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CHAPTER FIVE

Access to Medicines: Pharmaceutical Patents and the Right to Health

Monica Steffen Guise Rosina

Daniel Wei Liang Wang

Thana Cristina de Campos*

Research Team and Support: *Gabriela Costa Chaves; José Antonio Batista de Moura Ziebarth; Karina Grou; Renata Reis.*

The concept of “access to knowledge” encompasses a variety of values, including access to knowledge goods (Shaver 2008, 253–256). These goods may be “better, more plentiful or cheaper because of some technological advance embedded in them or in their production,” and their affordability is greatly influenced by patent regimes (Benkler 2006, 311–312). This chapter focuses on access to medicines in Brazil, with particular attention to the impact of recent legislative reforms that implemented the TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights).

For some time, Brazil has been a world leader in the area of access to health – and in particular, access to medicines. The country has developed a comprehensive national system that aims to secure access to health as a constitutional right to all Brazilian citizens. There is, however, a complex story behind the implementation of this constitutional provision. Lessons may be learned not only from its successful results but also from its failures. The objective of this chapter is to outline and assess how – and if – access to medicines is assured in Brazil, with particular attention to the role of

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information policy, including the pharmaceutical patent regime. The chapter is divided into four parts.

Part one presents the legal framework governing access to medicines in Brazil. Starting from the constitutional text on the right to health, this part reviews the federal legislation that specifically implements a right of access to medicines, as part of the constitutional right to health.

Part two examines Brazilian case law on access to medicines. Brazilian courts have traditionally been very generous in ordering the government to supply medicines sought by special petition, regardless of cost. Recently, however, the courts have shown signs of rethinking this approach, as the financial impact of high drug costs has become increasingly unsustainable.

Part three takes a closer look at the dynamics underlying these financial pressures, examining the role played by pharmaceutical patenting in the rising cost of medicines. This part concludes that the Brazilian government made three mistakes in implementing TRIPS: opting for early implementation, approving pipeline patents, and prohibiting parallel imports.

Part four examines the efforts Brazil has made to control drug costs post-TRIPS, including: price negotiations and compulsory licenses, the prior consent mechanism, the Bolar exception and the Popular Drugstore program. This part concludes that Brazil's experiences do provide some success stories, but further efforts are still needed to control rising costs.

Access to medicines as a constitutional right

Access to medicines in Brazil must be viewed within the broader context of the national legal framework on the right to health. As we will see in this section, several sources of Brazilian law guarantee the right to health, with specific reference to a universal right of access to medicines.

The constitutional right to health

In 1988, as a result of the redemocratization process and civil society pressure (Escorel et al. 2005, 59–81, Labra 2005, 260–262), Brazil approved a new federal constitution.¹ Article 196 of the Brazilian Federal

1 The full texts of all constitutional, statutory, and regulatory materials cited in this chapter may be accessed online in Portuguese. Please consult the Bibliography for direct links.

Constitution – Constituição da República Federativa do Brasil de 1988 – states that:

Health is the right of all and the responsibility of the State, to be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards, and at the universal and equal access to actions and services for its promotion, protection and recovery.

The constitution also qualifies health as a fundamental right, thus giving it an instantly binding application.² The right to health in Brazilian law is not understood as an aspirational development goal, but immediately creates citizen rights and state obligations.³

To implement the constitutional right to health, Lei 8.080/90 and Lei 8.142/90 established the National Health System – Sistema Único de Saúde (SUS). This single public health system guarantees universal health care coverage to all Brazilian citizens, providing access to health care to 60 million people who had been excluded from the previous national public health services (Sobrinho 2002, 7).

The legislation established three foundational principles of the Brazilian National Health System. First, it should be universal – meaning that no citizen can be excluded from SUS coverage. Second, it should be characterized by equality of access – with no discrimination regarding the public health services and products provided to users. Third, it should provide *full* health care coverage – from the most basic to the most complex health care needs. The three principles of universality, equality and integrality define the Brazilian state's promotion of health as a fundamental social right (Cohn 2005, 387).

The right of access to medicines as part of the right to health

The constitution does not specifically mention access to medicines as part of the right to health, but this understanding is established by the implementing legislation. Article 6(I)(d) of Lei 8.080/90 specifically provides that SUS

2 Art. 6 (Title II, “Fundamental Rights and Guarantees,” chapter II, “Social Rights”): “Education, health, work, leisure, security, social security, protection of motherhood and childhood, and assistance to the destitute, are social rights, as set forth by this Constitution.”

3 Art. 5, para. 1: “Rules defining fundamental rights and guarantees have instantly binding application.” For further information on the “instantly binding” nature of fundamental rights, see Silva (2005, 177).

“must be responsible for promoting full medical assistance, which includes pharmaceutical assistance.” Several other national laws and regulations also address the issue of access to medicines in Brazil.

