker 2005: 226). To an extent this is correct, as the legislative initiative proposed to reform Mexico's patent regulations made, in the motivations, explicit reference to Brazilian reforms that were to be emulated. Yet, as we shall see, the ensuing events should provide a caution against overstating the importance to ideas and policy communities and understating the importance of interests and power. Mexico's attempt to emulate Brazil became commandeered by those who did not want Mexico's patent rules to be made more flexible but rather more rigid. The end-product of diffusion was not emulation, but processes and outcomes that were the mirror image of each other. The politics of IP is not a story about laws and ideas, but power.

The paper has four sections. First, I present a framework for comparing and assessing the health-related aspects of national IP regimes, focusing on patents, and I apply this descriptive framework to the cases of Brazil and Mexico. In doing so I demonstrate how fundamentally different the two countries' health-related IP systems have become, despite similar origins. In the second and third sections I explain this variation by analyzing the politics of patents and drugs in Brazil and Mexico, respectively. In the fourth section I conclude, synthesizing the key findings and pointing to some broader implications of the study for analysis of the political economy of late development. Importantly, I draw attention to the way that IP and pharmaceutical development can bridge the divide between industrial transformation and humanitarianism.

Patents, Patent Regimes, and Drugs

Prior to explaining the differences between Brazil and Mexico on the health-related dimensions of IP, we need to establish a way of showing and understanding the differences. In other words, we need to develop a way of making comparative analysis of IP regimes useful. The first step is to provide an operational definition of patent regimes that allows us to conceptualize and observe variation with regard to drugs and health.[4] Patents confer limited rights of exclusion over inventions that are new, non-obvious, and have industrial use. Some aspects of this simple definition merit emphasis. For example, it is important to emphasize the criteria for patentability: patents are available for inventions, not discoveries, and applicants must demonstrate that their inventions satisfy standards of being new, non-obvious, and having industrial utility. Moreover, although the grant of right of exclusion constitutes turning knowledge into private property, the subsequent rights of owners over their property are limited.

The rights conferred by patents are limited in three significant ways, and the politics of IP can be conceptualized as conflicts over these limitations. First, patents are not conferred to owners automatically upon possession. Rather, private ownership rights are granted by the state, typically a national patent office, only where applicants demonstrate that their inventions satisfy the criteria of patentability. With application central to the process of establishing ownership, governments can delineate what ideas and innovations can be owned privately within their territory. A second limitation is that patent rights include various exceptions to patent-holders' ability to exert control over the use and distribution of their property. Patent regimes include provisions by which third parties have the right to use knowledge that is owned by someone else, and they also include provisions that allow third parties to receive permission from the state to use other actors' privately owned knowledge in ways that would otherwise constitute violations patent-holders' rights. A third limitation is temporal. Patents expire: at some point what is treated as private property enters the public domain, where access to and use of the knowledge is unrestricted.

The three limitations map onto three lines of political conflict.[5] The first limitation corresponds to conflicts over what can be owned privately, the second limitation corresponds to conflicts between the rights of owners and users of private property, and the third limitation corresponds to conflicts over the duration of rights. These lines of conflict, in turn, map on to axes of policy variation. Each row in Table 1 takes us from a limitation to a political conflict and then provides policy examples.

[4]See Correa (2000), CIPR (2002: Chapter 2).

[5]These lines of political conflict are germane to all politics over property, not just intellectual property. I develop this point in more detail in the first chapter of my book manuscript, *The New Politics of Intellectual Property in Latin America*.

Table 1
Law, Politics, and Health Policy

Limitations	Political Conflict	Health-Related Policy Areas
Not automatic	What can be owned	Pharmaceutical patents "Pipeline" Patents
Not Absolute	Rights of owners vs. users	Parallel Imports Compulsory Licenses
Not Permanent	Length of Rights	Post-patent generic entry (Bolar Exceptions, Drug Registration)

The policy areas that correspond to the conflict over what sort of knowledge can be owned are generally about "patent scope." For the purposes of this paper, the fundamental policy issue in patent scope is whether or not countries grant pharmaceutical patents. As indicated, many developing countries did not do so prior to the 1990s, but TRIPS (and NAFTA) requires that all countries grant patents on pharmaceutical products.[6]

A second important policy issue regards "pipeline" patents. Here the issue is how to deal with inventions that are not new but that are unpatented because the previous regime did not allow patents. For example, if a country begins granting pharmaceutical patents in 1995, a drug that was invented in 1991 would not have been eligible for a patent at the time it was new. Strict interpretation of novelty would make such a drug ineligible for patents in 1995 too, because by the time the patent scope was changed to make drugs patentable the drug in question did not satisfy the novelty requirement. Yet some countries opted to grant patents to older drugs in the "pipeline," provided they were not already on the market. Countries were not obligated under TRIPS to offer "pipeline" patents, but they came under considerable pressure to do so. This is an area where NAFTA exceeds TRIPS, in that the requirement to offer pipeline patents is included in the agreement.[7]

The policy areas that correspond to the conflict over the rights of owners vs. users regard parallel imports and compulsory licenses. Parallel importation consists of allowing patented goods to enter the market once the patent-holder has placed the good on the market elsewhere. Countries that permit parallel imports typically do so to increase

[6]Developing countries that did not grant patents to pharmaceuticals prior to 1995, when TRIPS entered into effect, had until 2005 to begin doing so. Few countries took full advantage of this transition period.

