

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

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ABSTRACT

After introducing pharmaceutical patents in the 1990s, Brazil subsequently adjusted the patent system to ameliorate its effects on drug prices while Mexico introduced measures that reinforce and intensify these effects. The different trajectories are due to the nature of the actors pushing for reform and subsequent patterns of coalitional formation and political mobilization. In Brazil, government demand for expensive, patented drugs made health-oriented patent reform a priority, and the existence of an autonomous local pharmaceutical sector allowed the Ministry of Health to build a supportive coalition. In Mexico, government demand made reforms less urgent, and transformations of the pharmaceutical sector allowed patent-holding firms to commandeer a reform project. The existence of indigenous pharmaceutical capacities can broaden the political coalitions underpinning health reforms.

Intellectual property (IP) policies influence trajectories of industrial development and capacities to address humanitarian concerns.* As pillars of national systems of innovation, IP regimes drive technological change through their effect on knowledge-creation and knowledge-diffusion. By affecting access to technologically-intensive goods, such as pharmaceuticals, IP regimes influence national public health programs. This article bridges these dimensions. Analysis of the politics of drug patents in Brazil and Mexico shows that how IP affects the industrial sector – particularly the pharmaceutical industry – establishes the political economic parameters affecting countries’ abilities to use IP to promote public health.

Prior to the 1990s, neither Brazil nor Mexico (nor many other developing countries) granted patents on pharmaceuticals.¹ Local firms could produce “generic” versions of new drugs – drugs that typically were patented in the OECD.² In the 1990s, both countries introduced pharmaceutical patents to comply with new international obligations. The World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the IP provisions of the North American Free Trade Agreement (NAFTA) prohibit countries from declaring pharmaceuticals non-patentable; and the agreements require countries to provide patent-holders with strong rights of exclusion over the knowledge contained in the patent.

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¹Until the 1970s and 1980s many developed countries did not issue pharmaceutical patents either.

²By “generic” I refer to drugs un-protected by patents. Some definitions also stipulate that the drug be un-protected by trademark. Although “generic” does not mean the same thing everywhere, Brazilian and Mexican regulations share a common definition. Núria Homedes and Antonio Ugalde, “Multisource drug policies in Latin America: survey of 10 countries,” *Bulletin of the World Health Organization*, 83 (January 2005), 64-70.

Providing market exclusivity to owners of drugs can raise prices, place drugs out of consumers' reach, and strain governments' health budgets.³ Not surprisingly, the introduction of drug patents was followed by backlash, and by the late 1990s policymakers in many developing countries faced subsequent pressures to modify their new IP systems.

Policy in Brazil and Mexico took different courses in response to this changing scenario. Brazil adjusted the IP system to ameliorate the effects that drug patents can have on prices and access; Mexico introduced few adjustments, and where changes were introduced they tended to reinforce and intensify the effects of drug patents. Variation in IP policy 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 become more difficult, and the rights of third parties to use knowledge simplified. In Mexico, 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 in NAFTA, while Brazil has no external obligations beyond its membership in the WTO. Although NAFTA places greater restrictions on IP policy, reliance on NAFTA as an explanatory factor is inadequate. Differences in the two countries' international legal obligations 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 that Mexico could not take the same path as Brazil on

³World Health Organization, "Intellectual Property Protection: Impact on Public Health," *WHO Drug Information*, 19 (August 2005), 236-241; Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: CIPR, 2002), ch. 2; Brigitte Granville, ed., *The Economics of Essential Medicines* (London: Royal Institute of International Affairs, 2002); Julio Nogués, "Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries," *The Developing Economies*, 31 (March 1993), 24-53.

account of its “WTO-Plus” commitments. But the reforms introduced by Brazil would not violate NAFTA; legally, Mexico could imitate Brazil. Moreover, a strict emphasis on NAFTA cannot explain why Mexico reformed its IP system by moving in the opposite direction as Brazil. Mexico did not simply fail to emulate Brazil’s IP move from away from “TRIPS-Plus” but rather moved to an extended version of TRIPS-Plus.

Nor can the outcome be explained by focusing on political bias.⁴ To be sure, the Brazilian governments in the period under study (Cardoso 1994-2002; Lula 2002 --) were more “left-leaning” than their Mexican counterparts (Zedillo 1994-2000; Fox 2000-2006), which perhaps might lead us to expect Brazil to prioritize health. Yet the major health-oriented reforms occurred under President Cardoso, the more centrist of the two Brazilian presidents. This is the same Cardoso that championed the original TRIPS-Plus patent law in 1996, and the subsequent policy shift is not linked to prior changes in ideological disposition or political bias. In Mexico, the “right-leaning” Fox government introduced progressive reforms to the health system, initiating reforms to make access to healthcare a citizen-based rather than employment-based right.⁵

A political economy explanation for Brazil and Mexico’s divergent trajectories of patent policy focuses on the actors pushing for reform and subsequent patterns of coalitional formation and political mobilization. In both countries, drug patents and high prices yielded initiatives for health-oriented IP reform. What varies is who led these initiatives and the extent to which important actors in local pharmaceutical sectors were available as coalition partners. In Brazil, the existence of an economically and politically more autonomous local pharmaceutical sector allowed the Ministry of Health to build a coalition in support of IP

⁴Maria Victoria Murillo, “Political Bias in Policy Convergence: Privatization Choices in Latin America,” *World Politics*, 54 (July 2002), 462-493.

⁵In fact, Fox’s appointment as Health Secretary was well-known for his long-standing call for universal health coverage.

reform. In Mexico, fundamental transformations of the pharmaceutical sector yielded a different terrain. In fact, the reform project in Mexico became commandeered by IP owners and ultimately had the perverse effect of reinforcing the system that was challenged.

Of course, the transformation of Mexico's pharmaceutical sector that I emphasize are not unrelated to NAFTA, which implied substantial tariff reduction and revisions to government procurement practices that previously afforded special treatment to local firms. These broad shifts in policy, including pharmaceutical patent protection, induced changes to Mexico's industrial sector that would ultimately restrict the realm of feasible policy alternatives. NAFTA is indeed significant, then, but in a broad political economy sense. A lesson of this article for scholars of international and comparative political economy is that we need to reorient our attention from the legal to the political economy aspects of international agreements, i.e. not the rules per se but how such agreements unleash economic and social changes that, in turn, affect subsequent policy choices.