Ordinance 3.916/98 created the National Policy on Medicines, aimed at guaranteeing access to medicines through affordable prices, as well as their safety, efficiency and quality. The National Policy on Medicines also directed the Ministry of Health to issue a list of essential medicines – *Relação Nacional de Medicamentos Essenciais (RENAME)*.⁴ The RENAME list is to be periodically updated by the Ministry of Health according to criteria of drug effectiveness, security and costs of the medicines available in the market. The list includes all drugs needed for the treatment and control of the main diseases in the country. Drugs necessary for the treatment of less common and very expensive to treat conditions – such as chronic kidney failure, organ transplants or refractory schizophrenia – are not included on the list. The RENAME list represents an important framework for public health policies, including: 1) the granting and revision of drug certificates; 2) the analysis of information that public health professionals must communicate to the population; and 3) the standardization and modernization of drug labeling and package inserts.

In order to comply with the constitutional right of integrality of access, SUS must give assistance not only to those who suffer from the most common diseases but also to patients who suffer from diseases that only affect a limited number of people and are most costly to treat. To provide for this type of treatment, Ordinance 2.577/06 established the National Program for Exceptional Medicines. This framework supplies strategic medicines for the treatment of HIV/AIDS, malaria, tuberculosis, influenza and meningitis.

In addition to these general frameworks, some laws have been specifically enacted for particular diseases or populations. Lei 8.069/90 explicitly provides that children and adolescents are entitled to full medical care. Lei 9.313/96 compels SUS to provide free medicines to all citizens infected with HIV/AIDS. Lei 10.741/03 requires that SUS accord full medical care to the elderly, and devotes special attention to their unique health needs – for example by means of specialized clinics and the availability of homecare services. Lei 11.347/06 guarantees free medicines to all diabetes patients.

4 According to Article 3.1 of Ordinance 3.916/98, “essential medicines are those considered to be basically indispensable to dealing with most of the population’s health problems. These products must be permanently available to those in society who need it, under proper pharmaceutical conditions.”

Judicial enforcement of access to medicines

As the previous section demonstrates, the Brazilian State's duty to provide full health care to all its citizens is well defined by the law. Implementing this duty, however, has proven to be a major challenge, particularly in regard to the provision of medicines. The tension between universal access to medicines and limited state resources has already found expression in several important court cases. An analysis of the judicial holdings in these cases will be the focus of this section.

In theory, Brazilian citizens should be able to access whatever medicines their doctors prescribe through SUS. In practice, however, the medicines sought are sometimes not made available. When this is the case, individuals may seek access by going to court. Depending on the case, such petitions may be based either on the constitutional right to health or on specific laws and statutes. These lawsuits usually demand: 1) medicines that are included on one of the Ministry of Health's supply lists but that, for a number of reasons,⁵ are not available; 2) medicines that are not included on the supply lists due to considerations of cost, including those for which cheaper generic versions are available; and 3) medicines that have not yet been established as safe and effective through national testing. Regardless of which category an individual's request falls into, Brazilian courts almost always rule in favor of the petitioner and order the State to provide the medicines sought.

The traditional approach: ruling in favor of access

In general, Brazilian courts have ruled in favor of petitioners demanding medicines. The judicial consensus is that, every time the government denies a medicine, it violates a fundamental constitutional right. The study of Brazilian case law shows that most judges: 1) consider the right to health individually, and not collectively; 2) interpret the right to health and the principles of SUS as the individual's right to any health-related expense; 3) ignore that the fulfillment of such rights is costly, that the needs of the health system as a whole are enormous and that the scarcity of public funds makes budgetary trade-offs necessary; and 4) do not take into consideration the already existing medicine distribution policies (Ferreira et al. 2004, 38–41, Wang 2006, 42–79, Marques et al. 2007, 103–106).

5 Reasons for unavailability may include: insufficient budgets to purchase all drugs approved for distribution, lapse of time between purchase and arrival of the drugs due to complicated administrative procedures, or simple logistic incompetence.

When analyzing the Superior Court of the State of São Paulo – Tribunal de Justiça de São Paulo (TJSP) – case law concerning specific demands for HIV medicines, Ferreira et al. (2004, 22) found that, in 84.7% of the cases, the Court considered the provision of health care to be an individual right, without any regard to further social and economic consequences. Marques et al. (2007, 105–106), analyzing the same Court from 1997 to 2004, came to a similar conclusion: in more than 80% of the cases that demanded medicines, judges considered that the right to health should be universally guaranteed but did not take into consideration other issues relevant to the discussion of public policies, such as the scarcity of resources.

The Brazilian Superior Court of Justice – Superior Tribunal de Justiça (STJ) – is the second most important court in the Brazilian legal system, receiving cases on appeal from all state courts. An analysis of its case law shows a similar pattern of judgment. In the great majority of the cases, the STJ decided that the State must provide the medicines demanded, regardless of: 1) their cost; 2) the scarcity of public resources; 3) the priorities established by the National Health System's pharmaceutical policy; 4) Lei 6.360/76 forbidding distribution of medicines not registered by the Ministry of Health; and 5) doubts regarding the effectiveness of the treatment (Wang 2006, 44–46).