[7]Though the rule applies to all three of the parties to NAFTA, because the US and Canada already granted pharmaceutical patents, the pipeline requirement in effect only applied to Mexico. Note that Mexico introduced this into national legislation in 1991, before NAFTA negotiations were initiated (indeed, that was a condition for negotiations to proceed) and before the TRIPS Agreement was completed and signed.

competition, encourage arbitrage, and thus ensure affordability of patented goods. TRIPS allows countries to engage in parallel importation by adopting *international* doctrines of patent exhaustion, i.e. once patent-holders place their goods on the international market, their rights are exhausted. Because NAFTA requires that countries adopt *national* doctrines of patent exhaustion, parallel importing is prohibited.

A compulsory license allows a domestic manufacturer (public or private) to produce and distribute a patented good without the authorization of the patent-holder. TRIPS allows countries to determine the grounds on which they grant compulsory licenses, provided that a set of procedural conditions are met, as stipulated in Article 31. These conditions include, for example, prior negotiations with the patent holder. In the case of one sub-type of compulsory license, known as "public utility" or "government use" licenses, countries are released from most of the procedural obligations under TRIPS. That is, in times of national emergency or when the CL is granted for public use, countries do not have to abide by most of the ordinary conditions (such as prior negotiations with the patent holder).[8] Because potential delays introduced by negotiations are removed in the case of public utility licenses, they are easier and quicker to grant and, arguably, of most relevance for discussions of public health. TRIPS and NAFTA are identical with regard to CLs.

While parallel imports and compulsory licenses regard the rights of owners vs. users of knowledge that is patented, the health-related policy areas corresponding to conflicts over the length of rights regard post-patent generic entry. The most important are early working provisions and procedures for registration of generic drugs. Early working provisions allow generic firms to use patented knowledge and produce generic versions of patented drugs to prepare to obtain marketing approval once the patent expires.[9] Without such provisions, a firm would be infringing a patent if were to make generic versions of a patented drug prior to the expiration of the patent. But if firms must wait until the patent expires to make generic versions and to submit data to health authorities, the patent term is effectively extended by the amount of time it takes to take these steps. Early working provisions, then, by allowing generic firms to use the knowledge to prepare for market entry, expedite competition at the point that the patent expires. Such provisions do not shorten patent terms but rather eliminate the effective extension of patent terms. TRIPS and NAFTA both permit early working provisions.

[8]This provision that if the CL is issued on grounds of national emergency that countries are released from procedural obligations (Article 31.b) is often misrepresented as saying that countries can only issue CLs in cases of national emergency. It bears repeating that countries can issue CLs on whatever grounds they establish in national legislation, but they can only do so without entering into negotiations and complying with other procedural requirements in times of declared national emergency (and government use).

[9]These are typically called "Bolar" provisions, after the US case that established this practice as legal. Formally, early working exceptions should be considered an example of owners' rights of exclusion being limited, but effectively where this most matters is how such provisions affect the effective duration of owners' rights.

But some generic firms simply choose to launch their products early, prior to the end of the patent term, believing that their products do not infringe on existing patents or that the patents in question are invalid.[10] To market a drug, however, the firm needs to receive authorization from national health authorities. The related policy issued, then, is whether and how the activities of IP and health officials are coordinated. Neither TRIPS nor NAFTA addresses this issue. More recently, and as we shall see below, the United States (on behalf of the pharmaceutical sector) has pushed strongly for a form of coordination known as "linkage," whereby health authorities consult with IP authorities and deny registration to drugs when patents are still in force. While this form of linkage seems unproblematic on the face of it (if the drug is patented, then the sale of generic versions would be illegal), many developing countries have resisted pressures to proceed in this direction. One objection, typically articulated by health officials, is that such linkage places a legal responsibility on government agencies whose remit is not IP law but health and safety regulation. A second, more general, objection is that this form of linkage transfers the burden of defending a patent from the private rights-holder to the public.[11] In any case, this form of linkage, though included in more recent RBTAs that the US has negotiated, is not part of NAFTA.

Table 2
IP and Health Policy: WTO vs. NAFTA

Policy Issue	**WTO (TRIPS)**	**NAFTA (Chapter 17)**
Pharmaceutical Patents	Required (product and process)	--
Pipeline Patents	Not required	Required
Parallel Imports	Permitted	Not permitted
Compulsory Licenses	Permitted; ample discretion	--
Early Working Provisions	Permitted	--
Drug Registration	Not addressed	--

Note: -- indicates that NAFTA is identical to TRIPS on this dimension

Table 2 summarizes the important similarities and differences between TRIPS and NAFTA with regard to the health-policy dimensions of IP. It is clear that there are indeed important differences with regard to pipeline patents and parallel imports. Yet the similarities are greater than the differences: with regards to IP, NAFTA is more like WTO than it is like the many RBTAs that would follow in its wake. Moreover, these agreements do not tell us what countries will do, they merely provide some guidelines as to what countries can and cannot do. As we shall see, Brazil offered pipeline patents despite not being required to do so, and Brazil did not allow parallel imports despite being allowed to do so. Mexico would, eventually, tighten its compulsory licensing provisions and introduce a USTR-style linkage system, despite not being required to do

[10]The reason for this is that the boundaries of patents are intrinsically uncertain; it is difficult to know where a patent owners' rights end (and thus where the public domain begins) until patents are challenged and litigated. See Lemley and Shapiro (2005); Thambisetty (2007).

[11]I am not addressing data exclusivity in this text.

so by NAFTA. These brief remarks underscore the importance of moving the level of analysis from international agreement to national legislation, and from law to politics.

