6. Corporate power and state resistance: Brazil's use of TRIPS flexibilities for its National AIDS Program[1]

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Brazil provides one of the most unique cases for exploring the impact of intellectual property on sustaining a social program based on social democratic principles. In 1996, Brazil passed legislation mandating the state to provide expensive anti-retroviral (ARV) medication to its citizens who have contracted the human immunodeficiency virus (HIV) that causes the acquired immunodeficiency syndrome (AIDS). Also in 1996, Brazil was one of the first countries to change its domestic patent laws as a result of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), one of the pillars of the global trading system governed by the newly created World Trade Organization (WTO). In terms of both TRIPS and universal AIDS treatment, Brazil was ahead of its time. The country subsequently became one of the first countries to begin resorting to the use of the humanitarian safeguards outlined in the TRIPS accord. Specifically, Brazil began using compulsory licenses to drive down the price of medicines. By allowing other producers to enter the market, this legal device allows states to remove the market exclusivity a patent holder retains to set monopoly prices.

A close review of the Brazilian experience with the TRIPS accord and use of its flexibilities provides insight into the different forms of corporate power and state resistance related to intellectual property (IP). Brazil's experience with using TRIPS flexibilities reveals the importance of institutionalizing a universal public health system and construction of state

[1] This chapter is based on original field research involving over 50 interviews with policymakers, activists, and managers and representatives of private and public sector drug companies in Brazil carried out from October 2007 to September 2008.

organizations responsible for its administration. The legal and political commitments to universal health care are best illustrated by the establishment of the National AIDS Program. Having to sustain a long-term commitment to AIDS treatment with a limited amount of resources is what shapes policymakers' interests, drives them to use humanitarian flexibilities, and lays the groundwork for alliances with civil society. The right to health shapes a human rights discourse that is shared by both committed public servants and civil society activists. Domestic economic interests and threats by foreign economic forces may result in local industry vetoing initiatives by public health officials and/or resistance by other government ministries. But without the commitment to universal access to essential medicines, the Brazilian case suggests that the struggle for and use of TRIPS flexibilities would have been minimal. In the Brazilian case, coping with AIDS in Brazil has enhanced state powers.

THE POWER OF TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property is the most impressive attempt to construct a worldwide patent regime. TRIPS stipulates that all WTO member countries must provide the same patent protection of twenty years, and domestic patent authorities cannot discriminate against foreign patent applications in favor of local applicants. Since TRIPS also mandated the inclusion of pharmaceuticals, the accord represents a qualitative shift in the role of IP in domestic legislation. Many countries, including Brazil, provided patent protections for other goods but not for pharmaceuticals due to the importance of a local drug industry in economic development and provision of medicines for health systems (Bermudez and Oliveira 2004).

Owing to the increasing economic competition in the world economy beginning in the 1970s, the salience of intellectual property in a knowledge-based economy has grown. The US's Section 301 of the Trade Act of 1974, for example, authorizes the United States Trade Representative (USTR) to impose tariffs on goods from countries engaging in unfair trade practices including infringements on intellectual property. Corporations not only from the US, but also from Europe and Japan, mobilized their governments to push for strong intellectual property rules through the WTO. While some developing countries hoped that after the creation of the WTO US bilateral trade pressure would end, industry associations continued to lobby the USTR to apply pressure on countries with regard to their IP laws (Sell 2003).

Despite the tremendous pressure brought to bear on developing coun-

tries to conform to the IP standards employed by wealthy nations, several flexibilities and humanitarian safeguards were included in the final TRIPS accord. Countries must adhere to the minimum obligations of TRIPS but could still determine the criteria of patentability based on claims of novelty, inventiveness and industrial applicability. WTO member states could also determine which government agency would adjudicate patent applications, whether other government bodies or civil society organizations could participate in the process, and how many flexibilities outlined in TRIPS could be included in domestic legislation (see Appendix 1 for a list of TRIPS flexibilities).

Just as there is great diversity across the levels of economic development and capabilities of state institutions throughout the developing world, compliance with the TRIPS accord and use of TRIPS flexibilities have also varied. There are a number of countervailing forces scholars have highlighted concerning the incorporation of TRIPS flexibilities and their use. The first concerns the presence of a weak, domestic-owned pharmaceutical industry. Since drug makers in the developing world tend to produce generic medicines, patents do not play an important role in their business strategies and often operate as a market barrier. Consequently, domestic drug firms lobby their government to include more TRIPS flexibilities. Thus countries like India and China, which are home to robust generic pharmaceutical firms, waited until the 2005 TRIPS deadline before changing their patent laws.

Another factor is civil society pressure. Health activists, for example, have become increasingly aware of the impact that patents have on access to essential medicines. Global outrage against the 39 pharmaceutical companies that sued the South African government for changing its patent laws to allow for parallel importing of cheaper AIDS medicines galvanized transnational advocacy networks across the world. Closely associated with the civil society pressure are issue area discourses or the framing of social conflicts. On the one hand, intellectual property is framed as a fundamental right to ownership of property; but on the other, health activists have coalesced around the frame of access to medicines as the fundamental right to life.

Additional related factors are the balance of needs between corporate investors and host countries, as well as pressures from hegemonic countries, for example the United States. Foreign investors seek out opportunities in developing countries based on the size of domestic markets, availability of cheap labor, and/or natural resource endowments. Host countries, depending on the degree of integration in the world economy and reliance on export markets for growth, seek to attract foreign companies for technology, capital, and foreign exchange. The balance of power varies depending

on the size of the host country, the nature of the industry, and potential returns. Also weighing in on this relation is the ability of the corporation to elicit the support of the United States to support its interests. The degree to which a host country is dependent on the US market or susceptible to US trade or diplomatic threats will affect the balance of power.

These are important factors regarding the degree to which developing countries are affected by intellectual property regimes, as many of the chapters in this book detail. But one factor that has been under-emphasized in the literature on TRIPS compliance and use of humanitarian safeguards is the importance of social-democratic commitments by states. This institutionalist or state-centered approach argues that the *substantive* fulfillment of social policies empowers state actors, especially those state organizations responsible for carrying out successful programs, who then become the main proponents for the use of humanitarian safeguards. As Skocpol (1992, 59) describes: "a policy is 'successful' if it enhances the kinds of state capacities that can promote its future development, and especially if it stimulates groups and political alliances to defend the policy's continuation and expansion." The "lock-in" mechanism, in the case of successful AIDS policies, is the effective roll-out of treatment to all those requiring medicines. It is not just the *de jure* or legal mandate to provide medicines; it is also the *de facto* achievement that transforms the fulfillment of a social right into a powerful mobilizing force.