The exception to this pattern is that the STJ has proved willing to deny requests for medical treatments outside of Brazil (Superior Tribunal de Justiça 2003a, 2003b, 2004, 2005). On such occasions, the typical line of reasoning was as follows: 1) the payment of such treatments would impose great difficulties on public authorities and make the public health system impracticable; 2) the scarcity of resources could not be ignored; and 3) the technical and administrative criteria chosen by the public administration to elect priorities for public health policy should be respected in order to promote a more rational spending of public funds and benefit as many citizens as possible. Some members of the Court, however, still voted in favor of granting the requests. Wang (2006, 54–58) relates that these members' considerations arrive at the conclusion that financial and economic issues cannot outweigh the constitutional right to health. It is interesting to note that this court did credit budgetary concerns when deciding lawsuits that involved treatments abroad, but not when it came to domestic treatments and access to drugs. In many cases, however, providing access to high-cost medicines can be just as expensive as providing treatment abroad.

In granting the vast majority of individual petitions for access to medicines, both the TJSP and the STJ were following the lead of the Supreme Federal Court – Supremo Tribunal Federal (STF).⁶ The STF is the highest court in Brazil and must judge appeals of decisions that: 1) are contrary to the provisions of the Federal Constitution; or 2) validate a statute or act of local government that may be interpreted as contrary to the Federal Constitution. Most of the lawsuits demanding access to medicines that have reached the STF are related to anti-HIV treatments, followed by phenylketonuria, Duchenne muscular dystrophy and cancer (Wang 2006, 67–79, Wang et al. 2007, 7–13). The STF has traditionally upheld all lower-court decisions that granted the medicines demanded.

In this line of cases, the STF's decisions portray the judiciary as a powerful tool for protecting the constitutional right to health. In the Court's understanding of its role, such lawsuits protect citizens against government irresponsibility and omission in regards to health issues. This stance is highlighted in a decision often cited as precedent by lower courts (Supremo Tribunal Federal 2000b):

FREE DISTRIBUTION OF MEDICINES TO PEOPLE IN NEED. When recognizing the legal validity of programs that distribute medicines free of charge to people in need [...] this Court puts the rules contained in the Constitution into effect [...]. It is not enough for the State to merely proclaim the recognition of a right. It becomes essential that the constitutional declaration be completely respected and fully complied with, especially in cases where the right – such as the right to health – qualifies as a judicial prerogative that ensures the right of the citizen to demand from the State the implementation of constructive actions [...] The importance of the right to health [...] legitimizes the actions of prosecutors and the Judiciary in those situations where State bodies refuse to respect the constitutional commandment, thus betraying legal and social obligations, whether by default, or by any other form of governmentally deviant behavior.

Traditionally, the STF precedents have understood budgetary considerations as a “secondary governmental interest” (Supremo Tribunal Federal

6 Lower courts are not, however, required to follow the STF's lead in these matters. A 2004 amendment to the Brazilian constitution gives the STF power to approve binding synopses – *súmulas vinculantes* – of its jurisprudence (Constituição da República Federativa do Brasil de 1988, art. 103-A). No binding synopsis concerning the right to health or access to medicines has been approved yet.

2000a), and of “minor importance” (Supremo Tribunal Federal 2001). The quote below exemplifies this rationale (Supremo Tribunal Federal 1998):

Forced to choose between protecting the essential right to life – an unalienable right assured by the Constitution (art. 5º) – or overruling it in favor of secondary or financial interests of the State, I understand, as this dilemma is set out, that judicial ethics dictate to the judge only one possible option: to decide in favor of the undeniable right to life.

The year of 2007, however, set a new landmark, as the STF started to reconsider its stance.

Courts at the crossroads: rethinking the right to medicines?

In 2007, the pattern of STF decisions regarding individual demands for medicines or medical treatments shifted significantly, as the Court started to deny some petitions, perhaps in recognition of the increasingly critical pressure the earlier approach was placing upon public health budgets. In this new line of cases, arguments that had not been considered relevant in previous decisions appeared: 1) public resources are limited, so there needs to be rationalization of public spending in order to provide health care to most people; 2) the right to health cannot be seen from an individual perspective, but as a right to be made concrete through public policies for collective, equal and universal access; 3) the administration’s funding allocation decisions should be respected.

The first two decisions denying medicines were issued in February and March of 2007 (Supremo Tribunal Federal, 2007a and 2007b). In her March vote, Minister Ellen Gracie, then President of the STF, stated that:

The administration of national health policies – which is done on a regional basis – must search for a better rationalization between the costs and benefits of treatments available for free, in order to reach the largest number of beneficiaries. It is my understanding that art. 196 of the Constitution, that assures the right to health, refers mostly to the carrying out of policies that reach the population as a whole, assuring them universal and equal access, and not in individual situations. The responsibility of the State to provide the resources necessary

to the health care of its citizens cannot endanger the public health system. In the present case, by conceding the effects of guardianship to determine that the State provides the related medicines [...] the possibility of offering basic services to the rest of society is being diminished.