Patents, Patent Regimes, and Drugs in Brazil and Mexico

The three limitations, lines of conflict, and policy dimensions allow us to compare patent regimes across time and space. Table 3 examines Brazil and Mexico according to these policy dimensions, in terms of their original IP systems instituted to comply with TRIPS (and NAFTA as well, in the case of Mexico). Both countries implemented IP systems that would be classified as "TRIPS Plus," in that they went far beyond their multilateral obligations in establishing new IP systems that were immensely favorable to the transnational pharmaceutical industry: ownership was easy to obtain over a wide variety of drugs, knowledge owners had strong – and effectively long – rights of exclusion. For example, both countries offered pipeline patents, neither allowed parallel imports, both had only rudimentary and complex mechanisms for compulsory and public utility licenses, and neither had early working provisions. The result, then, was that not only would more drugs become patented, but in both countries it would be difficult for to get alternative drugs on the market or compel competition with generics.

Table 3
Law, Politics, and Health Policy in Brazil and Mexico: Common Origins

Limitations	Political Conflict	Health-Related Policy Areas	Brazil and Mexico
Not Automatic	What can be owned	Pharmaceutical patents "Pipeline" Patents	• Pharmaceutical Patents introduced (Brazil, 1997; Mexico, 1991) • Pipeline Patents granted
Not Absolute	Rights of owners vs. users	Compulsory Licenses Parallel Imports	• Basic CL (PUL) systems in conformity with TRIPS (Brazil, Article 71; Mexico, Article 77) • No parallel imports
Not Permanent	Length of Rights	Post-patent generic entry (Bolar Exceptions, Drug Registration)	• No Bolar Exceptions • Pro-generic drug approval processes

Beginning in the late 1990s, however, the two countries diverge in dramatic fashion (see Table 4). In Brazil, obtaining ownership was made more difficult, the patent law was modified to facilitate third-party use and lower prices through compulsory licensing, and the government took a number of steps to encourage competition in the pharmaceutical market with generic drugs. In Mexico, in contrast, obtaining ownership became simplified, the patent law was reformed to make use more difficult and complicate the process by which CLs could be issued, and modest measures to encourage generic competition were introduced but slowly and in a minimal and self-undermining fashion. The subsequent sections provide more explanation of this divergence, drawing

our attention to the important role of local pharmaceutical industries as alliance partners for coalitions seeking IP reform.

Table 4
Law, Politics, and Health Policy in Brazil and Mexico: Divergence

Limitations	Political Conflict	Health-Related Policy Areas	Brazil	Mexico
Not Automatic	What can be owned	Pharmaceutical patents "Pipeline" Patents	Make ownership more difficult	No Change
Not Absolute	Rights of owners vs. users	Compulsory Licenses Parallel Imports	Strengthen rights for public use	Strengthen rights of owners (make use more difficult)
Not Permanent	Length of Rights	Post-patent generic entry (Bolar Exceptions, Drug Registration)	Delimit terms of protection	Extend effective terms of protection

Brazil: From TRIPS Plus to TRIPS Just

A key factor motivating change in Brazil was the HIV/AIDS epidemic. Brazil has, by Latin America standards, high rates of prevalence (UNAIDS 2006) and a long history of AIDS activism (Smith and Siplon 2006; Biehl 2004). In addition, the government had extensive obligations on account of a 1996 law (Lei Sarney) that guaranteed free universal anti-retroviral treatment for people with HIV/AIDS. The combined result was that the Ministry of Health was intensely concerned about prices and receptive to societal demands for modifying the IP system to lower prices.

The late 1990s was not merely a period in which IP would become a more prominent issue for the MoH, but also the MoH would become more prominent in IP matters. It is worth recalling that when the new patent legislation was being drafted and negotiated with congress in the 1990s, the MoH was not formally included in the government's inter-ministerial group on IP. Yet this would change in the late 1990s, especially in the second Cardoso government, as the ministry would be under the control of José Serra, a prominent economist and close political ally of President Cardoso. Thus, we can say that one set of factors drove the MoH into action and another set of factors created space within the state apparatus for the MoH to lead government policy on IP-related policy.

But this constellation of forces alone is not sufficient to explain the changes implemented in Brazil. A key point of the story in Brazil is that the local pharmaceutical sector remained vibrant. Here the on-going existence – and activism – of associations representing the pharmo-chemical (ABIFINA) and final pharmaceutical sectors

(ANALAC) is critical. One reason why these sectors were able to remain prominent in Brazilian political economy is the comparatively late introduction of drug patents. The bill was introduced in 1991 but not passed until 1996, and did not go into effect until May 1997. To be sure, by global standards patents were introduced anything but "late" in Brazil, as the country had until 2005 to begin doing so; but in contrast to Mexico, where drug patents were introduced in 1991, and relative to the period when the health-related IP reforms became political issue, it is a fair characterization of the timing. The local pharmaceutical sector also benefited from significant public-sector investment in pharmaceutical research and production, some of it through the Ministry of Health itself (note, for example, the network of labs and even an association of official, public-sector labs, ALFOB).[12]

By the late 1990s, then, Brazil had a resilient national pharmaceutical sector that was growing in strength.[13] Brazilian firms (private and public) account for one-fourth of the pharmaceutical sector, by number of firms, and a comparable amount by volume (IMS data). Organizations such as ABIFINA, ALANAC, and ALFOB could present positions contrary to those of the transnational sector's body, INTERFARMA. Indeed, the existence of a national pharmaceutical sector that identified itself as having interests distinct from the TNC sector is critical, for this made alliance partners available NGOs and the activist MoH. Concretely, what it meant was that when the Ministry of Health began pushing for these changes in the late 1990s, it engendered little domestic backlash. Reforms were not industry-led, but initiatives to modify the IP for public health purposes were not rejected by the pharmaceutical industry and assailed as assaults on "private property."