This article also presents lessons for analysts relying on models of policy diffusion.⁶ Diffusion models depict policymaking as an interdependent and interactive process, in which the likelihood that a given policy will be adopted in one country is a function of its adoption (or non-adoption) in other countries. Some analysts apply this logic to the case of IP and drugs. Nunn *et al* suggest that Brazilian officials learned from Thailand's example of using IP regulations to challenge transnational pharmaceutical firms' pricing practices.⁷ Cohen and

⁶Special issues dedicated to the theme of policy diffusion of *Annals of the American Academy of Political and Social Sciences*, 598 (March 2005) and *International Organization*, 60 (October 2006). See also Beth Simmons and Zachary Elkins, "The Globalization of Liberalization: Policy Diffusion in the International Political Economy," *American Political Science Review*, 98 (February 2004), 171-189; Jeffrey Chwierorth, "Neoliberal Economists and Capital Account Liberalization in Emerging Markets," *International Organization*, 61 (Spring 2007), 443-463; Sarah Brooks, "When Does Diffusion Matter? Explaining the Spread of Structural Pension Reforms Across Nations," *Journal of Politics*, 69 (August 2007), 701-715.

⁷Amy S. Nunn, et al., "Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment," *PLoS Medicine*, 4 (November 2007), 1-13.

Lybecker suggest that the Brazilian example of health-oriented IP reform can lead other countries to act similarly, even citing Mexico as a country so inspired by Brazil.⁸ Indeed, learning from members of countries' "peer groups" is a principal mechanism of diffusion in this literature.

Although the *idea* of reforming the IP system for public health purposes diffused from Brazil to Mexico, the *policy* did not. The legislative initiative proposed to modify Mexico's patent system made explicit reference to the Brazilian experience that was to be replicated, but once the diffused idea placed IP on the political agenda in Mexico, the initiative became commandeered by those who did not want Mexico's patent rules to be made more useful for the government to negotiate price reductions, but rather more useful for patent-holding firms to strengthen their property rights and ward-off competition. The product of diffusion was not Mexico adopting policies that worked in Brazil, but rather policies that were the mirror image of those in Brazil. The explanation for this difference is in the identity of the actors receiving and attempting to implement the diffused idea of health-oriented IP, and the availability of powerful alliance partners for those actors advocating reform. The article, thus, provides a caution against overstating the significance of ideas and policy communities, and calls for renewed attention to traditional variables such as interests and resources.

In the next section I present a framework for comparing health-related aspects of national patent regimes, which I use to illustrate commonalities between Brazil and Mexico in the mid-1990s. I then explain subsequent divergence in the health-related aspects of these two countries' patent systems. In the fourth section I conclude, synthesizing the key findings and pointing to broader implications for analysis of the political economy of late development.

⁸Jillian Clare Cohen and Kristina M. Lybecker, "AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health," *The World Economy* 28 (February 2005), 226.

Patents, Pharmaceuticals, and Health Policy

Prior to explaining the different policy trajectories experienced by Brazil and Mexico in health-related dimensions of IP, we need understand the range of variation. In this section I provide a framework that allows us to conceptualize variation with regard to patents, pharmaceuticals, and health policy.⁹

Patents confer limited rights of exclusion over inventions that are new, non-obvious, and have industrial use. Although the grant of a patent constitutes turning knowledge into private property, the subsequent rights of owners over their property are limited in that they are not automatic, not absolute, and not permanent. Patents are granted only where applicants demonstrate that their inventions satisfy the criteria of patentability. With application and examination central – and prior – to the process of establishing ownership, governments can control what knowledge becomes private property within their territory. Another limitation is that patent rights include various exceptions to patent-holders' ability to control the use and distribution of their property. Patent regimes include provisions by which third parties can – without requesting permission – 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 of patent-holders' rights. Lastly, patents expire: at some point the private property enters the public domain, where access to and use of the knowledge is unrestricted.

These three limitations map onto lines of political conflict over what can be owned privately, between the rights of owners and users of private property, and over the duration of rights. These lines of conflict, in turn, map roughly¹⁰ on to axes of policy variation. The rows

⁹For detailed discussion, see Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in the Developing Countries* (Geneva: South Centre, 2000); CIPR, ch. 2.

¹⁰In fact, some policy areas are relevant to multiple lines of conflict.

in Table 1 take us from a limitation to a political conflict and then provide health-related policy examples.

-- Table 1 --

With regard to conflicts over what sort of knowledge can be owned privately, the most important policy issue 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 countries grant patents on pharmaceutical products and processes.¹¹

A second policy issue regards how to deal with inventions that are not new but that were not patented when they were new because the previous regime did not allow the sort of knowledge to be patented. If a country began granting pharmaceutical patents in 1995, for example, a drug that was invented in 1990 would not have been eligible for a patent when it was new. The novelty requirement would also make the drug unpatentable in 1995, even with the introduction of pharmaceutical patents, because it was no longer new. Since drugs are patented before marketing authority is secured, the 1990 drug would most likely be undergoing clinical trials in 1995 – it would be in the “pipeline.” How do countries introducing pharmaceutical patents treat drugs in the pipeline? On this dimension NAFTA exceeds TRIPS by obligating countries to offer “pipeline patents.”¹²

Policy areas that correspond to conflicts over the rights of owners vs. users regard compulsory licenses (CLs) and parallel imports. CLs allow domestic entities (public or private) to import, produce, and distribute patented goods without the patent-holders’ consent. TRIPS and NAFTA allow countries to determine the grounds on which they grant CLs, provided that a set of procedural conditions (e.g. prior negotiations with the patent

¹¹Countries that did not grant pharmaceutical patents prior to 1995 had until 2005 to begin doing so.

¹²In addition to stretching the definition of “novelty,” the problem with pipeline patents is that that they are not examined but rather revalidated.

holder, payment of royalties are met).¹³ In the case of CLs granted during times of national emergency or for government use, countries are released from the obligation of prior negotiations.¹⁴ Because potential delays introduced by negotiations are removed with this latter type of CL, they are easier and quicker to grant and, arguably, of most relevance for discussions of health.

Parallel importation consists of allowing patented goods to enter the market once patent-holders have placed the goods on the market elsewhere. Parallel imports can help ensure affordability of patented products by facilitating arbitrage and thus constraining patent-holders' ability to set monopoly prices. TRIPS allows countries to engage in parallel importation by adopting *international* doctrines of patent exhaustion, i.e. once products are placed on the international market, patent-holders' exclusive rights are exhausted. NAFTA prohibits parallel importation by requiring *national* doctrines of patent exhaustion.