Much of the literature about the new institutionalism in the social sciences focuses on the constraints that institutions impose on actors. But institutions empower as well as constrain. Institutions are the formal and informal rules, as well as the systems of meanings, governing relationships among individuals and groups. The substantive fulfillment of a social program not only imbues certain values, such as 'the right to access to medicines,' amongst the members of the state organizations responsible for its execution, but also provides a platform for these actors to affect policy arenas that impinge on their mandate.

Two additional concepts underlie the state-centered approach. First is the concept of bureaucratic autonomy. According to Carpenter (2001), bureaucratic autonomy develops when state organizations develop strong reputations based on efficacy, professionalism and uniqueness of service. "It occurs, further, when [managers] ground this reputation in a diverse coalition wrought from the multiple networks in which they are engaged. These coalitions, suspended in beliefs and in networks, and uncontrollable by politicians, are the stuff of autonomous bureaucratic policy innovation" (Carpenter 2001, 353). The social power of a bureaucratic agency involves the active support and participation of numerous stakeholders both inside and outside of government.

Reinforcing bureaucratic autonomy are the actions of institutional activists. Santoro and McGuire (1997, 504) define institutional activists as "social movement participants who occupy formal statuses within the government and who pursue movement goals through conventional bureaucratic channels." The 'revolving door' not only occurs between government and industry, but can also arise between government and social movement organizations. Social movement insiders leading highly successful agencies responsible for a health program can be empowered to act in other government arenas such as foreign relations and industrial policies often viewed as outside their purview.

In relation to intellectual property, state agencies that have developed strong reputations for excellence in implementing universal drug policies and that are staffed by social movement activists would lead the charge in the incorporation and use of TRIPS safeguards. In sum, the success of a health program based on universalistic criteria drives the government agenda on medicines policies, lays the groundwork for alliances with civil society and/or the private domestic drug industry, and shapes discourses concerning human rights. Countries with weak social-democratic commitments in their health systems tend not to defend the inclusion of humanitarian safeguards in domestic IP legislation or take advantage of these TRIPS flexibilities once incorporated, while countries committed to the provision of universal care and state agencies that have powerful reputations lobby for more TRIPS flexibilities and use of compulsory licenses.

The Brazilian case demonstrates close co-variation between increasing success of its AIDS treatment program with the increasing "flexibilization" of its intellectual property laws backed by aggressive price tactics threatening the use of compulsory licenses. A close study of the Brazilian experience through a state-centered lens helps explain why the country passed highly restrictive patent legislation in 1996 and then pursued its subsequent flexibilization in following years. The next section explains the passage of that law along with the growing success of its national treatment program for people with HIV/AIDS.

INCORPORATING TRIPS INTO BRAZILIAN LEGISLATION

As mentioned, the irony of the Brazilian case is that in the same year, 1996, two laws – one providing patent protections for medicines and the other mandating the state to provide free and universal AIDS treatment – were passed. Had the successful and costly treatment program already been in place, resistance against reforming intellectual property laws would have

been greater and probably have led to incorporating more TRIPS flexibilities instead of piecemeal changes at later dates when the high price of patented medicines began to threaten the sustainability of its treatment program (see Appendix 6A for a list of Brazilian legislation related to TRIPS flexibilities).

In May, 1996, Brazil passed Industrial Property Law 9.279 which reinstated patent protection for all pharmaceutical processes and patents. Since 1969 when all patents on pharmaceuticals were abolished to encourage the growth of the domestic industry, firms could legally copy medicines and sell them on the market. Patents existed for other industries – just not for pharmaceuticals. Why then did Brazil pass new IP legislation that went beyond the minimum requirements of the TRIPS accord? In particular, why did the country not wait until the deadline of 2005 like China and India in order to become TRIPS compliant? US pressures, beginning in the 1980s, had a direct impact on early compliance with TRIPS. In 1988, President Reagan, using Section 301 of the Trade Act of 1974, imposed a 100 percent tariff on imports of Brazilian paper products, consumer electronics and Brazilian medicines.[2] In the view of Rubens Ricupero, Brazil's ambassador to the General Agreement on Tariffs and Trade (GATT), which preceded the WTO, the US could never prove that its pharmaceutical companies were losing profits due to the lack of patent protection on pharmaceuticals, and furthermore the unilateral trade sanctions were illegal under international trade law. "We lost out because of power politics," summed up Ricupero.[3]

Foreign pressures were important and came at a time when the Brazilian political economy was vulnerable to trade threats and was undergoing important structural changes. Brazil abandoned a program of import substitution and liberalized trade in the early 1990s. The effect on the pharmaceutical industry was devastating. As tariffs on pharmo-chemicals and fine chemicals fell from 65 to 20 percent and state petrochemical firms were privatized, several upstream plants established to produce active pharmaceutical ingredients were phased out. In the first half of the 1990s, 1,700 production lines of synthetic intermediates and inputs were

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[2] "We regret that it is necessary to take this step. Retaliation should be an action of last resort in any trade dispute; that has not been the case here. The administration has made every effort to resolve this issue over the past two years . . . We hope that it will be possible to lift these sanctions in the near future," US Trade commissioner Clayton Yeutter is quoted as saying in Silverman et al. (1992, 53).

[3] The ambassador believes that the US' strategy was to pressure Brazil to its side concerning intellectual property in order to obtain concessions from other countries like India and China (Ricupero 2007).

shut down (Orsi et al. 2003). The economic basis of the nationally owned drug sector and thus its ability to withstand the early adoption of TRIPS had been undercut. In China and India, by contrast, trade liberalization proceeded at a slower pace and industrial policies to support the domestic drug industry were maintained.