Three important changes are introduced: health authorities gain prominence in reviewing patent applications, compulsory licensing provisions are made more flexible and easier to use, and regulatory reforms are introduced to expedite post-patent generic entry.

All patent applications for pharmaceutical products, once approved by patent examiners in the INPI, are then passed along to the health ministry for review. The patent is issued only after ANVISA offers "prior consent". This reform, introduced in 1999 and 2001, makes it more difficult to obtain private rights of exclusion over knowledge for pharmaceuticals.

The requirement to obtain ANVISA's prior consent has roots in the system of pipeline protection. In the two years after the LPI came into effect in May 1997, the INPI was flooded with thousands of applications under the pipeline provision – pharmaceutical firms had been eagerly awaiting patentability in Brazil since the 1980s, and they were falling over themselves to get their applications. According to the LPI, however, pipeline patents were only available for drugs that had not already been placed on the market. But

[12] Biehl (2004: 115-116) and Nunn et al (2007: 7-8) both emphasize the importance of public sector pharmaceutical production.

[13] The sector was smaller and weaker than Mexico's in the late 1980s.

how were INPI officials to know? After all, they are patent examiners, and not necessarily informed about retail drug markets. (Applicants, of course, have every reason to deny their products are on the market, since the penalty for being caught is to lose patent protection, and in the meanwhile they have market exclusivity.) The Brazilian solution to this problem was to engage health authorities, the body responsible for approving drug marketing, to make a technical judgment of the invention's eligibility. Thus, Brazil introduced a requirement of "prior consent" on the part of ANVISA for patents filed under the pipeline provisions.

The trick was to universalize this requirement by applying it to all pharmaceutical patent applications. In 1999 the government, through decree, required that all applications for drug patents, thus, go to ANVISA. ANVISA's role is to provide "prior consent" on the basis of an evaluation of novelty, but the working definition of "novelty" differs from PP and ordinary applications. For new (non-PP) applications the relevant questions do not regard whether the drug has been on the market. Instead, novelty regards questions of "second use" and other criteria by which some argue that the application is not for a new molecular entity but rather a revised version of something that is already patented. This gets to hugely complicated issues in patent law, what is "new." For the sake of this analysis, the key point is that ANVISA's criteria for assessing "novelty" differs from INPI's in the important sense of being significantly stricter: "While the INPI adopts patentability guidelines that reproduce the practice of the European Patent Office, ANVISA has drafted its own guidelines, which are much stricter than the ones followed by INPI" (Basso 2006: 55).[14] Indeed, INPI is widely criticized by health activists[15] and lawyers (Basso 2006) for adopting overly broad definitions of novelty. In contrast, ANVISA denies patents to drugs that lack "genuine" inventive step and novelty, and are harmful to public health (Basso 2006).[16]

The prior consent requirement performs two objectives. First, it slows down the deluge of pipeline patents. Second, it controls the quality of non-pipeline patents. Table 5 provides data on non-pipeline pharmaceutical applications that have gone to ANVISA since the prior consent requirement was implemented in 1999. The data suggest this is a fairly conservative and precautionary measure to protect public health. Most patents, if approved by INPI, also receive ANVISA's approval. With only three percent of the decisions being denials, it is clear that the prior consent rule does not block pharmaceutical patenting in Brazil. Of course, these data only refer to pharmaceutical patents given preliminary approval by INPI, and the relatively small number (821) is

[14] One could argue, paraphrasing and adapting Basheer (2005), that Brazilian health officials use "health-policy-style reasoning".

[15]" Currently, the Brazilian Patent Office's (INPI) internal guidelines for evaluating pharmaceutical patents are very broad and go against public health and the Brazilian patent law" ("Note of the Working Group on Intellectual Property (GTPI) of the Brazilian Network for the Integration of Peoples (Rebrip) on Novartis' defeat in India's High Court, 20 August 2007, on file with author)

[16] Note that while ANVISA's position in the patent examination process is statutorily mandated, the examination guidelines it uses are not. Basso (2006) presents a depiction of ANVISA's examination guidelines on the basis of the agencies' actions and some public statements and technical notes.

itself an indication of the huge backlog of patents at INPI. In other words, to the extent that obtaining private ownership rights of knowledge is made more difficult in Brazil, it is only partially due to the prior consent requirement; it is also due to the slow rate by which INPI examines patent applications.[17]

Table 5
ANVISA's "Prior Consent" in Action (through June 2006)

Decision	Number of Cases	Percentage
Approvals	582	70.9
Denials	26	3.2
Pending (as of June 2006)	180	21.9
Other*	33	4.0
Total	*821*	*100.0*

*returned to INPI for further analysis or because judged not to be pharmaceutical patent applications

Source: ANVISA

Few if any aspects of contemporary IP have received so much attention as compulsory licensing, and Brazil has been at the forefront of these debates. The 1996 LPI includes multiple clauses that address CLs. The most significant for our purposes is Article 71, which allows rapid CLs without prior negotiation in the event of national emergencies.