Health-related policy areas corresponding to conflicts over the length of rights regard post-patent generic entry. When patents expire and knowledge enters the public domain, new actors gain rights to participate in markets that were reserved for patent-holders. How quickly new actors enter markets and the subsequent competitive effects are felt in terms of reduced prices depends on a number of important policies, particularly early working provisions and procedures for registering generic drugs. Early working provisions allow firms to use patented knowledge and produce generic versions of patented drugs to obtain marketing

¹³Compare the nearly identical CL provisions of TRIPS Article 31 (http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5) and NAFTA Article 1709.10 (<http://www.sice.oas.org/Trade/nafta/chap-171.asp>).

¹⁴This provision, that when CLs are issued on grounds of national emergency countries are released from procedural obligations, is often misrepresented to suggest that countries can only issue CLs in national emergencies. To repeat: countries can issue CLs on whatever grounds they establish in national legislation, but in times of national emergency (and government use) they can bypass negotiations.

approval once patents expire.¹⁵ Without such provisions firms might be infringing patents by producing generic versions prior to the patents' expiration. Yet if firms must wait until patents expire to produce generic versions and apply to health authorities for authorization, patent terms are effectively extended by the amount of time it takes to complete these not-insignificant steps. Early working provisions, then, by allowing generic firms to use patented knowledge to prepare for market entry, can expedite competition at the point that patents expire. TRIPS and NAFTA both permit early working provisions.¹⁶

Some pharmaceutical firms opt to launch generic versions prior to the end of patent terms, believing that their follow-on products do not infringe existing patents or that the patents in question are invalid. Since marketing drugs depends on authorization from health authorities, the subsequent question is whether and how the activities of IP and health officials are coordinated. Neither TRIPS nor NAFTA addresses this. More recently, as we shall see, the US 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 in force. While this form of coordination seems unproblematic on the face of it (if the drug is patented, then the sale of generic versions would be illegal), many developing countries resist pressures to proceed in this direction, arguing that linkage inappropriately transfers the burden of defending patents from the private rights-holder to the public. In any case, this form of linkage, though included in more recent regional and bilateral trade agreements (RBTAs) that the US has negotiated, is not in NAFTA.

¹⁵Formally, early working (also called "Bolar") provisions are examples of limiting owners' rights of exclusion, but where they most matter regards the effective duration of owners' rights.

¹⁶Such provisions do not shorten patent terms but rather eliminate the effective extension of terms that is yielded by leaving a single firm with market exclusivity despite the patents' expiration. I am not addressing data exclusivity.

Table 2 contrasts the WTO and NAFTA with regard to the health-policy dimensions of the two agreements' IP provisions. While it is clear that there are differences, such as pipeline patents and parallel imports, the similarities are certainly greater.

-- Table 2 --

The WTO's and NAFTA's provisions indicate the parameters of what countries can and cannot do, but not what they *do* do. Table 3 presents the main characteristics of the Brazilian and Mexican patent regimes implemented in the 1990s. Both countries greatly exceeded their new obligations, making ownership easy to obtain over a wide variety of pharmaceutical and pharmo-chemical products and processes, and giving owners strong – and effectively long – rights of exclusion. From a public health perspective, both countries' patent regimes were worrisome. For example, both countries offered pipeline patents, neither allowed parallel imports, both had only rudimentary mechanisms for compulsory licenses to deal with health concerns, and neither had early working provisions. As a result of these “TRIPS Plus” patent regimes, more drugs would become patented in both countries and it would be difficult to rely on generic competition to reduce prices. Beginning in the late 1990s, however, the two countries diverge in dramatic fashion. The subsequent sections explain this divergence, drawing our attention to the important role of local pharmaceutical industries in coalitions for health-oriented patent reform.

-- Table 3 --

Brazil: From TRIPS Plus to “TRIPS Just”

In the late 1990s and early 2000s, health-related aspects of Brazil's patent regime underwent substantial modifications. Obtaining pharmaceutical patents became more difficult, the patent law was modified to facilitate government efforts to lower prices through compulsory licensing, and the government enacted measures to encourage competition with generics. The nature of the Brazilian government's demand for patented and expensive drugs

made health-oriented IP reform a high priority, and the political organization and structure of the Brazilian pharmaceutical industry made reform politically feasible.

The Brazilian government's demand for drugs was strong – and relatively inelastic to price – on account of the Ministry of Health's (MH) extensive obligations to provide free medicines. These obligations are rooted in the 1988 Constitution, which establishes the right to health, including access to essential medicines through the new national healthcare system (SUS), as a universal right. Government demand was particularly shaped by the HIV/AIDS epidemic. Although Brazil's adult prevalence rate of 0.6% is not particularly high by international standards, the country stands out for its early (since the late 1980s) and comprehensive approach toward prevention and treatment. Importantly, a 1996 Law guaranteed free anti-retroviral (ARV) treatment through the MH's National HIV/AIDS Program, and intense social mobilization further reinforced the government's obligations.¹⁷

Brazil's approach to HIV/AIDS treatment affected the government's demand in such a way as to make IP reform an imperative. Because ARVs treat but do not cure HIV/AIDS, they need to be taken indefinitely; and patients need to change treatment regimens as immunities develop. By the late 1990s the annual per patient cost of treatment in Brazil was nearly US\$5000 and ARVs already consumed one-third of the MH's drug budget – and this

¹⁷Guido Carlos Levi and Marco Antonio A. Vitória, "Fighting Against AIDS: The Brazilian experience," *AIDS*, 16 (2002), 2373–2383; Paulo Texeira et al, "The Brazilian Experience in Providing Universal Access to Antiretroviral Therapy," in Moatti et al, ed., *Economics of AIDS and Access to HIV Care in Developing Countries* (Paris: ANRS, 2003), 69-88; Jane Galvão, "Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health," *American Journal of Public Health*, 95 (July 2005), 1110-1116; Alexandre Grangeiro et al, "Sustentabilidade da política de acesso a medicamentos anti-retrovirais no Brasil," *Revista de Saúde Pública* 40 (Supplement 2006), 60-69; João Biehl, *Will to Live: AIDS Therapies and the Politics of Survival* (Princeton: Princeton University Press, 2007); Anne-christine d'Adesky, *Moving Mountains: The Race to Treat Global AIDS* (New York: Verso, 2004), ch. 3. Mathew Flynn, "Public Production of Anti-Retroviral Medicines in Brazil, 1990-2007," *Development and Change* 39 (July 2008), 513-536. Thus, in the context of persistent inequities in health services (Kurt Weyland *Democracy Without Equity: Failures of Reform in Brazil* [Pittsburgh: University of Pittsburgh Press, 1996], ch. 7), the National HIV/AIDS Program offers an exception.

was at a time when treatment featured almost exclusively unpatented drugs. As more people began treatment and as patients migrated to expensive second-line regimens based on drugs that were patented under Brazil's new IP law, the program would be unsustainable.¹⁸

Since 1999, then, the government took a range of measures to improve the capacity of the National HIV/AIDS Program (and the SUS more generally) to acquire less-expensive, generic versions of newer drugs from both foreign and local suppliers. The MH's initiative to lower costs via promotion of generics led to three important modifications of Brazil's new IP system: health authorities gained prominence in reviewing patent applications, compulsory licensing provisions were made more flexible and easier to use, and regulatory reforms were introduced to expedite post-patent generic entry.