Immediately after these first two decisions were issued, there was a strong reaction from NGO activists, who criticized the STF and strongly advocated in favor of the right to health in the media. Local health officials, on the other hand, filed new suits to interrupt medicine provisions previously ordered by lower courts. Subsequent decisions issued by the STF show an attempt to deal with these conflicting pressures from public health managers and civil society activists. Several decisions return to the prior pattern, concluding that it is indeed the government's obligation to provide the medicines demanded (Supremo Tribunal Federal, 2007c, 2007d, 2007e, 2007h, 2007i, 2007j and 2008). Others emphasize the limitation of resources and the need to respect public managers' funding allocations (Supremo Tribunal Federal, 2007f and 2007g).

From 1988 to 2006, therefore, the Brazilian judiciary strongly supported citizens' attempts to demand the right of access to medicines through the courts. At all levels, the courts decided the vast majority of these cases in favor of the petitioners. In 2007, however, the first hint of serious judicial rethinking of this approach was seen in the STF, as the court started to deny some petitions for access, in light of public budgetary considerations. In the face of criticism, however, the STF has been inconsistent; from mid-2007 forward, some decisions have continued the new approach, while others reflect the traditional one.

Discussion: policy considerations facing the courts

The debate concerning judicial protection of the right to health in Brazil touches upon two particularly delicate issues: access to medicines and access to justice. Some consider these lawsuits to be a constructive means by which the government is pressured to play a more active role in ensuring access to medicines – an important mechanism to fight against governmental delay and omission. Litigation can also be an effective way to pressure the government toward better public policies. Several non-governmental organizations (NGOs) and Brazilian state and federal attorneys have successfully used

the courts to pressure the government to make certain drugs more easily available through SUS (Scheffer et al. 2005, 127). The pressure of litigation has also been one of the reasons why Brazil's HIV/AIDS program has been so successful.

It is important to keep in mind, however, that such judicial remedies do not benefit all people equally. With very few exceptions, successful legal claims in this field are brought by plaintiffs who can afford to hire a good lawyer (Silva 2007, 7). This is certainly not the profile of the great majority of Brazilians, who rely on the public health system as their only option for medical care. Empirical research has verified that most of those who go to courts demanding a certain drug or medical treatment not available through SUS hire private lawyers and live in high-income districts (Silva 2007, 7). A second study found that most people who went to court had medical prescriptions from private doctors and were assisted by private lawyers; moreover, those with the highest incomes were the ones who demanded the most expensive drugs (Terrazas 2008, 40–43). It thus appears that the system of individual petitions works relatively well for wealthier individuals, but fails the poor majority, which does not have access to the justice system.⁷

Given this reality, court decisions that grant medicines to individual patients may be harmful to the planning and execution of public health policies as a whole. When examining individual petitions, most judges do not take the public health budget into account (Vieira and Zucchi 2007, 8). Therefore, each time that an individual petitioner obtains costly medicines by judicial order, a portion of the public health budget is diverted toward benefiting that individual, at the expense of other patients.

In recent years, lawsuits ordering the public administration to distribute medicines have dramatically increased, placing a heavy burden on the public health budget. According to the Brazilian Ministry of Health, expenses to comply with successful petitions increased 211.4% from 2005 to 2006. In 2006, the city of São Paulo alone spent R\$65 million on medicines to settle lawsuits that benefited only 3600 people (Terrazas 2008, 38). This represents an average cost of R\$18,000 per patient, in a country where the

7 Research shows that the main reasons why poor people do not benefit from such lawsuits are: 1) lack of resources and information (Lopes 1994, 74); 2) lack of efficient pro-bono legal assistance in Brazil (Ministério da Justiça 2004); and 3) the fact that attorney offices have only recently directed attention to public health issues (Lopes 2006, 221–222).

total public health budget is only R\$450 per capita (Ministério da Saúde *Datasus* 2006).

The increasing scale of individual litigation asserting the right of access to medicines presents the Brazilian judicial system with a great challenge. On one hand, the success of these suits has facilitated activist efforts to push for better public health policies through the courts. In recent years, however, the number of individual suits has become overwhelming and resulted in enormous costs for the public health system. Access to the courts is mostly limited to the wealthy, and total budgets for drug procurement are not increased each time the courts order a particularly expensive medicine to be provided. This litigation has distorted the cost-effective allocation of resources, and exacerbated unequal access to public health resources.

Although ruling against petitioners is politically unpopular, pressure for courts to do so is likely to build in the near future, as rising costs of medicines make the current system unsustainable. There is an urgent need for a better balance between individual and collective rights in the administration of Brazilian laws concerning the right to health.

The impact of private litigation, however, is not the only source of financial pressure facing public provision of medicines. Indeed, the expanding scale of litigation may be a symptom of a more fundamental problem threatening the right to health in Brazil: the skyrocketing price of medicines.

