

Expanding Drug Access in Brazil

Lessons for Latin America and Canada

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ABSTRACT

This paper discusses Brazil's efforts to provide essential medicines for its population while meeting international trade obligations. In the 1950s and 1960s, Brazil's pharmaceutical industry was largely overtaken by foreign companies. To counteract this, Brazil enacted a law in 1971 that allowed the production of patented drugs in order to provide affordable medicines, encourage research and development, and reduce dependency on imports. Eventually, pressure from the United States government (through tariffs and sanctions) drove Brazil to introduce pharmaceutical patent laws. Local interests prevailed, however, through Brazil's liberal interpretation of the TRIPS Agreement, which included a provision that pharmaceutical products must be "worked" or manufactured locally or the government could turn to the use of compulsory licensing. Brazil's willingness to use the threat of compulsory licensing compelled drug companies to lower HIV/AIDS drug prices substantially. Finally, the paper discusses how Canada can facilitate improving drug access in Latin America through helping Brazil expand its role as a manufacturer and providing medicines to countries without manufacturing capabilities.

MeSH terms: Drug access; essential medicines; TRIPS Agreement; Brazil; Canada

La traduction du résumé se trouve à la fin de l'article.

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The management of pharmaceutical expenditure has become a focus of most governments around the world, irrespective of national income level, given the increasing demands (e.g., aging of the population, health care restructuring, the development of new drug therapies) for pharmaceutical products and their rising costs, both of which put pressure on public health budgets as well as on private health spending. For low- and middle-income countries, the standards imposed by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, are an additional obstacle in their efforts to ensure affordable medicines to their populations and manage pharmaceutical costs. The TRIPS Agreement is governed by the World Trade Organization (WTO) and obliges countries to harmonize intellectual property law for pharmaceutical products (thus reducing generic competition in the market). This obligation makes it increasingly challenging for governments in Latin America as well as in other regions to ensure that their populations have access to medicines and that they meet international trade obligations. Pharmaceuticals, when they are readily available, affordable, of good quality, and used appropriately, can provide a cost-effective solution to many health care problems. Essential drugs at a reasonable price can cure or prevent many of the diseases that plague the poor throughout Latin America.

This paper explores the history of how one country in the region – Brazil – has dealt with external pressures from international trade agreements on domestic policy priorities such as ensuring access to essential medicines. Given that pharmaceutical policy lies at the crossroads of commercial and social policy, it can result in uncomfortable choices or trade-offs for governments to make. The Brazilian case is highlighted because it has managed to make these choices well. Brazil's approach towards seeking to ensure access to essential medicines for its population while meeting international obligations is instructive for other countries in Latin America and for Canadian policy-makers working in the region, who all seek strategies to improve drug access while managing international obligations. Through the Canadian International Development Agency (CIDA), Canada has an interest in

seeing Brazil improve its health status and economic development.¹

Brazil is a middle-income country with a persistent and acute poverty problem. The Brazilian health system has both public and private facilities ranging from basic health care units to complex hospital facilities.² Pursuant to Article 196 of the 1988 Constitution, access to health services – which arguably includes access to basic medicines – is considered a constitutional right. Brazil has a per capita consumption of medicines of approximately US \$51 per year. Almost half the medicines are consumed by 15% of the population, who represent the wealthiest segment of the population.³ Small-scale studies have found that many low-income Brazilians do not adhere to their prescriptions because they cannot afford to buy medicines; drug costs can consume as much as 10% of a poor household's income.⁴

Pharmaceuticals and Intellectual Property Law

One of the major policy decisions governments in Latin America must face is the issue of whether to manufacture or import medicines – “make or buy?” This question is typically more meaningful for a country like Brazil with manufacturing capabilities. However, interestingly enough, even countries with limited or no manufacturing capabilities often think about domestic production as a means to protect drug access for its population.

Brazil once had a vibrant local pharmaceutical industry that became subject to much buy-out by foreign investors in the late 1950s. This compelled then President Janio Quadro in 1962 to form a Commission of Inquiry on the Pharmaceutical Industry to study its transformation. The commission found that foreign firms had been able to take over local firms easily because of government policies such as *Instrucao 113*, which provided favourable exchange rates for firms importing capital goods for the set-up of new factories in Brazil, and was considered to be advantageous for foreign investors in general.⁵ By the end of the 1960s, foreign firms had effectively captured the majority of the Brazilian pharmaceutical market. The predominance of foreign firms has remained relatively stable since, even after the revoking of patent law on pharmaceutical products and patents in 1969.