Any pharmaceutical patent application that is approved by the National Institute for Industrial Property (INPI) is sent to the MH for review. The patent is issued only after IP officials in the Ministry's health surveillance agency (ANVISA) issue "prior consent."¹⁹ This reform, introduced by decree by President Cardoso in 1999 and converted into law in 2001, aimed to provide the MH with an instrument to influence the patent-examination process, influence that it would otherwise lack on account of INPI being situated within a different ministry.

The prior consent requirement makes it more difficult to obtain private rights of exclusion over knowledge for pharmaceuticals. Many patent applications are not for new molecular entities (NMEs) but rather revised versions of NMEs that are already patented,

¹⁸Levi and Vitória; Grangeiro et al; Ministry of Health, "The Sustainability of Universal Access to Antiretroviral Medicines in Brazil," 157th Ordinary Meeting of the National Health Council, Brasília, August 2005. The former Minister of Health also emphasizes that an overvalued currency cheapened drug imports, a situation that changed with the Real's devaluation in 1999. José Serra, "The Political Economy of the Brazilian Struggle Against AIDS," Institute for Advanced Study, Occasional Paper 17, 2004, p. 9.

¹⁹ANVISA's IP division, established in 2001, was housed in INPI's Rio office building.

raising the question of how patent examiners define “novelty.”²⁰ ANVISA’s health-focused criteria are significantly stricter than INPI’s.²¹ Whereas INPI is criticized by health activists and lawyers for adopting an overly broad definition of novelty, ANVISA denies patents to drugs that lack “genuine” novelty and where it adjudges that providing exclusive rights would be harmful to public health. Typically ANVISA uses its authority to prevent patents that, by its judgment, would extend the terms of existing patents.²² As Table 4 indicates, 53 applications approved by INPI have been rejected by ANVISA since the prior consent process was initiated in 2001. Perhaps more critically, of the 68.9% of the applications that ANVISA has approved, in 42% of these cases the applicant first had to reduce the breadth of the patent’s claims.²³

-- Table 4 --

No aspect of the global politics of IP has received so much attention as compulsory licenses, and Brazil has been at the forefront of these debates. The 1996 LPI includes multiple articles that address CLs, the most significant for our purposes being Article 71 covering national emergencies and situations of “public interest.” Presidential directives in 1999 and 2003 reformed Article 71 to make it more useful and thus increase the MH’s

²⁰ Does showing a “second use” for an existing drug constitute “novelty” and warrant a patent?

²¹ Maristela Basso, “Intervention of Health Authorities in Patent Examination: The Brazilian Practice of the Prior Consent,” *International Journal of Intellectual Property Management*, 1 (2006), pp. 54-74; Maristela Basso and Edson Beas Rodrigues, “Direitos de Propriedade Intelectual, Desenvolvimento Humano e Tecnológico Local: Desafios para o Brasil no Cenário pós-TRIPS/OMC,” Unpublished UNDP working paper, 2006, Annex 1.

²² This policy corresponds to two types of conflicts, what knowledge can be owned and also the duration of private rights.

²³ Helen Miranda Silva, *Avaliação da análise dos pedidos de patentes farmacêuticas feita pela Anvisa no cumprimento do mandato legal da anuência prévia*. Masters Dissertation, National School of Public Health, 2008. One important hitch with the process is how INPI reacts when ANVISA rejects a patent. See Kenneth C. Shadlen, “The Political Contradictions of Incremental Innovation in Late Development: Lessons from Pharmaceutical Patent Examination in Brazil,” unpublished manuscript, London School of Economics, 2009.

capacity to leverage price reductions from patent-holding pharmaceutical firms.²⁴ These revisions gave clearer definitions of national emergency and public interest and simplified the mechanism for issuing CLs by giving the MH greater authority to act. Importantly, the 2003 directive stipulates that private firms supplying the government constitutes “public use” and is thus acceptable under Article 71, and also requires patent owners to transfer technological knowledge in the case of CLs.²⁵

The threat of a CL is a bargaining tool used to entice patent-holders to make their products available at lower prices. The effectiveness of the bargaining tool, however, depends on the credibility of the threat. The reforms to Article 71 make the Brazilian government’s threats more credible by making CLs easier to issue and less vulnerable to appeal, and by increasing the government’s ability to secure the relevant drugs from alternative suppliers.

Since 2001 the MH has repeatedly used the CL instruments to obtain price reductions on second-line ARVs that consume a disproportionate share of the MH’s drug budget. The key ARVs (patent-holders) are efavirenz (Merck), lopinavir/ritonavir (Abbott), and Nelfinavir (Roche), which account for roughly sixty percent of the government’s ARV expenditures. In August 2001, for example, the MH announced it would issue a compulsory license on nelfinavir, and Roche responded by reducing the price. Similar episodes occurred with Roche and also Abbott, and Merck in 2003, and then, again with Abbott in 2005. In 2007, following protracted negotiations with Merck, Brazil issued a CL on efavirenz. Note that these drugs are patented in Brazil because of the inclusion of pipeline patents in the 1996 LPI. Thus, to an important extent, the reforms to – and exercise of – the CL provisions can be understood as efforts to ameliorate the effects of the “TRIPS Plus” LPI.

²⁴Although presidential directives are meant to establish implementation guidelines and not formally reform laws, they are often substantive, as in this case.

²⁵A different article (Art. 68, which authorizes CLs where a patented good is not manufactured locally) was the subject of a WTO case that the US filed and later withdrew.