TRIPS and the rising costs of medicines

The increase in health care expenditure is a worldwide phenomenon (Berkman et al. 2005, 1171, Cohen et al. 2005, 217, Ford et al. 2007, 22, Organization for Economic Cooperation and Development 2007). Following this global trend, Brazilian expenditures on public health care by federal, state and municipal authorities have increased significantly in recent years (National STD and AIDS Program 2008, 14). The Brazilian Ministry of Health's budget for 2003 was R\$30.5 billion. Four years later, this figure rose to R\$46.4 billion, a 51.6% increase. Between 2003 and 2004, the expenditures of the DST/AIDS National Program alone increased 97.6%, going from R\$689 million to R\$1.36 billion (*ibid.*, 24).

The financing of SUS has always been a challenge for Brazil.⁸ The first reason for such a financial burden is the ambition of the public health system model conceived by the 1988 Constitution. Even though an increasing number of people are turning to private health insurance (as their prices become more competitive), 90% of the population still makes use of SUS (Conselho Nacional de Secretários de Saúde 2006, 64).⁹

Another reason for this pressure on the Brazilian public health budget is the country's demographic transition. Life expectancy has increased 33.15% in the past years, going from 54.6 years in 1960 to 72.7 years in 2008, while child mortality rate decreased 64% from 1980 to 2008 (Instituto Brasileiro de Geografia e Estatística 2008). As the population gets older, their health care needs become more complex and more expensive (Chaimowicz 1997, 185, Schramm et al. 2004, 898). Such demographic transition combined with increasing access to SUS services puts a natural pressure on the public health budget (Tren and Bate, 2006, 6). In the following section, we examine how much of the growing health budget strain can be attributed to medicine costs.

Impact of medicines on the public health budget

Medicines take up a significant portion of public health spending and their public purchase has become increasingly costly over the past decade. According to the Ministry of Health, the growth of drug expenditure has outpaced the total growth in health expenditure. A study conducted by Viera et al. (2007, 10–11) found that, while total health expenditures went up 9.6% between 2002 and 2006, drug expenditures alone increased by 123.9% over the same period. The same study also found that, in order to guarantee drug purchases, the Ministry of Health had to re-allocate its budget, thus significantly reducing expenses in other areas.¹⁰

8 In 1996, Lei 9.311/96 created a special tax on financial transactions – *Contribuição Provisória sobre Movimentação Financeira* (CPMF) – to finance health actions and services. The tax, originally created to last only 2 years, was successively extended by Constitutional amendments. A recent study found that, between 2001 and 2006, not all the resources generated by CPMF were actually used in the health sector, but rather allocated to finance other government expenses (Santi et al. 2007, 27). The Brazilian senate has recently extinguished this tax and as of January 2008 it no longer provides revenue for the public health system.

9 It is important to note that private health insurance policies typically only cover medicines provided while the insured patient is in a private hospital. High-complexity medical treatments, such as some kinds of transplantation and exceptional medicines, due to their high costs, are not offered by private health insurances. Since the high cost of these medicines also makes it less likely that patients will pay for them out-of-pocket, the public health system is primarily responsible for their supply (Vianna et al. 2005, 22).

10 For a complete analysis of the Brazilian Ministry of Health's expenses with medicines over the past decade, please see Vieira et al. (2007).

One of the main reasons for this increase in drug expenditure was the introduction of patent protection for pharmaceutical products in the country. The following sections examine how patents have affected access to medicines.

Impacts of patent protection on access to medicines

After Brazil joined the World Trade Organization (WTO) in 1995, the nation experienced a dramatic shift in pharmaceutical production policy. Prior Brazilian law forbade the patenting of pharmaceutical products and processes (Lei 5.772/71, art. 9c). This allowed the government to rely on cheap domestic copies to meet its public health needs. Under Article 27 of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), however, Brazil was required to start granting patents for medicines. This was accomplished through Lei 9.279/96.

Compliance with TRIPS provisions naturally affected the cost of medicines, as it eliminated the possibility of generic production during the term of a pharmaceutical patent. This impact was exacerbated, however, by the fact that Brazil failed to take advantage of several flexibilities and opportunities that would limit pharmaceutical patents and help keep drug prices manageable.

Early implementation

As a developing country, Brazil could have used the Transitional Arrangements established by Article 65 of the TRIPS Agreement to delay implementing its provisions until 2000 (WTO 1994).¹¹ Nevertheless, the country chose to implement its new Industrial Property Act as early as 1996, a decision attributed to pressure exerted by foreign pharmaceutical companies over Brazilian lawmakers (Tachinardi 1993, 19–35). Such quick implementation was in the interest of these companies, as patent protection allows industries to set monopoly prices and capture royalty revenues from their innovation. This rationale underlies the intellectual property system as a whole: the exclusive market right temporarily granted by intellectual property is intended to foster further innovation.