Nonetheless, the legal right of local firms to produce drugs under patent was expressed in Law No. 5772 on Industrial Policy, which took effect on 21 December 1971.⁶ This policy shift was viewed as a nationalist victory by many Brazilians who were employed by domestic pharmaceutical firms, as well as by those outside the industry. Those in the industry argued that the patent system, as well as limited access to raw materials, was hampering their industrial development. Law No. 5772 would help these local firms develop technical skills in order to make copies of patented drugs via “reverse engineering.” The long-term expectation was that local firms would export their products and eventually build their own research and development capacities. This approach also assumed that local production of patented drugs would help ensure affordable drugs for the consumer. The efforts by the Brazilian government to create a national industry and reduce dependence on the import of pharmaceuticals to meet the population's basic health needs were part of a larger economic strategy of import substitution.

The Pressure for Change

Eventually, however, external pressure from the United States, through trade sanctions for inadequate intellectual property rights, compelled Brazil to introduce pharmaceutical patent law reform. In 1988, the US-based Pharmaceutical Manufacturers Association (PMA, as it was then known) petitioned the United States Trade Representative, citing Brazil's lack of process and patent protection for pharmaceutical products as “an unreasonable practice that burdens or restricts U.S. commerce.”⁷ In response to the PMA petition, on 30 October 1988, the American government imposed a punitive tariff of 100% on US \$390 million worth of Brazilian goods in retaliation for Brazil's refusal to grant patent protection to pharmaceuticals and other information-intensive technologies.

Responding to these harsh external pressures, the Brazilian government announced its intention to draft a bill on intellectual property rights protection for processes and products, one that would modify the rights and duties pertaining to industrial property. Consequently, the American sanctions were lifted.⁸ The bill that was presented to Brazil's congress in April 1991 was mod-

elled after the one developed by the General Agreement on Tariffs and Trade (GATT), making it more in line with international obligations than with domestic health needs and preferences. Not surprisingly, the policy shift sparked immediate and wide negative reaction and led to a nationwide movement by professional organizations, business associations, and organized civil society in general, who charged that the bill violated consecrated international concepts, would have serious economic and social repercussions, and was out of step with an organized national industrial development plan.⁹

Given the controversy surrounding it, the bill passed first reading in the Chamber of Deputies only in 1993 and then stumbled.⁹ Pharmaceutical patent law, however, would be reintroduced into the Brazilian congress in 1996, as part of Brazil's obligations to the TRIPS Agreement as a WTO member. In January 1996, the Brazilian Senate's Economic Affairs Committee ratified a bill protecting industrial property. The Senate ratified the legislation on March 5 and the House followed suit by passing the legislation on April 10. On 14 May 1996, President Cardoso signed the Industrial Properties Law, which provides a higher level of protection for pharmaceutical patents than in most other low- and middle-income countries.¹⁰ The government passed the law primarily to appease demands from the WTO and help build support for Brazil in other trade areas.

Domestic Pressure to Protect Local Health Interests over Trade Interests

Despite these changes, pressure from domestic interest groups, particularly from people living with HIV/AIDS, helped ensure that the government drafted intellectual property legislation that expressed a liberal interpretation of the TRIPS obligations. For example, the Brazilian patent law requires that “unless the holder of the patent uses or produces innovation within national boundaries, other producers wishing to use the patented technique will be entitled to a license even without the patent holder's consent.”¹¹ What this means is that importation cannot be used to satisfy the condition that a patent be “worked” (manufactured) in the country.¹⁰ If a product is not manufactured, incompletely manufactured, or there is an established failure to make full use of the patented process,¹² it

could be subject to a compulsory license. Compulsory licensing enables the government to give a third party the right to use a patent without the patent holder's consent (Article 31). Brazil's legislation states that the decision to grant a compulsory license is at the national level and that the third party is responsible for paying a royalty to the patent holder.

The Brazilian government further modified the terms of the international trade agreement to meet local political realities by issuing a presidential decree on 6 October 1999. This decree regulates the implementation of the patent law and allows for the granting of compulsory licenses during national emergency situations. In December 1999, the government also issued *medidas provisórias* (temporary measures), which allowed (under a revised Article 229-C) the new drug regulatory agency, the Agência Nacional de Vigilância de Sanitária (ANVS), to approve all patent applications related to pharmaceutical products and processes.