Negotiations have not always been entirely successful: the 2005 agreement with Abbott left the price of lopinavir/ritonavir well above Abbott's most-discounted international price, for example, and the MH is widely criticized for not issuing more CLs.²⁶ Yet the MH's strategy, its shortcomings notwithstanding, has resulted in significant cost savings, even as patented second-line treatments play increasingly greater roles in the national treatment program.²⁷ In fact, while the affordability of second-line ARVs provided the main impetus for IP reform, the modifications have yielded lower drug prices across the board.²⁸

The Brazilian strategy to introduce generic competition also included amending the 1996 LPI to introduce an early working provision, which allows generic firms to prepare for market entry at the moment of patent expiration.²⁹ Importantly, Brazilian authorities refuse to adjust terms for patents granted under the pipeline mechanism. That is, if a patent had a priority date from its USPTO application of 31 January 1987, for example, and was granted in Brazil under the pipeline mechanism in 1999, the patent would be due to expire in both the US and Brazil on the same day, 30 January 2007. And even if the USPTO were to extend the expiry date by two years, so that the patent expired in January 2009 in the US, it would still expire in 2007 in Brazil. The transnational sector pushes strongly for adjusting patent terms in this way and regularly demands this in court, but doing so is not the norm in Brazil.³⁰ The bias against adjustments of patent terms provides generic producers with incentives to utilize the early working provision. The effectiveness of the system is further enhanced by

²⁶ Rebrip, "Acordo do Governo Brasileiro com a Abbot Frustra Expectativas dos Brasileiros," 13 July 2005 (http://www.rebrip.org.br/_rebrip/pagina.php?id=659); Grangeiro et al. See the comments of Pedro Chequer, former director of the National HIV/AIDS Program, in Jon Cohen "Brazil: Ten Years After," *Science*, 313 (28 July 2006), 484-487.

²⁷ Nunn et al; Cohen and Lybecker; Galvão; Cohen, "Brazil: Ten Years After."

²⁸ Nunn et al.

²⁹ Introduced by presidential decree, then converted into law in 2001.

³⁰ "Patent Term Extensions in Mexico Buck Latin American Trend," *Global Insight*, 2 January 2008 (<http://www.globalinsight.com/SDA/SDADetail11297.htm>).

ANVISA's policy of granting rapid approval of products that satisfy health criteria, leaving questions of potential patent infringement to be contested in courts.

While the nature of demand has driven the Brazilian government to introduce these health-oriented IP reforms, the support of the Brazilian pharmaceutical sector makes doing so feasible. The reforms have, not surprisingly, drawn strong criticism from the transnational pharmaceutical sector, both its representatives in Brazil (INTERFARMA) and the US (PHARMA). Actors that once heaped praise on Brazil for its "modern" 1996 LPI now complain of piracy and theft.³¹ But these attacks do not isolate the government, which can rest on the support of a coalition of actors representing the national pharmo-chemical (ABIFINA) and pharmaceutical (ALANAC, ALFOB, and ProGenéricos) producers. These organizations – some of which unsuccessfully resisted the 1996 LPI – act as a bulwark against INTERFARMA, consistently presenting positions contrary to those of the transnational sector. When INTERFARMA assailed the reforms introduced in 1999 and 2000 or the 2007 CL, for example, ABIFINA quickly came to the MH's defense.³²

The existence of a coalition supportive of health-oriented IP reforms is partially a function of state policy. After all, the local pharmaceutical sector benefited from significant

³¹ These complaints and accusations were repeated in multiple interviews with representatives from INTERFARMA, patent lawyers in Brazil, and USTR officials. See, as examples, Frederico Vasconcelos, "Mudanças na lei desagradam múltis," *Folha de São Paulo*, 21 February 2000; Lawrence A. Kogan, "Brazil's IP Opportunism Threatens U.S. Private Property Rights," *Inter-American Law Review*, 38 (Fall 2006), 1-139; Igor Leonardo Guimarães Simões, "A Guerra das patentes farmacêuticas," *Jus Navigandi*, 9 (28 May 2005). See also the USTR's annual "Special 301" reports on IP, and PHARMA's submissions to these reports.

³² See, for example, Vasconcelos, "Mudanças na lei desagradam múltis"; Marcos Oliveira, "A falácia da quebra de patente," *Jornal do Commercio*, 10 April 2006 (column by ABIFINA's vice-president published in newspapers throughout Brazil); Eduardo Costa and Nelson Brasil, "A Emancipação do Programa anti-Aids," *Jornal de Brasília*, 15 November 2007. Brazilian industry's position is not uniform, of course, nor its support rock-solid. On some issues, particularly those affecting patenting of incremental innovations, local firms are ambivalent and divided. Shadlen, "The Political Contradictions of Incremental Innovation in Late Development."

government investment in research and production, much of it through the MH itself.³³ The Ministry, acting as “health entrepreneur,” does not just purchase drugs but also takes an active role in their production.³⁴ Public-sector labs are important suppliers to the government, and, earlier on the production chain, the state works with private firms to help them develop synthesis technologies, produce necessary intermediates, and acquire capacities for reverse-engineering active principal ingredients (APIs).

Economic and technological collaboration between the public and private sectors created conditions for a political alliance and hospitable ground for the government’s health-oriented IP reforms. The transnational sector opposed the government at nearly every step, but INTERFARMA does not monopolize the sector politically. The existence of a national pharmaceutical sector with interests distinct from the transnationals and with productive capacity retained from an earlier period of industrialization presented the MH with friendly and cooperative interlocutors. Indeed, the 2003 presidential directive on CLs was drafted by a lawyer who works as an advisor to ABIFINA.³⁵

It is essential to emphasize that the virtuous circle – the government invests in industry and industry supports the government’s IP reforms – is possible because of the condition of the local pharmaceutical sector. Even with the introduction of pharmaceutical patents and in the context of trade liberalization and an overvalued currency, Brazilian firms

³³Of Brazil’s eighteen government-linked pharmaceutical producers, the most important is part of the MH: Farmanguinhos, in Rio de Janeiro. Public-sector labs mostly engage in formulation of final dosages, and to a lesser degree on pharmo-chemical inputs. Flynn 2008.

³⁴Maurice Cassier and Marilena Correa, “Intellectual Property and Public Health: Copying of HIV/Aids Drugs by Brazilian Public and Private Pharmaceutical Laboratories, *RECIIS Eletronical Journal in Communication, Information and Innovation in Health* 1 (January 2007), 84. See also, Claudia Chamas, “Developing Innovative Capacity in Brazil to Meet Health Needs,” World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health, 2005; Eduardo Costa, “Política de medicamentos: tecnologia e produção no país,” *ABIFINA Informa*, No. 216, March 2006.