Within the public health context, however, these incentives come at substantial cost: patent protection results in increased drug prices and, consequently, more limited access to medicines. Several studies show that

11 A broader interpretation of the Transitional Arrangements (Part 4 of Article 65) could have extended that period for yet another five years.

the introduction of patent protection has inhibited local generic production (Hanefeld 2002, 86–88, Thomas 2002, 262–264, Outtersson 2006, 3–5, Vasan et al. 2006, 394, Nunn et al. 2007, 1805–1809). This was, of course, precisely the strategy that had previously allowed Brazil to make progress in fulfilling the constitutional right to health. Implementing TRIPS provisions as early as 1997, before new national measures were developed to adequately protect access to medicines under these new circumstances, was a clear mistake.

Between 1995 – when Brazil joined the WTO – and the 1997 patent reforms, a number of companies filed lawsuits demanding the patentability of specific drugs. At the time, there was a lively debate among legal scholars over whether TRIPS provisions should be applied by the courts before implementing legislation was passed. Some Brazilian scholars favored immediate application (Araújo 2003, 14), while others advocated a more gradual approach (Basso 2000, 283, Soares 1995, 114). The courts, however, consistently ruled in favor of immediate patent protection (Tribunal Regional Federal 2000, 2002 and 2005a). This meant that even before the legislature passed the 1996 Industrial Property Act, TRIPS provisions for pharmaceutical products were put into effect by means of judicial decisions. Such decisions most certainly worked to the industry's advantage, but against public health interests. The majority of these judicial decisions, however, did not address public health arguments at all (Tribunal Regional Federal 2003 and 2004).

Therefore, when it comes to the implementation of the World Trade Organization's intellectual property provisions in Brazil, we can identify two major obstacles to access to medicines: 1) the legislature did not make use of the Transitional Arrangements allowed by TRIPS in revising the Industrial Property Act; and 2) the courts applied TRIPS provisions to individual cases even before the Industrial Property Act came into effect, thus granting patent protection for pharmaceutical products as early as January 1, 1995.

Pipeline patents

A second problem with the 1996 patent reforms was the recognition of a new category of patents not required by the TRIPS Agreement. Articles 230 and 231 of the 1996 Brazilian Industrial Property Act allow patent applications to be filed for previously nonpatentable subject matter with minimal administrative review, provided that the patent was already granted abroad. This TRIPS-plus mechanism is commonly known as “pipeline” review.

One of the main problems with the pipeline mechanism is that it subjects patent requests to a mere formal analysis by the national patent office – Instituto Nacional de Propriedade Industrial (INPI). Article 230 (3) of the Industrial Property Act determines that *“once the provisions established in this Article have been satisfied and the granting of the patent in the country where the first application was filed has been proven, the patent shall be granted in Brazil, just as it was granted in its country of origin.”* The assumption is that the product meets the requirement of patentability, as a patent was already granted somewhere else in the world. The patent may have been granted, however, in a country that is more flexible regarding novelty, inventiveness or industrial application. Thus, some medicines that should not qualify for a Brazilian patent under a conventional analysis may be waived in through the pipeline process.

A second problem with the pipeline mechanism is that it allows for retrospective patents of medicines already invented. The traditional argument for patent protection – that high prices must be assured to provide incentives for innovation – does not carry weight when considering innovations that have already been brought to market. Companies benefiting from pipeline patents received an additional reward – at great public cost – without having to invest in any additional innovation.

In practice, the pipeline patents granted in Brazil had a strong impact on the public health budgets as they inhibited the production and purchase of generic medicines. Important drugs used in the treatment of HIV/AIDS (*lopinavir/ritonavir*, *abacavir*, *nelfinavir*, *amprenavir*) and leukemia (*glivec*) were patented in Brazil via the pipeline mechanism, dramatically raising the public cost of supplying these drugs (Chaves et al. 2008, 182). A study conducted by the Federal University of Rio de Janeiro shows that, had pipeline patents not been granted to some of the drugs purchased by the Ministry of Health between 2001 and 2005, the country would have saved US\$420 million (Hasenclever 2006).¹²

In November 2007, the National Federation of Pharmacists – Federação Nacional de Farmacêuticos (FENAFAR) – on behalf of the Brazilian Network for the Integration of Peoples – Rede Brasileira pela Integração dos Povos (REBRIP) – filed a formal complaint to the General Attorney’s Office, claiming that pipeline provisions of the 1996 Industrial Property Act violate

12 The analysis assumes that in the absence of patents, the state would have paid the World Health Organization’s minimum drug prices for generic versions.

constitutional rights. The filing relies on constitutional texts asserting: 1) the supremacy of society's interests and the pursuit of the country's technological and economic development over intellectual property protection;¹³ and 2) society's vested right to the content of certain patents, as the objects of pipeline patents were already in the public domain before the Industrial Property Act was passed.¹⁴ As of late 2008, the complaint was still under analysis.

Parallel importation

Parallel importation refers to trade of genuine products outside official channels of distribution.¹⁵ It represents an alternative means for improving access to medicines that are lawfully sold at cheaper prices in different countries. Article 6 of the TRIPS Agreement states that WTO Members are free to decide whether parallel imports will be allowed under national legislation.