Brazil reformed Art 71 in 1999 to make the clause more useful. Specifically, the reform gave the health authority increased discretion in declaring "public interest" and clarified the grounds on which the article could be invoked. The concern motivating this reform was that in the case of a health emergency the article, as it was written, would leave the government vulnerable to appeal – and the subsequent uncertainty would reduce the credibility of any threat to issue a CL. The initial reform was announced by presidential decree (3201) and then converted into Law in 2001, as the LPI was reformed.[18]

The reform to Article 71 was done intentionally – and explicitly – to increase the capacity of the MoH to leverage price reductions from patent-holding pharmaceutical

[17] The transnational pharmaceutical sector claims that INPI has a backlog of approximately 20,000 pharmaceutical applications. See Pharma (2004). The estimate may be inflated, but no one denies the backlog is immense. In any case, from a public health perspective the problem with relying on slow examination is that once a patent is approved anyone who was using the knowledge must stop, which introduces uncertainty.

[18] In addition to increasing the discretion of the MoH, the reform to Article 71 also includes stipulations on technology transfer in the case of a CL being issued.

firms by threatening to issue CLs.[19] The revised law has provided the MoH with a powerful tool for bargaining with patent-holding firms. In August 2001, for example, Brazil announced its intention to issue a compulsory license on an ARV to which the patent was held by the Swiss firm Roche. Roche responded to the threat by reducing the price of the drug in Brazil, and subsequently no license was issued. Similar episodes occurred with Roche, Abbott, and Merck in 2003, and then, again with Abbott in 2005. And in 2007 the government did not just threaten but issued a CL on Merck's patented version of efavirenz. The threats are effective because the law is usable, but that was not the case prior to 1999. That Brazil reformed its CL provisions to make them more usable matters, and this was possible because doing so did not engender huge opposition. Again, it is not just about law and legal reform, but about the underlying political conditions.

A key dimension of any system to encourage generic competition is to regulate the prescription drug market by requiring physicians to use generic drug names in writing prescriptions. This was introduced in 1999, with the generic drug law, and, importantly, is enforced.[20] A critical dimension of the Brazilian strategy to introduce generic competition was a revision of the LPI to include an early working provision (Article 43, reformed in 2001). ANVISA's policy has been to grant rapid approval of like products, leaving the question of alleged patent infringement to be fought out in courts.

Brazilian authorities have also, for the most part, refused to extend terms for patents granted under the pipeline mechanism. That is, if a patent has a priority date from its USPTO application of 31 January 1985, for example, and was granted in Brazil under the pipeline mechanism in 1999, the patent is due to expire in Brazil (and in the US) on 30 January 2005. And even if the USPTO were to extend the expiry date by another two years, it would still expire in Brazil on 30 January 2005. The transnational pharmaceutical industry has pushed strongly for adjusting patent terms in this way, though this is not the norm in Brazil. It is worth noting that Brazilian jurisprudence is not entirely clear. The LPI itself does not include any statutory requirement to extend/correct patent terms, but patentees have demanded this. Courts mixed, though the trend is against such rulings (Nunes Barbosa 2007). The bias against adjustments of patent terms provides generic producers with incentives to utilize the early working provision introduced in 2001.

To conclude this section, in Brazil the IP system has been modified to address public health concerns. The process of obtaining private rights of exclusion over knowledge has become more difficult, the rights of users – especially the government – have been strengthened, and the government has taken steps to encourage price competition in pharmaceutical markets by expediting the entry of generic drugs once patents expire. To be sure, the transnational pharmaceutical sector opposes all of this – often vociferously – but, importantly, they are not the "voice of industry." Indeed, a key

[19] Worth noting that US filed a case in WTO against another CL provision in Brazil's patent regime, Art 68 on local working, but that is not directly related to drug patents. The focus of attention has been Article 71.

[20] One indicator of this would be generic share of retail market. I am working to obtain these data.

point about Brazil is that IP remains contested: the existence of powerful alliance partners means "IP for development" gets a hearing – may not win, but not easily dismissed as assault on property and basic rights.

Mexico: From TRIPS Plus to NAFTA Plus

Access to drugs became an increasingly prominent issue in Mexico in the late 1990s, as prices increased dramatically – and significantly above the rate of inflation – in the years following the 1994 devaluation of the peso. Historically medicines were made widely available – at deeply discounted prices or free – through the state health sector (IMSS and ISSSTE). Economic crisis in the 1990s, however, led to shortages in government supplies, and as more people turned to private, retail pharmacies, the high price of drugs became notable.

Yet activism around drug prices was incipient during this period. Mexico, in comparison with Brazil, lacks a history of vibrant health activism: there are fewer groups and there is significantly less history of political mobilization around issues of health and access to drugs. One reason for this of course is that the HIV/AIDS epidemic, which has sparked activism in so many countries (Smith and Siplon 2006) is not so large. Another important reason is that the state sector had wider coverage than in Brazil.

On the official side, the Mexican government was not bound by an equivalent to the Ley Sarney. Because Mexico did not guarantee universal treatment, the government's health obligations were less acute in high profile patented drugs, such as ARVs. As a result, the government of Ernesto Zedillo had less cause for alarm. The Secretariat of Health did seek to lower prices by increasing generic competition, but saw little reason to do so by adjusting the patent system.