³⁵Confidential interview, 18 May 2008 (Rio de Janeiro). For further illustration of this collaboration, see Cassier and Correa, “Intellectual Property and Public Health”; Costa and Brasil, “A emancipação.”

retained market share in the 1990s. By the time health-related IP reforms became politically salient, local firms still accounted for roughly one-quarter of sales and dominated the nascent generics market, and pharma-chemical firms retained twice the market share of Chinese and Indian combined imports.³⁶ A critical point here regards the remaining capacity to produce final drugs and APIs – capacity that is a legacy of the import-substituting period, particularly the push for backward integration of the pharmaceutical sector in the 1980s.³⁷ Furthermore, the “late” introduction of pharmaceutical patents in 1997 meant that the potential denationalizing effects had not yet materialized.³⁸ Because Brazilian firms were still capable of benefiting from the government’s strategy they were available alliance partners.

Mexico: From TRIPS Plus to NAFTA Plus

Policy in Mexico followed a fundamentally different trajectory. Whereas Brazil implemented reforms to ameliorate the effects of patents on drug prices, Mexico’s policies reinforce these effects. Changes to Mexico’s patent law make use more difficult and complicate the process by which CLs can be issued, and modest steps to encourage post-patent generic competition were introduced in a self-undermining fashion. The explanation for this different path is rooted in the Mexican government’s less comprehensive response to the HIV/AIDS epidemic, which made IP reforms less compelling, and the transformations of the

³⁶IMS and MH data; Chamas 2005.

³⁷Sérgio Queiroz, “La Industria Farmacéutica y Farmoquímica Brasileña en los Años 90,” in Jorge Katz et al, *Apertura Económica y Desregulación en el Mercado de Medicamentos* (Buenos Aires: Alianza Editorial, 1997), 125-165; José Eduardo Cassiolato et al, “Avaliação Econômica da Capacidade do Brasil para a Fabricação dos Medicamentos para HIV/AIDS,” Unpublished UNDP working paper, 2006; Joseph M. Fortunak and O.A.C. Antunes, *ARVs Production in Brazil: An Evaluation* (Rio de Janeiro: Associação Brasileira Interdisciplinar de AIDS, 2006); Lelio A. Maçaira, “A Capacitação Productiva Brasileira para Anti-Retrovirais,” ABIFINA Informa 216, March 2006.

³⁸Introducing pharmaceutical patents in 1997 is still early, since Brazil had until 2005.

pharmaceutical sector, which not only made coalition-building for health-oriented IP reform less feasible but facilitated a counter-mobilization on the part of patent owners.

Although the affordability of medicines became a prominent issue in Mexico in the late 1990s, as prices increased significantly above the rate of inflation in the years following the 1994 devaluation of the peso, the nature of government demand reduced the sensitivity to such changes. State provision of discounted and free medicines was far from universal, extending only to workers in the formal sector (IMSS) and government employees (ISSSTE). Nor, importantly, did Mexico's Secretariat of Health (SH) face Brazilian-like obligations with regards to ARVs. Most HIV/AIDS treatment was provided outside of the state system and the uninsured generally lacked access.³⁹ The SH, thus, had less cause for alarm in the face of higher prices and less motive to reform the patent system.

Rather than coming from within government, the initiative for health-oriented patent reform came from a segment of the local pharmaceutical sector that emerged in the 1990s in response to economic crisis and the limited coverage of IMSS/ISSSTE. In the late 1990s and early 2000s a chain of pharmacies selling non-bioequivalent generics under the mark *Similares* (Similar) expanded in low-income areas throughout the country.⁴⁰ The emergence of *Farmacias Similares* gave local firms that had traditionally supplied the state sector opportunities to sell to private pharmacies. The actors in the chain were closely related, in fact, with the leading producer of non-bioequivalent generics (*Laboratorios Best*) owned by

³⁹Patricia Uribe Zúñiga et al., "AIDS in Mexico," *The Body*, November 1998; dAdesky, ch. 7; Sergio Bautista et al., "Antiretroviral Treatment Costs in Mexico," WHO/UNAIDS Workshop on Strategic Information for Anti-Retroviral Therapy Programmes, June 2003.

⁴⁰Bioequivalent medicines feature the same APIs as reference drugs, and they perform identically in the human body. "Similar" may not satisfy the second criterion.

the same person who owned the *Farmacias Similares* chain, a physician-pharmacist-industrialist named Victor González Torres, aka “*Dr. Simi*.”⁴¹

The *Similares* sector and its allies in Congress spearheaded the initiative to reform the patent system. In December 2002 “Dr. Simi’s” nephew, a Green Party (PVEM) member of the Chamber of Deputies, presented an initiative that would reform the 1991 LPI by reducing patent terms to ten years in the case of serious health situations. The PVEM initiative would have violated Mexico’s TRIPS and NAFTA requirements for twenty-year patent terms, but instead of rejecting the proposal out of hand, the Science and Technology Commission (CCyT) modified it. For all the proposal’s faults, its motivations and context were not to be ignored: escalating drug prices were making access to medicines a growing problem, and – as the initiative’s authors emphasized – other developing countries (such as Brazil) were demonstrating the feasibility of health-oriented patent reforms. Thus, the president of the CCyT acknowledged the concerns expressed by the bill’s sponsors and decided to rewrite the proposal with proper legal assistance.⁴² While the original proposal addressed patent terms (Article 23), the revised bill addressed CLs (Article 77), an area where Mexico had discretion under TRIPS and NAFTA. In March 2003 the CCyT approved a modest reform that would increase the capacity of the SH to issue CLs in the case of health emergencies. The key elements were to make a state of “serious illness” declared by the SH a ground for CLs, to simplify the process by which “serious illness” is declared, and to assure rapid issue of CLs at low royalties.

The March 2003 bill, similar in many ways to Brazil’s 1999 CL reform, drew a sharp reaction from the transnational pharmaceutical industry and its local representatives.

⁴¹For analysis of *Farmacias Similares* and the *Dr. Simi* phenomenon, see Cori Hayden, “A Generic Solution? Pharmaceuticals and the Politics of the Similar in Mexico,” *Current Anthropology*, 48 (August 2007), 475-495.

⁴²Interview, former President of CCyT, 10 August 2007 (Mexico City).

Government officials and legislators found themselves besieged by letters, faxes, emails, phone calls and personal visits from the transnational sector's trade association (AMIIF), Mexico's leading law firms, the USTR, and foreign embassies (e.g. US, Switzerland).

