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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.

… **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 was made 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. (pp. 10-11)

… 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. (p.12)

…**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 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] (pp. 13-14)

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…**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.** (p.14)

…**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 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).**
(pp. 16-17)

… 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.**