US pressure on Brazil to change its patent legislation on pharmaceuticals explains part of the reason for Brazil's early adoption of TRIPS. Domestic factors and political ideologies also weigh in on the decision. Brazilian policymakers began discussing a new patent law in the early 1990s as part of the adoption of new neoliberal economic policies. Fernando Henrique Cardoso, Brazil's president at the time of passage and chief sponsor of the legislation, refused to comment on his motivations for pushing the bill (see Nunn 2007). But two factors stand out. First, Cardoso and other members of his economic team believed that embracing IPR would be a positive step for Brazil's economic liberalization, reduce Brazil's dependence for importing technology, and attract foreign investment (Nunn 2007; Palmeiro Filho and Capanema 2004). Second, policymakers believed that it would improve trade with the US. Since many members of Congress are tied to export-agriculture industry in Brazil and the US is one of the main destination markets, deputies and senators were susceptible to US trade threats. In the view of Abifina, an industry association representing the domestic pharmochemical industry and directly affected by the new patent law on pharmaceuticals, US pressure resulted in a patent law incorporating fewer safeguards outlined in the TRIPS accord.[4]

Apart from political economy considerations, there were few activist groups mobilized to resist early adoption of TRIPS. The one exception was the public health reform movement, whose members are also known as *sanitaristas*. These public health advocates raised awareness of the potential impact of patent protection on access to medicines and may have stalled the passage of earlier legislation (Pinheiro 2008). In terms of civil society, they acted alone. One important group that was unaware of the implications of IP on drug access were AIDS activists. Without the input

[4] "The initial bill was approved by consensus in the House of Deputies in 1993–1994 and was very good – Abifina had taken part in the negotiations with (then President) Itamar Franco and (then Minister of Foreign Relations) Cardoso. But when it went to the Senate, which at the time Cardoso had become president and had other commitments, the bill changed form. Because of pressure from the US, such as in 1995 and 1996, Lampreia, the Minister of Foreign Relations, warned that if Brazil did not pass the TRIPS-plus legislation, there would be trade sanctions on steel, orange juice, among items," said Nelson Brasil (2008), Vice President of Abifina.

of public health advocates who did not have any backing from AIDS activists or other mobilized sectors of civil society, new IP legislation had few of the flexibilities outlined by TRIPS designed to protect consumers and curtail industry abuses. The ties between these two important groups – *sanitaristas* acting as "institutional insiders" and AIDS activists outside of government – only crystallized when the country's National AIDS Program had been established and treatment scaled up.

ESTABLISHING THE UNIVERSAL AIDS TREATMENT PROGRAM

Brazil's model AIDS policies grew out of the country's democratic transition in the 1980s. A coalition of *sanitaristas* and progressive forces established health as a human right guaranteed by the state in Brazil's new Constitution of 1988. Two years later, Congress passed the Health Act of 1990 which established the operating principles of the Unified Health System (*Sistema Único de Saúde-SUS*). While SUS provides access to 90 percent of the population and 29 percent rely exclusively on the public health system, some 40 million Brazilians feel obliged to purchase additional health care through a system of private insurance and hospitals. Extending SUS coverage and improving service delivery continues to strain budgets. Jadib Jantene, Minister of Health during the 1990s, said that SUS should have a budget of R$120 billion (approximately US$60 billion) a year, but current amounts barely reach R$50 billion (US$25 billion) (Martins 2008). In the view of Weyland (1995), the *sanitaristas* failed to achieve their objectives of a robust universal health care system due to the intractable problems of political clientelism and the failure of establishing alliances with mobilized civil society.

In spite of the problems associated with Brazil's underfinanced public health system, the National AIDS Program stands out as an exception. It has overcome entrenched political interests, established strong civil society partnerships, and achieved worldwide fame and recognition for curbing incidence, rolling out treatment, and reducing morbidity and mortality rates. Since Brazil first established its National AIDS Program in 1985, modelled after successful efforts at the sub-national level in São Paulo state, it has retained a high degree of autonomy and has been staffed with dedicated social movement insiders. The organization represents a high degree of professionalism and commitment in comparison to other state institutions, many of which suffer from the country's chronic political clientelism.

The success of the Brazilian model has attracted significant scholarly attention. A full review of that literature is beyond the scope of this study,

but it is necessary to highlight a few factors. First, social movements and societal pressures were important for the establishment of Brazil's AIDS program (Nunn 2007; Teixeira et al. 2003; Passarelli and Júnior 2003). In the words of former president Fernando Henrique Cardoso, the "state and the social movement practically fused" (quoted in Biehl 2004, 114). The social origins of AIDS groups capable of pressuring the state resulted from contextual factors of Brazil's transition to democracy as well as the middle class position of AIDS activists capable of filing successful lawsuits for treatment (Parker 1997; Bastos 1999). Second, there is a tradition of state leadership in responding to communicable diseases (Gomez 2006) that transcends racial boundaries (Gauri and Lieberman 2006). My argument follows the tradition of other scholars who have employed a state-centrist approach when explaining Brazilian AIDS policies (Nunn 2007; Gomez 2006), but extend the analysis to the topic of intellectual property.

Why did this coalition of institutional insiders and AIDS activists not resist IP reform in 1996? At that time, the directors of the National AIDS Program and activists focused their efforts on obtaining universal access to treatment. Even after the passage of Sarney's Law 9.113 in 1996 mandating the state to provide AIDS medicines, the main challenge was to transform the formal law into substantive programs on the ground. Activists continued public protests; patients kept filing lawsuits to guarantee access; and the directors of the National AIDS Program stepped up criticism of ministers who failed to transfer sufficient resources to fund treatment. These actions were particularly evident in 1998–99 when the country suffered an economic crisis and the economic team imposed austerity measures. Despite the fiscal restraints, pro-treatment efforts prevailed, and efforts to scale up the program continued unabated. Only after successful treatment roll-out did intellectual property appear as a threat to the sustainability of universal treatment, and mobilization increased towards the inclusion of more humanitarian safeguards in domestic patent legislation and pressure build to make use of compulsory licenses to lower the price of patented ARVs.