The transnational sector did not just react defensively but went on the offensive, converting the threat into an opportunity. AMIIF had attempted to terminate the patent-reform project, though once it was kept alive by the CCyT, AMIIF and its allies mobilized to secure a reform that would make the granting of CLs less likely than under the 1991 law.⁴³ The campaign was successful, as the transnational sector essentially commandeered the initiative. The Fox government, never compelled by IP reform in the first place, joined the counter-offensive: the Secretary of Government's legislative liaison insisted that the March 2003 version could not proceed and provided the CCyT with a revised text.⁴⁴ This new version, which was passed by the full Chamber of Deputies and Senate and then signed into law by President Fox in 2004, *increases* the obstacles to issuing compulsory licenses by making the process by which "serious illness" declared more complicated, removing serious illness as a ground for a CL, and requiring high minimum royalty rates.⁴⁵

The transnational sector also secured favorable changes with regard to post-patent generic entry. In September 2003 – at the same time as the reform to the patent law was in the Senate – the Fox government announced a new linkage system that requires health authorities to consult with the IP office and deny marketing authority to drugs where patents remain in effect. Thus, while Brazil's prior consent measure integrates health criteria into patent policy, Mexico's linkage system subordinates health policy to patent criteria.

⁴³Interview, Director General of AMIIF, 14 August 2007 (Mexico City).

⁴⁴CCyT archives; interview, former official in Secretary of Government, 14 August 2007 (Mexico City).

⁴⁵ As an illustration of the perversity of this legislative process, note that the original sponsors of the initiative to reform Mexico's CL system (PVEM) ended up actively opposing the final bill that was passed in Congress.

Mexico also introduced an early working provision at this time, but this is largely undermined by the transnational sector's ability to secure routine adjustment of the expiration dates on pipeline patents.⁴⁶ The Mexican IP law stipulates that pipeline patents 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 expiry dates. Because patent terms are adjusted in Mexico when they are adjusted in the original country, industry actors cannot know when a drug's patent will expire, which makes it difficult to take advantage of any opportunities created by the early working provision.

The changes introduced to Mexico's IP system (and health regulatory structure more generally) mean that the prices of patented drugs remain higher in Mexico. Patent-holding pharmaceutical firms do not fear CLs, and thus feel little compulsion to reduce prices. Abbott, for example, prices its patented version of lopinavir/ritonavir at more than five times the Brazilian price, but the Mexican government lacks the instruments to negotiate price reductions. More accurately, such instruments, as they previously existed, were dulled by the reforms of 2003-04.

To make sense of the perverse experience of IP reform in Mexico, where an initiative to enhance the rights of knowledge-users ended up yielding a set of changes that strengthen the rights of knowledge-owners, it helps to consider the changing political economy of the pharmaceutical sector. In contrast to Brazil, where INTERFARMA's positions are regularly countered by rival actors, in Mexico AMIIF dominates the sector economically and politically. Of course, individual Mexican firms would benefit from Brazilian-style patent reforms, as originally approved by the CCyT, yet outside of *Farmacias Similares* (and its subsidiary firms and suppliers) not even the local pharmaceutical sector provided support for

⁴⁶“Patent Term Extensions in Mexico Buck Latin American Trend.”

the favorable version of the CCyT's initiative or opposed the revised and unfavorable version. Nor did they much contest the linkage system.

The early – and, with the inclusion of pipeline patents, retroactive – introduction of pharmaceutical patents transformed Mexico's pharmaceutical sector. Through the mid-1980s the national pharmaceutical sector thrived on reverse-engineering unpatented drugs.⁴⁷ By the late 1990s, however, trade liberalization had undermined the pharma-chemical sector and patent protection transformed the industrial structure. The decline of local firms in Mexico was much more accentuated than in Brazil. Mexican firms account for less than fifteen percent of sales. In fact, nearly two-thirds of Mexico's pharma-chemical firms disappeared from 1987 to 1998 as the sector became subject to import competition and patent protection.⁴⁸

The transformation in industrial structure is reflected in the realm of politics. Whereas AMIIF and the principal association representing local firms (CANIFARMA) 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 organizations were formally fused, with the president of CANIFARMA an invited member of AMIIF's board and the CANIFARMA's two-year presidency alternating between Mexican and foreign firms. Nor does Mexico have an equivalent to Brazil's ABIFINA. Instead the pharma-chemical sector's representative body consists of a small unit within a broader multi-sectoral industrial chamber of manufacturing

⁴⁷Gary Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton: Princeton University Press, 1983); Joan Brodovsky, "Industria farmacéutica y farmoquímica mexicana en el marco regulatorio de los años noventa," in Jorge Katz et al, *Apertura Económica y Desregulación en el Mercado de Medicamentos* (Buenos Aires: Alianza Editorial, 1997), 167-199.

⁴⁸ CEPAL, "Las Industrias Farmacéutica y Farmoquímica en México y el Distrito Federal," LC/MEXL.400, 1999, p. 49; María Fabiana Jorge, "Efectos de la Globalización en la Industria Farmacéutica en México," in ANAFAM, *La Industria Farmacéutica Mexicana* (México, D.F.: Editorial Porrúa, 2006).

industries (CANACINTRA), which itself experienced dramatic decay in this period.⁴⁹ In short, Mexico's pharmaceutical and pharma-chemical producers could not articulate positions independent from the transnational sector's because the local sector was neither economically nor politically independent.

A potential source of support for the CCyT's initiative was from the segment of industry that focuses on bioequivalent generics, represented by the National Pharmaceutical Association (ANAFAM). Yet this organization found itself in stark decline in the late 1990s and early 2000s, with a shrinking membership. In fact, ANAFAM did not represent a "national" pharmaceutical sector either, for this segment was undergoing transnationalization of its own, with international generic firms purchasing long-established Mexican firms.⁵⁰ ANAFAM's strategizing in response to the CCyT initiative reflects this politically precarious position: ANAFAM advised CANIFARMA that, despite the likelihood that members of the two organizations would benefit from the proposed reform, they should lay low and refrain from showing support to avoid the appearance of conflicts of interest.⁵¹ Fighting on two fronts – against AMIIF and *Similares* – and politically unstable on account of its own transnationalization, the bioequivalent generics sector was in no position to lend its support to the CL initiative, nor to oppose the revised pro-AMIIF version.

CANIFARMA and ANAFAM's economic and political weakness meant that AMIIF came to dictate the positions of the "pharmaceutical industry" on matters of policy. The lone alternative voice came from the *Similares* sector – purveyors of non-bioequivalent medicines (which most countries, including Mexico, are eliminating from the market) and closely tied to the fringe PVEM. AMIIF, thus, was able to do better than prevent Mexico's patent law from

⁴⁹Kenneth C. Shadlen, "Orphaned by Democracy: Small Industry in Contemporary Mexico," *Comparative Politics* 35 (October 2002), 43-62.

⁵⁰The leading generics firms in Mexico are Israeli, British, French, and Canadian.