In Mexico, then, the demand for patent reform came not from the civil society or the state, but rather from a segment of local industry. But, importantly, the industry actors pushing for patent reform were from a marginal segment that had little political legitimacy.[21] To understand where the movement came from, it is important to understand how the government reacted to drug-price inflation in the late 1990s. Rather than adjusting the IP system, as we saw in Brazil, Mexican authorities introduced two regulations to the General Health Law (LGS), a requirement that doctors prescribe in the generic name, and the formal creation of a category of generic "bioequivalent" drugs, GI.

The government's response to the high price of drugs in the 1990s ultimately planted the seeds for a conflict that would come in the early 2000s. By creating a formal category of generic bioequivalent drugs without also making marketing authorization dependent on demonstrating bioequivalence, the government was, de facto, formalizing

[21] Here a useful contrast is to be made with the case of Argentina, where local industry pushed to reform the IP system as well. The difference is that the actors pushing the envelope in Argentina were among the countries' largest firms, with long histories of political activism.

an already-existent market for generic non-bioquivalent drugs. And this sector, known as the "branded generic" sector, took off in the late 1990s, as a chain of pharmacies selling generic non-bioquivalent drugs under the mark of *Similares* (Similars) expanded in low-income areas throughout the country (Hayden 2007). The pharmaceutical firms supplying these pharmacies were local firms that had existed for quite some time, typically selling through the state sector. The emergence of Farmacias Similares in the late 1990s gave these firms the opportunity to begin selling directly to the public in private pharmacies. In fact, the actors in the chain were closely related, for the most important firm (Laboratorios Best), in fact, was owned by the same person who launched the *Similares* brand.

The initiative to reform the patent was spearheaded by the generic non-bioequivalent (i.e. "branded generics") sector and its allies in Congress. In 2003, the Mexican Chamber of Deputies considered a reform to the compulsory licensing provisions of the IP law. The bill had its origins in an initiative presented by the Green Party (PVEM) in December 2002, which would have curtailed patent terms to ten years in the case of serious health situations, as declared by the Secretariat of Health. The original initiative, which was sponsored by the nephew of the owner of *Farmacias Similares* and Laboratorios Best, the giant "branded generics" enterprise that grew since the late 1990s and its principal supplier, was clearly afoul of Mexico's obligations under TRIPS (and NAFTA): both of these agreements require patents terms of twenty years, and nowhere in the agreements can one find a justification for curtailing the term to ten years.[22]

Instead of rejecting the proposal out of hand, the Chamber's Science and Technology Commission (CCyT) modified it. The president of the Commission, who acknowledged the basic concern expressed by the bill's sponsors, namely the effect of patent protection on access to essential medicines, decided to rewrite the proposal with proper legal assistance.[23] While the original proposal addressed patent terms (Article 23), the revised bill addressed "public utility licenses" (Article 77), an area where Mexico had significant policy flexibility under both TRIPS and NAFTA (indeed, the two agreements are identical with regard to their constraints on countries' provisions for compulsory licenses). In March 2003 the CCyT passed a modest reform that increased the capacity of the Health Secretariat to issue CLs in the case of health emergencies.

The March 2003 bill drew an astounding reaction from the transnational pharmaceutical industry, which put its full political machinery in action to stop the bill. Government officials and legislators immediately found themselves under pressure, besieged by letters, faxes, emails, and every other form of communication from the pharmaceutical industry's trade association, the USTR, embassies, and lawyers (CCyT

[22] The initiative suffered from other fundamental problems of logic too. For example, according to the proposal, firms that began producing drugs after the patent had been terminated would pay royalty fees to the patent "owner," – but if the patent has been terminated there are no owners, so no reason anyone should be paying royalties.

[23] Interview with former President of CCyT, 10 August 2007 (Mexico City).

archives; interviews). The lobbying was successful, for prior to the proposal being submitted to the full Chamber of Deputies for consideration, it was revised once again. This time, however, time bill *increased* the obstacles to issuing compulsory licenses. Once the issue of patent reform was introduced and opened, the transnational pharmaceutical sector then sought to secure a reform that was very much to its liking, one that would make the CL provisions less deployable than under the original 1991 law.[24] And it was this revised version that was passed by the Chamber of Deputies and Senate and then signed into law by President Fox in 2004.

In addition to the intense opposition that came from the transnational pharmaceutical sector, which is not surprising, a remarkable aspect of the Mexican effort to reform the patent system was the reaction of local industry. Outside of Similares and Best, even the local pharmaceutical sector rejected the initiative as originally passed by the CCyT. To understand this, it is important to underscore how the early implementation of pharmaceutical patents – indeed, the early and retroactive implementation, with the inclusion of pipeline patents – led to a fundamental transformation of local industry. In the late 1980s Mexico had a vibrant and large national pharmaceutical sector that thrived reverse-engineering and selling generic versions of drugs, a strategy that was feasible – and encouraged – by the pre-TRIPS patent system. Indeed, within Latin America, only Argentina had a larger national pharmaceutical sector (Gereffi 1983). By the early 2000s, however, patent protection – combined with a huge inflow of DFI in the pharmaceutical sector – led to a transformation of the industrial structure. Local industry was wiped out, essentially absorbed by the transnational sector. In contrast to Brazil, where national firms accounted for a quarter of the market, in Mexico local firms account for roughly 12% by number of firms, and even less in terms of market share (IMS data).

The transformation in industrial structure is reflected in the realm of politics. Whereas the local chamber (CANIFARMA) and the association representing the TNCs (AMIIF [had earlier name prior to 1994]) were arch-enemies during the IP debates of the 1980s and early 1990s, by the early 2000s they were speaking with one voice. Indeed, the two organizations were formally fused, with the president of CANIFARMA an invited member of the board of AMIIF and the two-year presidency of CANIFARMA alternating in each period between Mexican and foreign firms.