Brazil's Department of DST/AIDS and Hepatitis[5] reported that some 200,000 patients were in treatment in 2010, out of a total seropositive population estimated at 630,000. According to UNAIDS (2008), access to anti-retroviral (ARVs) medicines in Brazil reaches 80 percent of those who require treatment – one of the highest rates of coverage in the developing world and comparable to wealthy country standards. Brazilian authorities

[5] In 2009 the National DST/AIDS Program and National Hepatitis Program were merged into a single department under the Secretary of Health Surveillance.

have also made an effort to incorporate the latest AIDS medicines into their treatment regimens. Specialists meet annually to evaluate best treatment practices and consider new drugs for incorporating into the therapeutic consensus. When legislation was passed in 1996 mandating that AIDS patients should receive free and universal access to treatment, the Ministry of Health mobilized federal drug maker Farmanguinhos, part of the Oswaldo Cruz Foundation (FioCruz) and other labs operated by state governments to supply the public health system (Flynn 2008; Cassier and Correa 2003). At the start of free and universal care in the 1990s, few of the medicines were protected by patents. Now 13 of the 20 medicines employed are patent-protected thus increasing the cost of the program.[6] Since anti-retroviral therapy does not cure the disease but transforms it into a chronic condition, patients must be provided with a continuous supply of medicines. As viral resistance develops and/or adverse reactions occur, users migrate to more expensive second- and third-line treatments protected by patent.

The TRIPS accord, stipulating exclusive marketing rights to pharmaceutical firms, has had a direct impact on Brazil's social program. If the Brazilian government had waited until the 2005 deadline to change national legislation, the cost of Brazil's AIDS program would be less and local industry would have had more time to develop local formulas of patented medicines, or procure supplies from Asian countries that had not yet incorporated patent protections for pharmaceuticals. The politics surrounding AIDS treatments and patents is thus illustrative of the factors contributing to TRIPS compliance and the role played by 'institutional insiders' in promoting increased use of humanitarian safeguards, especially the use of compulsory licenses, in order to drive down prices.

FIVE INSTANCES WHEN A COMPULSORY LICENSE WAS THREATENED DURING PRICE NEGOTIATIONS

Brazil's use of compulsory licenses stems from the fact that health officials must balance the ministry's available resources with necessary inputs

[6] As of 2010, ARVs produced in public and national labs included didanosine, estavudine, indinavir, lamivudine, nevirapine, ritonavir, saquinavir, zidovudine, efavirenz and zidovudine+lamivudine. Imported and patent-protected ARVs include abacavir, amprenavir, atazanavir, darunavir, etravirine, enfuvirtide, fosaprenavir, lopinavir/ritonavir (Kaletra), and raltegravir. The production of tenofovir, whose patent request by Gilead was denied in 2008, is being scaled up locally.

Table 6.1 Use of compulsory license and results of ARV negotiations, 2001–2007

Year	Medicine (brand name)	Patent holder/licensee	Result
2001	Efavirenz (Sustiva)	Merck	59% discount
	Nelfinavir (Viracept)	Hoffman-LaRoche	40% discount
2003	Efavirenz (Sustiva)	Merck	25% discount
	Nelfinavir (Viracept)	Hoffman-LaRoche	10% discount
	Lopinavir/ritonavir (Kaletra)	Abbott	13% discount
2005	Lopinavir/ritonavir (Kaletra)	Abbott	46% discount
2006	Tenofovir (Viread)	Gilead	51% discount
2007	Efavirenz (Stocrin)	Merck	Compulsory license 75% price reduction

for its health system.[7] Interviewees from Brazil's Ministry of Health and National AIDS Program consistently repeat that the overall objective is to ensure the sustainability of universal access without interruption (Costa 2008; Alvares 2008; Chequer 2008). Sustainability also includes the program's medium- and long-term financial viability. To this end, negotiators from the Ministry of Health have sought commodity prices. That is, policymakers want a price offering reduced premiums (i.e. profits) to the seller based upon Farmanguinhos' cost-of-production parameters or lowest available prices on the international market. The institutionalized commitment to providing universal ARV therapy has driven the Ministry of Health to propose legislative changes in IP law and use compulsory licenses in price negotiations.

Since the time when Jose Serra was Brazil's Minister of Health (1999–2002), negotiators have on several occasions threatened to issue compulsory licenses during price talks with foreign patent holders of AIDS medicines. Table 6.1 provides a list of the different episodes, the drugs and patent holders involved, and the results of the negotiation. A negotiated settlement resulting in a price discount occurred in every instance

[7] Many other articles have highlighted how limited fiscal resources threaten the sustainability of important health programs such as free and universal access to AIDS treatment (Biehl 2004; Cassier and Correa 2007; Cassier and Correa 2003; Grangeiro et al. 2006; Greco and Simão 2007; Teixeira et al. 2003; Wogart and Calcagnotto 2006; Cohen and Lybecker 2005; Bermudez and Oliveira 2004; Serra 2004; Passos 2008; Coriat 2008; Orsi et al. 2003).

except one in 2007 when Brazil followed through with its threats against Merck. Analyzing the use of this legal instrument will allow us to explore the social forces involved in the use of TRIPS flexibilities. These factors include civil society support; presence of a weak, domestic-owned pharmaceutical industry; balance of needs between corporate investors and host countries; pressures from foreign governments; and issue area discourses, or how certain issues are framed.

Role of Domestic Pharmaceutical Sector

Brazil had the ninth largest pharmaceutical market in the world in 2007 with sales totaling US$15.7 billion (IMS Health 2008). Brazil's pharmaceutical sector consists of four distinct players: (1) foreign-based pharmaceutical companies which account for about 70 percent of the market; (2) 18 public labs, responsible for less than five percent of production (mainly sent to the public health sector); (3) local, privately owned firms which produce generic formulations; and (4) a local pharmochemical sector that produces the raw materials and active pharmaceutical ingredients for drug production. Generic medicines comprise almost 20 percent of the entire market, up from zero when the legislation regulating generics was passed in 1999. Of the generic medicines market, Brazilian companies account for 80 percent of sales (Pro-Genericos 2009). Few domestic drug makers are vertically integrated, that is, produce both APIs and finished dosage forms. The one notable exception is São Paulo-based Cristália, which has an ARV product line.

Brazil's market remains heavily dependent on imports. In 2006, medicine imports of US$1.7 billion surpassed exports of US$435 million; and imports of pharmaceutical raw materials such as active pharmaceutical ingredients amounted to US$1.3 billion compared to US$272 million in exports (Gadelha 2007). Currently, there are only 23 Brazilian pharmochemical producers in Brazil which supply about 20 percent of the domestic market (Chamas 2005). As a result of persistent external dependency, Brazilian officials included the pharmaceutical sector in new industrial policies implemented during the government of President Luis Inacio Lula da Silva (2003–2010).