Brazil's 1996 patent reforms, however, rule out the possibility of parallel imports, by adopting the principle of national exhaustion of rights.¹⁶ This allows patent holders to prevent the importation of their products into Brazil by unauthorized parties. In practice, it means that pharmaceutical companies may set and enforce higher prices for drugs in Brazil when the same product is lawfully sold at a cheaper price somewhere else in the world.

Allowing parallel imports could effectively increase access to essential drugs. A number of developing countries – including Argentina, Thailand and South Africa – have enacted laws permitting parallel imports of pharmaceutical products. When analyzing the implications of parallel imports in pharmaceuticals for competition and prices, Maskus (2001, 2) points out that the mere threat of accessing parallel import drugs could be sufficient to provide governments enough negotiating leverage with original

13 Brazilian Federal Constitution, Art. 5, XXIX: "The law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, weighing the social interest against the country's technological and economic development."

14 Brazilian Federal Constitution, Art. 5, XXXVI: "The law shall not injure the vested right, the perfect juridical act and the *res judicata*."

15 It should not be confused with trade in counterfeit goods.

16 Art. 43 "The provisions of the previous Article [the right to prevent a third party from, without his consent, producing, using, offering for sale, selling or importing the product subject to patent protection] do not apply: [...] IV. To a product manufactured in accordance with a process or product patent that has been introduced onto the domestic market directly by the patent holder or with his consent."

manufacturers so that they would accept lower prices. Although most developed countries maintain significant restrictions on parallel imports, recent initiatives by policymakers in several OECD countries have been favorable to international exhaustion (Fink 2005, 176).

By ruling out parallel imports, Brazil failed to make use of an important tool considered legitimate by the WTO, which could improve access to medicines. Similar to the pipeline mechanism and the early implementation of the TRIPS agreement, the impossibility of parallel imports reflects a failure to consider the public health impacts of pharmaceutical patent law.

A bill proposed by congressional representative Alberto Goldman in 1999 (Bill no. 139) would explicitly allow parallel importation, including but not limited to medicines. After nine years, it still awaits approval. In order to fulfill the constitutional right to health, lawmakers should speed up further discussion on parallel imports. Authorizing parallel imports would not violate WTO rules to which the country is bound, and would aid the nation in meeting its public health goals at reduced cost.

Evaluation of current cost-cutting efforts

As we have seen, since implementing the TRIPS agreement, Brazil has taken a number of steps that have rewarded international intellectual property holders, but undermined the country's ability to fulfill the constitutional right to access to medicines. The government has also implemented several initiatives that go in the opposite direction, however, to make medicines more accessible. The following sections discuss these mechanisms in further detail, analyzing whether they are sufficient to ensure the long-term sustainability of the public health system.

Price negotiations and compulsory licenses

Brazil is widely recognized as the leading example of integrated HIV/AIDS prevention, care and treatment in a developing country (Berkman et al. 2005, 1162, Galvão 2005, 1110, Okie 2006, 1977). In 1996, Lei 9.313/96 made it mandatory for SUS to provide free access to ARV drugs to all HIV/AIDS patients in the country.¹⁷ Today, the Brazilian National STD and AIDS

17 Brazil's highly successful HIV/AIDS treatment experience, it should be noted, is the result of access to medicines demands from civil society. Prior to 1996, hundreds of lawsuits demanding access to HIV drugs were filed in Brazilian courts. The lawsuits, in this case, worked in favor of all. The government not only provided ARV drugs to individual petitioners who had access to the courts, but introduced a comprehensive program to make the drugs easily available to all Brazilians.

Program – Programa Nacional de Doenças Sexualmente Transmissíveis e AIDS – provides eighteen antiretroviral (ARV) drugs – as well as medicines to combat opportunistic infections¹⁸ – to over 220,000 patients.¹⁹

While 1996 marked the beginning of the HIV/AIDS program, this is also the year that the Industrial Property Act was enacted. The introduction of patent protection for pharmaceutical products would raise prices of the same drugs the government was now obliged to purchase for thousands of patients. Until 1996, these medicines were in the Brazilian public domain and could be reproduced without licenses. The Brazilian network of public pharmaceutical laboratories thus played an important role in the cost-effective implementation of the program. Today, of the eighteen drugs supplied by the government, only eight are produced by Brazilian laboratories (National STD and AIDS Program 2008, 80).

To ensure public access to the remaining medicines, the government must purchase the drugs from the pharmaceutical companies that hold the patents. The Brazilian generic drugs industry (public and private laboratories) has thus seen a substantial reduction in its share of the national ARV market, while the international pharmaceutical industry has seen its share of this market grow rapidly (National STD and AIDS Program 2008, 81–83).