⁵¹CCyT archives, letter on file with author; interview, ex-President of ANAFAM, 21 August 2007 (Mexico City).

being reformed – a la Brazil – to simplify CLs. The transnational sector engineered reforms to Article 77 and the health regulatory system that strengthen the rights of knowledge-owners.

Conclusion

In this article I have introduced a framework for comparing countries' patent systems, and I have explained Brazil's and Mexico's distinct trajectories of patent policy since the late 1990s. On each of the three dimensions presented in section two – what knowledge can be owned as property, the rights of owners vs. users of property, and the effective duration of property owners' rights – the Brazilian tendency has been to increase the capacities of knowledge-users while the Mexican tendency has been to reinforce the rights of knowledge-owners.⁵²

The article brings politics to bear on a topic that has been dominated by analyses of laws and formal international agreements. Comparing Brazil and Mexico, for example, a focus on external legal obligations calls attention to NAFTA, which includes IP provisions that differ from TRIPS (Table 2). Yet this is an insufficient explanation: as of the late 1990s the health dimensions of the two countries' patent systems were similar, and the subsequent divergence did not conform to unique obligations that Mexico had under NAFTA.⁵³ All the reforms implemented in Brazil would be acceptable under NAFTA too.

I attribute the divergence to distinct interests and alliances over IP policy. In Brazil, the nature of government demand for patented and expensive drugs made health-oriented IP reform a high priority, and the political and economic characteristics of the pharmaceutical sector facilitated the creation of a coalition for IP reform. In Mexico, however, a less

⁵²Space prevents discussion of data exclusivity, but the same pattern prevails.

⁵³Although neither restrictions on CLs nor the type of linkage introduced in Mexico are required by NAFTA, both sorts of provisions feature in many recent RBTA's.

comprehensive response to the HIV/AIDS epidemic made IP reforms less compelling, and a transformed pharmaceutical sector not only prevented coalition-building for health-oriented IP reform but facilitated a counter-mobilization that strengthened the rights of patent owners. The argument is not that local pharmaceutical sectors drove policy change, but that their economic and political characteristics affected the receptiveness to such policy initiatives. The Brazilian reforms were state-led, but they were feasible because the government could elicit the support of local actors that had retained valuable economic and political assets. Different legacies of industrialization combined with Brazil's comparatively later retiring of industrial policies and introduction of pharmaceutical patents meant that Brazil was less advanced along the pharmaceutical-denationalization curve than Mexico.

To the extent that the argument rests on the actions of Brazilian and Mexican health officials, it is not a matter of institutional structure but power vis-à-vis society. Brazil's IP reforms were spearheaded by Health Minister José Serra, a close ally of the President who would run for the presidency in 2002, and Brazil's health activism certainly needs to be understood in this larger political-electoral context. Yet Mexico's Health Secretary Julio Frenk was a prominent figure within President Fox's cabinet as well. Mexico moved toward universalizing of health coverage under Frenk's tutelage, a measure that reflects the Secretary's authority. Yet state power is situational and relational, depending on what societal allies are available and against what opponents. The nature of Mexico's transnationalized pharmaceutical sector meant that Frenk could not – and therefore would not – attempt to go down the Brazilian path.

To understand the importance of industrial structure, consider a counterfactual: the Mexican government was not motivated to pursue health-oriented IP reform, but suppose that it were so inclined. It is difficult to imagine how the SH could have created the sort of pro-reform coalition as Brazil's MH did, because the early introduction of pharmaceutical patents

and the subsequent transformation of the sector deprived it of potential allies. Indeed, on a number of issues related to health provision, Mexico's SH sought the collaboration of local producers only to be stymied by AMIIF's dominance of the sector and the absence of local interlocutors. Industrial transformation and denationalization have political and policy consequences.

My emphasis on industrial structure aims to supplement (not substitute) prevailing emphases on Brazilian civil society's role in pushing government to make AIDS treatment a high priority and introduce health-oriented IP reforms. Whatever inspired the Brazilian government to act, local industry was crucial in not blocking – and, indeed, eventually supporting – the reforms. The difference with Mexico, where domestic industry ended up actively opposing health-oriented IP reforms and effectively supporting a strengthening of patent-holders' rights hand-in-hand with the transnational sector, is stark.

To conclude, it is worth returning to the two areas where IP matters, as the paper began: technology and industrialization, and health and humanitarianism. My analysis bridges these two realms, for the key variable explaining differences between Brazil and Mexico has been the existence of indigenous pharmaceutical and pharma-chemical capacities. An earlier generation of scholarship argued that promotion of local pharmaceutical sectors may be important for industrial development, but that because promotional measures may also raise the final prices of medicines, such strategies were less beneficial on the humanitarian axis of development.⁵⁴ The argument and findings in this paper invert this line of reasoning: to use IP to achieve humanitarian goals, countries also need to use IP to achieve industrial goals – they need local pharmaceutical industries that can act as a countervailing

⁵⁴Gereffi; Daniel Chudnovski. "The Challenge by Domestic Enterprises to the Transnational Corporations' Domination: A Case Study of the Argentinean Pharmaceutical Industry" *World Development*, 7 (January 1979), 45-58.

political force to the transnational sector. Indeed, whereas previous scholars have depicted pharmaceutical development as good for industrialization but not for humanitarianism, I show how pharmaceutical development may be good for both, because it makes humanitarianism *politically* feasible in world of strong IP. My analysis suggests that the key to reforming patent systems to increase access to drugs is the presence of economically and politically autonomous, national pharmaceutical industries that are available as coalition partners for those advocating such reforms.

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	compulsory licenses parallel imports
Not Permanent	Duration of rights	post-patent generic entry (early working provisions, drug registration procedures)

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
compulsory licenses	permitted; ample discretion	--
parallel imports	permitted	not permitted
early working provisions	permitted	--
drug registration procedures	not addressed	--

Note: -- indicates that NAFTA and TRIPS are identical

Table 3
Health-Related IP Policy: Common Origins

Policy	Brazil	Mexico
Pharmaceutical patents	yes (1997)	yes (1991)
“Pipeline patents”	yes (1996)	yes (1991)
Compulsory licenses	yes (basic, Art. 77)	yes (basic, Art. 71)
Parallel imports	no	no
Early working provisions	no	no
Linkage	no	no

Note: The shaded text indicates important differences.

Table 4
ANVISA's Prior Consent

Decision	Number of Cases	Percentage
Approvals	752	68.9
Denials	53	4.9
Pending (as of July 2008)	122	11.2
Other*	165	15.1
<i>Total</i>	<i>1092</i>	<i>100.0</i>

*Includes applications returned to INPI for further documentation and because determined not to be pharmaceutical patent applications

Source: ANVISA