Shadlen (2009) argues that the presence of an indigenous pharmaceutical sector that is weak relative to large transnational drug firms, but strong enough to lobby lawmakers, plays a significant role in pressing for TRIPS flexibilities. A domestic generic drug industry seeks weak IP legislation as opposed to strong laws that would benefit foreign-based companies. In the case of Brazil's use of CLs, the indigenous private drug industry has played an important supportive role. But the Ministry of Health has

only purchased a small fraction of the ARVs used in its treatment program from the domestic private sector (Flynn 2008). Although Brazilian private company Microbiologica was the first to reverse-engineer AZT (zidovudine) in the early 1990s, the government's decision to produce ARVs in public labs (in effect, state nationalization of production) has kept the participation of private domestic drug makers to a minimum.

By the end of 2002, there were 19 national drug makers registered with ANVISA to sell ARVs. Only Laob, Eurofarma, Neo-Quimica and Cristália had closed large contracts during the early years of the program (Orsi et al. 2003). Most private domestic drug makers see few economic benefits to investing in ARVs, if the government crowds out their participation. Even public labs run by state governments are hesitant to dedicate resources to produce medicines for the national program if production is concentrated in Farmanguinhos and there are no firm purchase guarantees. The same logic affects upstream industries. Brazil's pharmochemical sector, including Microbiologica, has not benefitted from the billions spent on ARV procurement. Instead of purchasing raw materials from domestic producers, the drive to reduce costs, and strict tender laws, have forced public labs to source inputs from lowest-priced Asian producers (Marques and Hasenclever 2006).

Brazilian private sector producers said that government officials consulted them every time a compulsory license was threatened during price talks with foreign drug makers, except on the last occasion in 2007 when one was actually issued (Maçiara 2007; Neto 2008). Pedro Chequer, the former director of the AIDS program, is credited for reaching out to local industry to produce Kaletra during the tense 2005 confrontation with US-based Abbott. When a CL was finally issued in 2007, however, the Ministry of Health imported the drug from WHO pre-qualified Indian suppliers until its public labs ramped up production. The latest policy innovation following the CL is that Farmanguinhos has subcontracted production of the API of efavirenz to three domestic suppliers (Nortec, Globe, and Cristália) instead of obtaining inputs from foreign firms.

Having domestic pharmaceutical capabilities strengthens the bargaining hand of Brazilian negotiators. But apart from Farmanguinhos' managers, they have not played a proactive role in pressing for TRIPS flexibilities. The most dynamic indigenous drug sector is Brazil's generics industry, but they have been sidelined as a result of government monopolization of ARV production. Domestic firms did not object to changes to IP legislation to use of compulsory licenses because their interests were not threatened. Rather, they have played an important supportive role as Shadlen's (2009) account suggests. This is especially true for the domestic

pharmochemical sector which has sought out increased government support over the past decade.[8]

Civil Society Pressure

Civil society support has been important in Brazil's battles with companies over the use of compulsory licenses. The Consumer Project on Technology (2009), a US-based consumer rights group,[9] lists on its website numerous examples of declarations from activists around the world in support of Brazil's AIDS program and right to use compulsory licenses. Domestic groups[10] are also networked in with other international health activists in both the global South and North. Globalization in this sense has empowered states in their relations with transnational corporations. My review suggests that support from health activists, though perhaps necessary, is not sufficient to explain the use of humanitarian safeguards.

The tradition of proactivity by the Brazilian National AIDS Program in establishing alliances with civil society through formal institutional and informal channels to fight the disease (Rich 2009) has been extended to the case of patents. During the 2001 WTO dispute with the US concerning the use of a compulsory license when a product is not "worked" locally, Brazilian officials enlisted the support of civil society for the country's defense. According to Paulo Teixeira (2008), the director of Brazil's National AIDS Program at the time, health officials took the initiative to reach out to local and foreign activists. The strategy worked, and the

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[8] Shadlen highlights the importance of Brazil's pharmaceutical sector for promulgating more TRIPS flexibilities. Indeed, Brazil's pharmochemical industry association Abifina helped pen the 2003 legislation related to the use of compulsory licenses (Shadlen 2009; Maçiara 2007). While Abifina representatives have defended the government's use of humanitarian safeguards and criticized early adoption of TRIPS, few other pharmaceutical industry associations have because, in part, the market is dominated by foreign companies. In either case, my interviews with public health officials said they took the initiative to review laws regarding parallel importing, compulsory licenses, and other drug-related IP issues in 2003 after the election of Luiz Inacio Lula da Silva (Grangeiro 2008).

[9] The NGO is also known as Knowledge Ecology International – KEI.

[10] The most prominent is the Working Group on Intellectual Property from the Brazilian Network of Peoples Integration (Grupo de Trabalho em Propriedade Intelectual da Rede Brasileira pela Integração dos Povos – GTPI/Rebrip). The group, established in 2001, is comprised of local NGO groups ABIA, CONECTAS, GAPA – SP, GAPA – RS, Gestos, GIV – Grupo de Incentivo a Vida, INESC, INTERVOZES, and Pela Vida, as well as international groups MSF and OXFAM.

US removed the WTO panel.[11] Indeed, price negotiations with Merck and Roche occurring at the same time as the panel dispute resulted in a negotiated settlement with steep discounts.

Pressure from the activist community to "break patents"[12] was greatest in 2005 during negotiations with Abbott over the price of Kaletra. In August of 2005 in the midst of price talks, Brazil's National Health Council (Conselho Nacional de Saúde) – the highest instance of societal participation in the public health system – unanimously voted in favor of compulsory licenses for patented ARVs that burdened Brazil's health system. Brazil's Minister of Health at the time, Saraiva Felipe, dismissed the motion and completed price negotiations without decreeing the CL. In the aftermath, several Brazilian organizations filed a lawsuit against the government for not rescinding Abbott's exclusive marketing rights.[13] But the efforts were in vain, and Abbott did not lose its monopoly on Kaletra, although it did provide a price discount.

When Brazil's current Minister of Health finally decreed a CL for Merck's efavirenz in May 2007, many activists were surprised (as well as many other observers and Merck itself), especially since many previous threats had never materialized. Nevertheless, domestic and international health rights groups voiced their support and educated the public about the measure (Chaves 2008). In terms of the use of compulsory licenses, civil society pressures have been important but not determinative in their effective implementation. One could rightly argue, though, that Brazil's National AIDS Program represents the institutional manifestation of a powerful social movement.