Compulsory Licensing: Not an Empty Threat

One of the main reasons for Brazil's success in negotiating price discounts from the pharmaceutical industry is the presence of its public and private local industry. The government provides seventeen anti-retroviral drugs free of charge; eight are generic drugs produced locally and nine are imported brand-name drugs. Public manufacturers, such as the Fundação para o Remédio Popular (FURP), based in Sao Paulo, import generic raw materials and use their local facilities to produce finished medicines. The decision by the Brazilian government in 1997 to include highly active anti-retroviral therapy (HAART) in its policy of universal access to health care appears to have led to a sharp decline in AIDS morbidity, mortality, opportunistic infection rates, and hospitalizations.¹³ Brazil's approach is being lauded by public health activists as a model for other states to emulate or benefit from. Developing countries such as Burkina Faso, Cambodia, Guatemala, South Africa, and Uganda have been approaching Brazil to purchase its generic anti-retroviral medicines. Brazil has also been discussing technology transfer with other developing states, so that they can begin to produce pharmaceuticals themselves.¹⁴ In short, Brazil has

put the international pharmaceutical industry on notice that unless they lower the prices of the remaining anti-retroviral drugs still under patent, the government is prepared to break patent licenses under the terms of a national emergency.

Cohen and Lybecker have pointed out that just prior to the Doha talks in 2003, then Minister of Health of Brazil, Jose Serra, was on the brink of issuing the first compulsory license for an HIV/AIDS drug, demonstrating to the world that health concerns took precedence over patent obligations (and thus gaining political currency domestically).¹⁵ Serra announced that Brazil had started the process to domestically produce nelfinavir (one of twelve drugs used by the health ministry to treat HIV/AIDS), following failed negotiations with Hoffmann-La Roche Inc. (Roche) for a lower price for the drug. He cited a "national emergency" due to excessive prices of pharmaceuticals. The threat to invoke a compulsory license was not an empty threat given that Brazil possesses the manufacturing capacity to produce the drug. If this threat came to fruition, international producers would lose valuable market share to domestic producers. Recognizing this, Roche offered to lower the price of nelfinavir (Viracept®) by 13%. At a cost of over US \$88 million for Roche's Viracept, this sole drug accounted for 28% of government spending on HIV/AIDS treatment in 2000.

Roche's initial offer was rejected by Brazil and efforts were made for Far-Manguinhos, a state-owned laboratory in Rio de Janeiro, to produce the drug. As the Roche negotiations continued, the Brazilian health ministry continued securing lower prices for many of the drugs for the HIV/AIDS cocktail in an effort to control the spread of HIV. Merck reduced their prices by 65% and 59% on the two HIV/AIDS drugs they provide to Brazil. By August 2001, it was clear that the Brazilian strategy had worked: Roche cut the price of nelfinavir by 40%.

Impact of Policy Shifts on Market Dynamics

The Brazilian pharmaceutical market is changing: sales of generic drugs are on the rise as a result of a government focussed policy to foster generic drug consumption in an attempt to avoid some of the price problems that can arise from robust pharmaceutical patent protection. As part of a program to

expand access to medicines for the country's poorest, the Brazilian government has become the largest purchaser of low-cost generic drugs for its public health care system. (It is important to note here that generic drugs are not always priced more reasonably than patented medicines, although this tends to be the exception rather than the rule.) This policy direction was continued despite a change in government in 2001. Doctors at public hospitals must now prescribe only generics, which cost an average of 40% less than original brand-name drugs, resulting in tremendous budget savings. As patents continue to expire on core drug therapies, "the government aims to make Brazil an important generics production centre for Latin America."¹⁶ It is likely that with the new flexibilities offered by the Doha Agreement and with international interest in Brazil's generic pharmaceutical industry, Brazil may become an important source of medicines not only for Latin America but also for many low- and middle-income countries in other regions as well.

Brazil: Lessons for Other Countries in Latin America

Brazil had to reform its intellectual property law for pharmaceuticals primarily due to pressure from the WTO. However, Brazil has interpreted international obligations in a way that allows it to mitigate the harshest effects of intellectual property law on its population – through the threat of compulsory licensing and the inclusion of a local working requirement in its law. Even though patent protection for pharmaceuticals is not the only obstacle in access to drugs, it undeniably leads to higher prices for medicines due to monopolies, and thus alters the market structure. Brazil's experience matters because it demonstrates how a country can ensure that global standards do not necessarily have to result in the erosion of social institutions.