What about the industries selling bioequivalent generics to the local market? These, after all, are the firms that would stand to benefit from the proposal as passed by the CCyT. Were the Secretariat of Health to issue a public utility license to a local firm, it is fairly certain that such a license would go to one of the larger firms able to satisfy conditions of bioequivalence, not to one of the branded generics. Left to represent this segment of industry was ANAFAM (Mexican National Farmaceutical Association). Yet this organization found itself in stark decline in the late 1990s and early 2000s. In fact, ANAFAM did not represent a "national" pharmaceutical sector either, for this segment was undergoing transnationalization of its own, with large generic firms coming to

[24] Interview with Director General of AMIIF, 14 August 2007 (Mexico City).

Mexico and purchasing long-established Mexican firms. The largest generic firms in Mexico are transnationals (Teva, Kendrik, Quifa, Apotex).[25]Thus the bioequivalent generic sector, fighting on two fronts – against the TNCs and against the non-bioequivalent generics – and politically isolated on account of its own transnationalization, was in no position to lend its support to the CL initiative.[26]

The absence of a national pharmaceutical sector with interests and voice that were distinct from the transnational sector doomed the initiative. The advocates for change were isolated and lacked powerful allies. Those who could have benefited (the bioequivalent generic sector) were isolated in their own right, lacking ties to civil society or the state and caught between two threatening sectors, the non-bioequivalent producers on the one hand and the transnational originator firms on the other hand. What happened, then, was that the initiative to reform Mexico's CL clauses became a debate between these two antagonists, Similares vs. AMIIF, with the formal position of the "pharmaceutical industry" commandeered by the transnational sector. As indicated, Article 77 did end up being reformed, but perversely: the reforms strengthened the rights of patent owners; the revised article for CLs is more difficult to use than the original.

The mechanisms for post-patent generic entry were also reformed in this period. First, it is worth noting that the regulations on prescriptions (requiring physicians to prescribe by generic name) are not enforced and generally ignored.[27] Mexico also came under considerable pressure during this time to introduce a linkage system for marketing approval of generic drugs. In fact, Mexico was placed on the USTR's Priority Watch List in 2003 on account of its lack of linkage: according to the USTR, the health authorities regularly granted marketing approval to drugs where patents existed, and the public health sector purchased these non-patented products (USTR 2003 and 2004). In September 2003 – at the same time as the reform to the patent law was in the Senate – President Fox and Health Secretary Julio Frenk announced that a new linkage system would be put in place. Accordingly, the health authorities are required to consult with the IP office and not grant marketing authority to drugs where patents remain in effect.[28]

In thinking about the linkage system introduced in Mexico, the contrast with the Brazilian linkage system is noteworthy. In Brazil, the requirement that ANVISA grant "prior consent" to pharmaceutical patents formally subordinates IP authorities to health authorities. In Mexico, the requirement that COFEPRIS consult with IMPI formally

[25]Here it's worth noting that TNCs' strength depends, in part, on alliance with home states, and these TNCs were not the segment of pharmaceutical industry that had close links with policymakers in home countries.

[26]ANAFAM's strategy was clear: we know some of our firms could stand to benefit from this, but it would be politically risky – and thus unadvisable – to publicly push for the initiative (letter in CCyT archive).

[27] I lack the sort of data that could provide firm evidence to demonstrate this, but the uselessness of this law was noted by virtually everyone with whom I spoke, and is regularly commented on in press too.

[28] In 2003 the Secretariat of Health also pledged that IMSS and ISSSTE would cease purchasing generic versions of drugs that are patented in Mexico (USTR 2004).

subordinates health authorities to IP authorities. The different trajectories could hardly be more different, and the differences cannot be explained by NAFTA. Though the type of linkage system introduced in Mexico is typically included in recent RBTAs that the USA signs, it was not a part of NAFTA. Indeed, the change came nearly a decade after NAFTA entered into force. The driving force here was not NAFTA, per se, but rather the increased strength in the Mexican political economy of the transnational pharmaceutical industry, and increased power of the IP coalition within the Mexican state. It's not a story about ideas and laws, but interests and power.

At the same time as introducing the linkage system, Mexico also introduced an early working provision. Yet this is largely undermined by the routine adjustment of the expiration dates on pipeline patents. The Mexican articles on pipeline patents (transitory articles 11-12) include provisions that explicitly state that patents filed under pipeline provisions retain their date of filing from original PCT countries and that they expire in Mexico on the same date as they expire in the first country where the patent was filed. These clauses, though contested in courts, essentially commit Mexico to adjust (i.e. extend, in the language of the generic firms, or correct, in the language of the originator firms) expiry dates.[29] Because patent terms are adjusted in Mexico when they adjusted in the original country, no one really knows when the patent terms will end. The result, then, is that the early working provisions are rendered essentially useless.

Conclusion

The episodes of national IP reform discussed in this paper mirror and correspond to episodes of IP reform that occurred at the international level. Unfortunately analysts of the politics of IP have focused almost exclusively on the latter set of events (see note 3 above, which includes references to only a tiny share of the countless studies on the international dimensions of IP and health). A critical objective of this paper is to emphasize the importance of studying the national politics as well. International rules need to be transmitted and implemented nationally. Why Mexico takes comparatively less advantage of TRIPS flexibilities – and why Mexico takes little advantage of prerogatives set by its own IP system – are questions that cannot be answered just by looking at the international politics of IP.