Issue Area Discourses

The way in which issues concerning intellectual property rights and the legitimate employment of compulsory licenses are framed have the potential to augment state power vis-à-vis corporations (Blanchard 2004; Greenhill and Busby 2008). For Brazilian health officials, this discourse is rooted in notions of collective rights and institutionalized in a public health system. In every instance in which Brazil has threatened to use a

[11] Brazilian AIDS activists interviewed for this research said they began to become aware about and mobilize against TRIPS during the WTO dispute.

[12] The "breaking of a patent" is a misnomer when a compulsory license is decreed since the patent remains in place. Only market exclusivity is revoked.

[13] Pedro Chequer (2008), the director of Brazil's National AIDS Program at the time, said he provided NGOs all the information necessary to proceed with a lawsuit.

compulsory license, negotiators based their arguments on international human rights treaties and domestic laws upholding these social rights. Additional frames have been used, but these have shifted over time. In the first episode, Brazil declared that its model AIDS program represented a case of urgency and public emergency. But on later occasions, the Ministry of Health employed the public interest clause (or public non-commercial use) in intellectual property legislation instead of emergency use. Since Brazil's AIDS program is considered one of the most successful in the developing world, it is difficult to classify AIDS as an out-of-control epidemic.[14]

The frames employed by patent holders have been less consistent, less coherent across the different groups of IP defenders, and evolved more over time. Indeed, industry has grudgingly adapted to the new reality after the Doha Declaration on TRIPS and Public Health of 2001. Although some industry advocates such as USA for Innovation call Brazil's and Thailand's actions 'theft' (USA for Innovation 2007) and strong IP defenders advocate a forceful US response (Kogan 2006), spokespeople for drug companies and industry associations concede that they are not against compulsory licenses per se. Rather, they argue that the measure should only be used in the last instance, specifically for national emergencies such as after the 9/11 terrorist attacks. A Pharmaceutical Research and Manufacturers of America (PhRMA) representative said that the Brazilian government acted within the TRIPS agreement but "against the spirit of the law" when issuing its first compulsory licenses for efavirenz in May 2007 (Singer 2007). Brazilian drug industry spokespeople also uphold this normative view that CLs should only be used in times of public emergency and not as a form of price regulation (Mortella 2008). For Brazilian health officials, however, the use of humanitarian safeguards remains important as a tool for market regulation since other governmental bodies responsible for enforcing antitrust legislation remain weak and fragmented (Rech 2008).

In the more recent price negotiations and compulsory license threats, the issues of differential pricing schemes and the necessity of funding research have become more salient. Industry argues that Brazil's effective treatment program would not be possible without innovations carried out in the private sector that result from strong IP protection. In order to ensure a steady stream of new medicines into the future, even developing countries should pay for part of the R&D expenses. Additionally, when Brazil

[14] UNAIDS (2008) estimates Brazil's prevalence rate (adults aged 15 to 49) at 0.7 percent, compared to Thailand (1.5 percent) or South Africa (21.5 percent).

requested during 2007 talks that Merck reduce unit prices from US$1.65 to the price offered to Thailand of US$0.65, the company responded that it would undo its tiered pricing scheme. Merck's formula for pricing the medicine in developing countries is based on a country's score on the Human Development Index and HIV prevalence rates. In Thailand, prevalence is three times greater than Brazil. Brazilian negotiators countered that since they purchase larger quantities of efavirenz they should receive a deeper discount. Merck initially provided a discount of 5 percent, which increased to 30 percent in its last proposal, effectively reducing the unit price to US$1.10. But the amount was not compatible with commodity prices sought by Brazilian negotiators (Passarelli 2007; Passos 2008).

The last means by which the use of compulsory licenses has been framed is the impact on a country's industrial development. Negotiations also included offers to transfer technology to produce efavirenz. In the 2007 Merck negotiations, Brazilian officials rejected company proposals because the transfer was only to be concluded a year before the patent expires in 2012 and with the condition that the active pharmaceutical ingredient be provided by the company. For Brazilian officials, offers of technology transfer in the area of ARVs have never been acceptable.[15] An additional factor weighing in on Brazil's decision to use a compulsory license was Merck's efforts in the courts to block Farmanguinhos' access to the API of efavirenz to develop the drug.

Since there were no local producers registered to supply efavirenz after a compulsory license was issued, Brazil decided to import it from three WHO pre-qualified Indian companies until Farmanguinhos scaled up production. The measure left the Health Ministry open to charges by Merck's president, Tadeu Alves, that "Brazil is creating jobs in India" (Borsato 2007). Asked about the potential impact of the compulsory license on pharmaceutical research in Brazil, José Temporão responded that "when they say that multinational industry is going to stop doing research in Brazil, there the history is different: it never has done research in Brazil" (Lago 2007). The Minister of Health was referring to the high-end R&D of discovering new chemical entities. In the area of clinical testing, Brazil has a long history of volunteering its bodies for evaluating the effects of ARVs and other medicines.[16]

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[15] There are cases in which foreign drug firms have joint ventures with Brazil's public labs. FioCruz has joint projects with GlaxoSmithKline and the Butanta Institute, another government research institute with Sanofi Pasteur.

[16] Transnational drug companies carry out clinical testing in Brazil, in part, to market their product. Brazil is the third largest market in ARVs after the United States and South Africa.

Tracing the discourses related to CLs reveals the importance of human rights trumping the intellectual property rights of drug companies during battles over prices. However, in later confrontations, concerns over the sustainability of the treatment program were subsumed under the state's interest in promoting economic and technological development.

Balance of Needs

Brazil's need for investment versus a company's need for markets affects the power plays involved in using humanitarian safeguards (Blanchard 2004). As the Brazilian economy has strengthened during the administration of Lula, it has become less vulnerable to drug company threats. Consequently, AIDS officials have become more successful in lobbying for support from other government ministries.