Brazil's approach has been one that seeks to respond to international pressures (by reforming intellectual property law) while establishing sufficient safeguards within the law to ensure that domestic social priorities (such as improving drug access) are not jeopardized. This approach is instructive for policy-makers in Canada and throughout Latin America. In addition, complementary policies, such as price control, are critical

here. Countries in Latin America need to make use of the provisions within the TRIPS Agreement and implement complementary health policies that can help ensure their populations will have access to essential medicines. However, it must be stated that the options exploited by Brazil were until recently only available to countries with manufacturing capacity.

Brazil has had to make some unwieldy policy twists and turns in the past decade in order to deal with international trade imperatives and its domestic health needs. While at the cursory level, it may appear that Brazil has moved very close towards meeting its international obligations, what is apparent when careful study is undertaken is that despite these shifts, Brazil has tried very hard to maintain the integrity of its social programs – for example, ensuring the viability of public drug manufacturers and making it clear that access to essential medicines, particularly those needed to treat HIV/AIDS, takes precedence over trade concerns. Brazil is an example of a country that has managed to interpret international obligations in ways that respect historical social policies and preferences – albeit with a significant risk of economic sanctions. Furthermore, through the implementation of complementary public policies (imperfect though they may be), Brazil has managed to protect, for the most part, its population's access to essential medicines. In short, Brazil has shown a resolve to assert national sovereignty in setting priorities that correspond to domestic social and economic priorities and to not yield to international pressure that favours private corporate interests.

Closing Thoughts: A Role for Canada in Improving Access to Medicines in Latin America?

Turning to the question: Is there a role for Canada in improving access to medicines in Latin America? The answer is a resounding yes. Canada's patent law in recent years has been the focus of intense debate in view of international developments dealing with the WTO's Doha Declaration on TRIPS and Public Health and the Doha Accord of August 2003. This treaty provides flexibility by permitting those countries that do not have the capacity to manufacture medicines to still use compulsory licensing by entering into contracts with firms in other countries. Quickly moving to take advantage of this

shift in international patent law, on 7 November 2003, the Canadian government approved Bill C-56 (later renamed Bill C-9 or the Jean Chrétien Pledge to Africa Bill), which amends Canada's Patent Act to allow for limited compulsory licensing. Bill C-9 was passed on 14 May 2004.

While imperfect, it is consequential in that it permits generic manufacturers in Canada to use compulsory licensing (which is not permitted in Canada for domestic use) to produce and export patented medicines to those developing countries deemed by the WTO as having insufficient local manufacturing capabilities. In principle, Canada could export generic drugs to those countries in Latin America that do not have manufacturing capability. It too suggests that Canada is willing to shore up its role as social caretaker for countries around the world in need of greater access to medicines. And importantly, given Canada's experience with compulsory licensing and the growth of its generic drug industry, Canada has the capacity to share its knowledge with a country like Brazil that is poised to act as a supplier of medicines for its region. What remains to be seen, however, is whether the legislation will achieve its intent. But regardless of the success of the legislation, Canada can use it as a facilitator to assume an important role in other critical areas (such as technology transfer) that could help improve medicine access in Latin America.

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RÉSUMÉ

Cet article porte sur les efforts du Brésil pour offrir des médicaments essentiels à sa population tout en respectant ses obligations commerciales internationales. Durant les années 1950 et 1960, l'industrie pharmaceutique brésilienne a été en grande partie supplantée par des sociétés étrangères. Pour contrer ce mouvement, le Brésil votait en 1971 une loi autorisant la fabrication de médicaments brevetés afin d'offrir à la population des médicaments à prix abordable, d'encourager la recherche-développement et de réduire la dépendance du pays envers les importations. Par la suite, sous la pression du gouvernement des États-Unis (qui avait imposé des droits de douane et des sanctions), le Brésil déposait un ensemble de projets de loi sur les brevets pharmaceutiques. Les intérêts locaux eurent cependant préséance en raison de l'interprétation libérale, par le Brésil, de l'Accord sur les ADPIC (aspects des droits de propriété intellectuelle touchant au commerce), dont l'une des clauses prévoit que les produits pharmaceutiques doivent être « exploités » ou fabriqués localement sans quoi le gouvernement peut recourir aux licences obligatoires. La volonté manifestée par le Brésil de se prévaloir de cette clause a astreint les compagnies pharmaceutiques à réduire considérablement le prix de leurs médicaments contre le VIH et le sida. À la fin de l'article, il est question des moyens pour le Canada de faciliter l'accès aux médicaments en Amérique latine en aidant le Brésil à développer ses capacités de fabrication et à approvisionner en médicaments les pays qui n'ont pas d'industrie pharmaceutique.

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