Obviously the internal is affected by the external, but the paper also aims to bring politics to bear on a topic that has been dominated by analysts of laws and formal international agreements. In the case of the comparison between Brazil and Mexico, for example, a focus on external legal obligations would bring our attention to NAFTA, which includes IP provisions that differ from TRIPS (Table 2). Mexico signed NAFTA in 1993, and it went into effect in 1994, even before TRIPS. Yet this is an insufficient explanation. Mexico's patent regime differs from Brazil's not because of the former

[29] I'm not explaining the origins of these different clauses here, but it's worth noting that the inclusion of PP provisions was much more controversial in Brazil than in Mexico, and this likely contributes to the less-expansive version in Brazil.

countries' legal obligations under NAFTA.[30] Indeed, as discussed above and illustrated in Table 3, in the late 1990s the two countries had nearly identical patent systems regarding health (not in other realms), and the subsequent divergence did not in any way conform to unique obligations that Mexico had under NAFTA (indeed, everything that Brazil did would be acceptable under NAFTA too).

Rather than focus on laws and external obligations, I have attributed the divergence to politics and alliances over IP management. Nor is it enough just to focus on backlash and health activism, which we witness in both countries. We need to ask how and why backlash does or does not affect policy. To that end I focus on how transformation of interests in state and industry affect the nature of available alliance partners, placing particular emphasis on the transformation of local pharmaceutical sectors.

What is clear from the analysis is that NAFTA is indeed extremely significant, but in a broader political economy sense than the way NAFTA is typically invoked as an explanation. After all, the first wave of IP reform (complying with TRIPS) sets the countries on different paths, for that is what drives the changes in industry and thus affects the subsequent availability of alliance partners. Mexico introduced pharmaceutical patents – and pipeline patents – considerably earlier than Brazil. By the time the relationship between patents, drugs, and health became a prominent political issue, internationally and nationally, the Mexican pharmaceutical industry had already been reshaped by the first wave of reform, while pharmaceutical patenting in Brazil had just kicked in. NAFTA, then, is essential not on account of the IP provisions per se, but rather the broader effects that NAFTA has had on Mexican economy and politics. That is, the real and more profound effects of NAFTA are in how it triggers different patterns of industrial change, which in turn affect politics and policy choice. In sum, we should reorient our attention from NAFTA as treaty to NAFTA as political economy.

Of course, a number of factors distinguish Brazil from Mexico, not just the availability of local pharmaceutical firms as an ally of the IP-for-health coalition. Brazil's Minister of Health was a prominent political figure, who was not just uncharacteristically close to the President but who had his own presidential ambitions. Indeed, in 2002 José Serra would run (unsuccessfully) for the presidency, and health activism certainly needs to be understood in this larger political-electoral context. In Mexico the Ministry of Health remained subordinated within the cabinet, as it always had been (and as it was in Brazil, pre-Serra). But institutional institutions of this sort have their limits. Were the Brazilian Ministry of Health transported to Mexico, it is likely that efforts to emulate the Brazilian strategy would have failed, because of the strong reaction of the transnational pharmaceutical sector and local industry's political disarticulation and lack of independent voice. Indeed, on a number of issues related to generic medicines, the Ministry of Health in Mexico made extensive efforts to reach out to and collaborate with

[30] To be sure, the IP provisions of more recent RBTAs are much more restrictive (Shadlen 2005), but NAFTA, as the first sort of RBTA to include IP and prior to TRIPS, does not constitute a strong case in this regard.

local, generic producers, but it received little response. At each turn, the landscape looked the same: transnationals vs similares. Thus, there is good reason to believe that even a more prominent and ambitious Ministry of Health would have lacked reliable allies in the pharmaceutical industry. Industrial transformation and denationalization have political and policy consequences.

To conclude, it is worth returning to the two areas where IP matters, as the paper began: technology and industrialization, and health and humanitarianism. The findings in this paper bridge these two realms, for the key variable explaining differences between Brazil and Mexico has been the existence of local pharmaceutical sectors. A quarter-century ago, in a famous book on pharmaceutical industries in the developing world, Gereffi (1983) argued that successful promotion of local pharmaceutical sectors may be good for industrial development, but that because such sectors tend to extract rents in goods of great importance to most consumers (i.e. medicines), such strategies were less beneficial on the humanitarian axis of development.[31] The argument and findings in this paper invert this line of reasoning: to use IP to achieve humanitarian goals, countries need to first use IP to achieve industrial goals – they need have independent, local pharmaceutical sectors. Indeed, whereas as Gereffi (1983) depicted pharmaceutical development as good for industrialization but not for humanitarianism, I have shown how pharmaceutical development may be good for both, because it makes humanitarianism politically feasible in world of strong IP. The key variable in explaining efforts to reform patent systems to increase access to drugs is the presence of an autonomous, national pharmaceutical industry that is available as an alliance partner for those pushing for such reforms. In short, the key to IP-for-humanitarianism is maintenance of some degree of IP-for-industrialization.

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[31]Writing about Argentina, for example, where industrial policy successfully promoted a local pharmaceutical sector that then charged high prices to consumers, Gereffi concluded that "high prices of drugs thus may be viewed as an acceptable trade-off for the consolidation of a local industrial bourgeoisie, which is often considered an essential step in achieving some form of nondependent development" (1983: 223). See also Chudnovoski (1979: 55-56).

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