Brazil changed its IP legislation nine years before the expiration of the TRIPS transition period because of its susceptibility to US trade pressure. This was due to the fragile economy undergoing macroeconomic stabilization and embracing of neoliberal policy initiatives. During the first confrontation over prices and patents in 2001, Brazil faced down a WTO panel brought against it by rallying world support, yet in the end achieved a negotiated settlement. During the 2003 and 2005 negotiations in President Lula's first term, the primary concern was placating foreign investors who were worried about the macroeconomic policies of the left-of-center president. When negotiations with Abbott in 2005 came to a head, for example, ministries related to trade and finance voiced concerns about the possible ramifications of trade sanctions if Brazil were to issue a compulsory license for Kaletra.[17] Members of the US Congress urged the USTR to withdraw Brazil's trade privileges provided under the General System of Preferences.[18] Estimates of Brazilian exports affected by the possible trade retaliation range from US$48 million (Boletín Farmacos 2005) to US$3.6 billion (Kogan 2006).

In the lead-up to the compulsory license of efavirenz which happened in May 2007, the situation had changed. All ministries agreed that Merck was being intransigent during negotiations and thus provided key support in the Ministry of Health's decision (Passarelli 2007). After the decree, Tadeu Alves, the president of Merck's Latin American division, said

[17] In fact, Minister Fernando Furlan from the Ministry of Development, Industry and Trade broke ministerial protocol by convening meetings concerning the issue that was the prerogative of the Ministry of Health (Alvares 2008).

[18] General System of Preferences provides additional market access beyond what is stipulated in the World Trade Organization.

that "the perception of Brazil will not be the same" and declared that the company was reviewing its investment plan in the country (Borsato 2007). The following year, however, Merck announced plans to invest in clinical testing and was willing to work with the Ministry of Health on common projects, including the local production of efavirenz (Vieira 2008). The company also had another ARV, raltegravir (brand name Isentress), for which it lobbied and obtained inclusion in Brazil's AIDS program in 2008. Another factor weighing in Brazil's favor was its consumer reputation. Several executives from foreign drug companies mentioned in interviews: "Brazil is a good client that pays in full and on time."[19]

A critical issue concerning the balance of needs is whether a country has access to alternative drug suppliers where a compulsory license is issued. While Brazil's economy has strengthened, its local ARV production has not. This fact has tilted the balance of need in favor of patent holders. In the first round of negotiations in 2001 with Roche, Farmanguinhos provided information on production costs and produced samples of the drug. But due to organizational changes and obstacles in obtaining patented raw materials to produce medicines, its capability to rapidly reverse-engineer and scale up production had declined. Health officials who concluded the Abbott negotiations without issuing a compulsory license for Kaletra said during interviews that one factor that influenced their decision was the lack of guarantees from FioCruz's laboratory to scale up production fast enough to supply the critical ARV.[20] Having pre-qualified Indian suppliers by the World Health Organization, as in the case of efavirenz, improved the government's bargaining position.

The changing balance of needs varies at the macroeconomic level from a position of weakness to increasing strength. But at the microeconomic level, the capabilities of public labs have declined as a result of IP barriers to patented APIs and organizational changes. This factor remains contradictory in terms of its effects on Brazil's promulgation of TRIPS flexibilities. Policymakers, nonetheless, as a result of the requirements of its AIDS program, have pushed for industrial policies to develop local pharmaceutical-making capacity and overcome upstream weaknesses in local pharmochemical production.

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[19] Personal interviews with corporate government relation managers (Sanches 2008; Salles 2008).

[20] Personal interviews with Ministers of Health (Felipe 2008; Alvares 2008). The question about Brazil's capacity to produce ARVs resulted in a flurry of studies and evaluations including UNDP (2006), Clinton Foundation (2006), and NGO-sponsored reviews (Fortunak and Antunes 2006).

Support of Home Governments

Another factor having an impact on the use of compulsory licenses is the role of the US government. In the first negotiations in 2001, price talks occurred in the midst of a WTO panel against Brazilian IP legislation related to the 'local working' provision. Although the US complaint had been brewing since Brazil's new Industrial Property Law was passed in 1996 and would have reached the WTO regardless of the price negotiations, that the two disputes coincided underscored US influence. In the 2005 price talks, cables between US diplomats in Brazil and the State Department reveal the US' direct involvement of the negotiations between the Ministry of Health and Abbott over the price of Kaletra.[21] One top Brazilian official involved in the price negotiations said that a US diplomat threatened to terminate all Brazilian scientific projects and studies at US universities if Brazil were to use a compulsory license (Alvares 2008).

A review of US diplomatic cables and interviews with a US diplomat and Brazilian participants suggests that the US Embassy was far less involved in the efavirenz negotiations in 2007 as compared to previous confrontations. Only after efavirenz was decreed in the public interest did US officials voice their concerns and warn Brazilian health authorities of the 'political storm' if a CL was issued. In fact, the USTR (2007) had removed Brazil from its Priority Watch list owing to the country's efforts to protect intellectual property, although it continued to highlight concern over the use of compulsory licenses. Furthermore, the US has not applied any trade sanctions nor carried out any out-of-cycle reviews of Brazil's IP protection, despite pressure from PhRMA.

This leads to two possible conclusions: either Abbott has more influence than Merck in obtaining the support of the US government in IP disputes, or the US has become more permissive towards the use of CL in the case of medicines used to treat AIDS. Concerning the latter possibility, the US again may be susceptible to "rhetorical entrapment" (Greenhill and Busby 2008). How could the US, while providing billions of dollars to fight HIV/AIDS through the Presidential Emergency Plan for AIDS Relief (PEPFAR), not allow a country that has become a model in fighting AIDS to economize resources? Here again, the success of Brazil's social policy of universal treatment may have undercut US pressure related to the use of a compulsory license. The US continues to back industry-favorable

[21] The cables made available through a Freedom of Information request are available at http://www.keionline.org/index.php?option=com_content& task =view&id=134.

positions in regional and bilateral trade agreements and global IP-related frameworks, but in individual cases concerning AIDS medicines, there may be a thawing.

CONCLUSION

The Brazilian case suggests that the TRIPS accord has had a significant impact on the political decision-making process in Brazil. The international IP framework has set up major obstacles and increased the political and economic costs of carrying out universal-based social policies. Patent monopolies have undoubtedly increased the bargaining power of TNCs. On balance, foreign drug firms have profited handsomely from Brazil's universal AIDS program. Between 1996 and 2007, the Brazilian government spent a total of US$2.71 billion on ARVs. Of this amount, foreign firms received US$1.85 billion[22] or 68 percent of the total.

Nonetheless, a strong health agency responsible for the substantiation of social rights, such as in the case of domestically driven AIDS policies, played an important role for incorporating more TRIPS safeguards in domestic legislation and resorting to their use. Policymakers responsible for maintaining the universal social programs sector must seek innovative ways between balancing limited budgets and increasing social demands. The right to health shapes a human rights discourse that is shared by both committed public servants and civil society activists. The interests of domestic drug companies and threats by foreign economic forces may result in local industry vetoing initiatives by public health officials and/or resistance by other government ministries. But without the bulwark of a strong federal agency to fight AIDS, my review of the Brazilian case suggests, the struggle for universal access to essential medicines, incorporation of more TRIPS flexibilities in local legislation, and their subsequent use would have been minimal.

After the compulsory license issued for efavirenz in 2007, Brazil was able to achieve favorable prices for tenofovir and Kaletra. In recent price negotiations, market exclusivity of patent holders of ARVs has not been threatened by Brazilian negotiators. Additional factors have kept the use of compulsory licenses from being employed. After years of delayed analysis, Brazil's intellectual property office finally made a ruling denying Gilead's patent request for high-priced tenofovir, and public labs are gearing up to produce the medicine locally. Brazil's Ministry of Health has

[22] In 2005 US dollars, based on data from Brazil's National AIDS Program.

also adopted new price control regulations. When a new patented medicine demonstrates therapeutic advantages over existing treatment, the Ministry of Health sets a price ceiling based on the lowest price of the drug in several countries[23] including the country of origin (PAHO 2009). These efforts allowed Brazil to reduce treatment expenditures by 12 percent or some US$60 million in a recent round of negotiations (Brazil 2010).

The Brazilian case suggests that when a social program achieves success in rolling out medicines, a strong constituency develops to ensure its continued success. In looking towards the future, flashpoints along the IP landscape are likely to occur where public commitments and national organizations that provide ARVs remain strong, but the global economic crisis has reduced donor budgets. As budgets decline, stakeholders in universalizing treatment will demand that corporations reduce prices and will insist on using more TRIPS flexibilities so as to allow for more generic competition. Brazil will surely play an important part in this on-going struggle.

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[23] Specifically, Australia, Canada, Spain, United States, France, Greece, Italy, New Zealand, and Portugal.

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APPENDIX 6A TRIPS FLEXIBILITIES AND RELATED BRAZILIAN INTELLECTUAL PROPERTY LEGISLATION

TRIPS FLEXIBILITY	BRAZILIAN IP LEGISLATION
(1) **Transition period**: The deadline that member countries have for making domestic laws compliant with TRIPS varies depending on their level of development. High-income countries had until 1996 to change their laws; middle-income countries, including Brazil and India, 2005; and least developed countries have until 2016 (Arts 65 and 66).	Brazil approved Industrial Property Law 9.279 in 1996 and implemented it the following year, several years before the 2005 deadline.
(2) **Experimental exception**: The patent will not prohibit the experimental use of an invention by third parties for scientific purposes.	Included in Industrial Property Law 9.279.
(3) **'Bolar'/early working exception**: Third parties may carry out all the necessary tests and procedures required for the registration of generic medicines before their patent expires (Art. 30).	Law 10.196 passed in 2001 amends Art. 43 in Law 9.279 to provide for this exception.
(4) **Parallel imports or exhaustion of rights**: Without the consent of the patent holder on the domestic market, a product may be resold or imported from another country where the patent holder has authorized it to be placed on the market (Art. 6).	Decree 4.830 of 2003 amends Decree 3.201 to allow parallel importing of patented products when a compulsory license is issued.

(5) **Prior use**: If a person uses an invention before a patent is filed for the product, s/he may be granted the right to continue using the invention despite the granting of the patent (Art. 30).	Included in Industrial Property Law 9.279.
(6) **Compulsory license**: The main legal instrument for correcting abuses by patent holders is the compulsory license (CL), which allows for the exploitation of a patent by third-parties without the consent of the patent holder. Use of a CL is permitted in six instances: (a) refusal to deal; (b) cases of emergency or extreme urgency; (c) to remedy anti-competitive practices; (d) failure to obtain voluntary license under reasonable terms; (e) public non-commercial use; and (f) dependent patents for innovations requiring patented inputs. Before issuing a CL, a government must first attempt to reach a negotiated settlement with the patent holder, who, in the case of the CL, still has the right to receive royalties. There are two exceptions. First, prior negotiations are not required in cases of a national emergency and public, non-commercial use. Second, royalty payments may not be necessary when a CL is issued to correct anti-competitive practices.	Industrial Property Law 9.279 states a CL can be issued for the following reasons: failure to exploit patent; public interest; national emergency; remedy for anti-competitive practices; and failure to produce locally and dependent patents. Decree 3.201 of 1999 specifies the criteria for issuing a compulsory license in cases of national emergency and public interest. Decree 4.830 of 2003 amends Decree 3.201 to allow parallel importing of patented products when a compulsory license is issued.

(7) **Prior consent and pre-grant opposition:** Countries can determine the appropriate method of implementing the provisions of TRIPS within their legal system; consequently, domestic legislation may allow other government agencies or members of society to participate in patent application process (Art. 1.1).	Law 10.196 of 2001 amends Art. 229 in Law 9.279 stating that National Health Surveillance Agency (ANVISA) must give prior consent before patents are granted on all pharmaceutical products and processes. (Prior consent was first established by Presidential Directive in 1999.)
(8) **Pipeline versus mailbox:** A pipeline patent is a form of retroactive protection for drugs already patented in other countries but not marketed at the time TRIPS comes into force. Otherwise, a mailbox system allows applications for patents for pharmaceutical product inventions to be filed but not examined until the end of the transition period (Art. 70.8).	Industrial Property Law 9.279 of 1996 allows for pipeline patents.
(9) **Data exclusivity**: Grants protection for undisclosed data that drug firms provide to regulatory officials in order to obtain marketing approval. Extending the timeframe for protecting undisclosed data, a TRIPS-plus measure, restricts competition from generic drugs makers that could lower prices (Art. 31).	Law 10.603 of 2002 provides protection to up to 10 years for drugs that include new chemical entities and 5 years for all other drugs for undisclosed test data that drug firms provide to ANVISA.