Faced with the challenge of carrying on its HIV/AIDS program at a considerably higher cost, in 2001 the Brazilian government started negotiations with the major pharmaceutical companies. Backed by the threat of compulsory licensing – a process permitted under Articles 68 to 71 of the Industrial Property Act – the government was able to effectively negotiate with pharmaceutical suppliers. The 2001 negotiations resulted in substantial reductions in prices: 64.8% for *indinavir*, 59.0% for *efavirenz*, 40.0% for *nelfinavir* and 46.0% for *lopinavir/r*. In addition, a technology transfer agreement was established between Merck & Co. Inc. and the Ministry's main national laboratory, FarManguinhos.²⁰

18 Opportunistic infections are those that would not usually affect healthy people, but can be deadly to persons with weaknesses in the immune system caused, for instance, by HIV/AIDS.

19 Life expectancy for HIV/AIDS patients in Brazil has significantly increased since the program was put into effect. Before the availability of ARV drugs, the average survival time of an AIDS patient was less than six months; it is currently over five years (National STD and AIDS Program 2008, 69–72). The program is also responsible for reduction in health care spending to treat patients for opportunistic infections. Between 1997 and 2002, about 358,000 admissions in public hospitals have been averted by the program (National STD and AIDS Program 2008, 19).

20 For further information, visit: <http://www.far.fiocruz.br>.

In 2003, the Ministry of Health created a special group to negotiate further issues related to the purchase and production of ARV drugs – Grupo de Negociação para Aquisição e Produção de ARVs. Besides the reduction of ARV drug purchase prices, the group's mandate was to negotiate for noncompulsory licenses that could boost domestic production. In the same year, the government decided to discuss the pricing of *nelfinavir*, *efavirenz* and *lopinavir/r* with the industry again. This time, however, the negotiations were unsuccessful; the government accomplished neither further price reduction nor voluntary licenses. In 2005, attempting to bring down the price of *kaletra*, the government commenced talks with Abbott Laboratories. In this case, also, the negotiations were unsuccessful.

As negotiations for reduced drug prices became less and less effective, the government explored a new approach. In the beginning of 2007, the Ministry of Health engaged in conversations with Merck & Co. Inc. This negotiation effort focused on the price of *efavirenz*, a highly effective drug used by 38% of HIV/AIDS patients in Brazil. After several months of unsuccessful negotiations, on April 24, Ordinance no. 886 declared *efavirenz* a drug of national public interest. On May 4, Presidential Decree no. 6.108 granted a compulsory license for the drug's patents – based on public interest and for noncommercial use only. The medicine is currently being imported from India, where it is already produced off patent. Government reports state that domestic production by Brazil's public laboratories should begin soon (National STD and AIDS Program 2008, 86). Already, the government has reported a reduction of 72.2% in the cost of supplying this drug.

As the Brazilian experience with HIV/AIDS drug provision shows, compulsory licenses can be an effective means to reduce the cost of providing patented medicines, when private negotiations fail.

The prior consent mechanism

The prior consent mechanism is another attempt to improve access to medicines in Brazil. Until 2001, the Brazilian Industrial Property Office (INPI) was the only body authorized to consider patent applications for pharmaceutical products. Lei 10.196/01, however, instituted the prior consent mechanism. Article 229-C was then added to the Brazilian Industrial Property Act, providing that “the grant of patents for pharmaceutical products and processes shall be subject to prior consent by the National Health Surveillance Agency – Agência Nacional de Vigilância Sanitária (ANVISA).”

ANVISA is an independently administered and financially autonomous regulatory agency. Among other functions, it administers the National Sanitary Surveillance System, monitors prices of drugs and medical equipment, regulates and inspects the production of generic medicines in the country and – since 2001 – works along with INPI in the granting of patents for pharmaceutical products and processes.

When an application for a pharmaceutical patent is filed, INPI first analyzes whether it meets patentability and formal requirements, as determined by the Brazilian Industrial Property Act. The applications are then sent to ANVISA for a separate analysis. This second stage of review is intended to guard against the danger that a weak examination process could lead to patent “evergreening.”²¹

In theory, ANVISA can deny the granting of a pharmaceutical patent or process against INPI’s recommendation. In practice, this rarely happens. ANVISA’s 2008 report shows that out of the 1083 patent requests sent to it for analysis, 709 (65%) were accepted, 44 (4%) were not, and 330 processes (30%) are still ongoing (Agência Nacional de Vigilância Sanitária, 2008). In the rare cases where a patent application is not accepted by ANVISA, the applicants have a right to appeal. In the event of a conflict between ANVISA and INPI, meetings are held in an attempt to reach consensus; in the event of an impasse, the patent will not be granted.

In theory, the prior consent mechanism is important, as it could prevent the granting of pharmaceutical patents that work against public health interests. In practice, however, the mechanism is quite flawed. Administrative procedures require that, in order to be valid, ANVISA’s denial of a patent must be officially published by INPI. It is not unusual, however, for such publications to be stalled for years. INPI took more than four years, for example, to publish ANVISA’s denial of patent request no. PI 9710693-3 (Instituto Nacional da Propriedade Industrial 2009). Although ANVISA review is in fact intended to be a check on INPI’s efforts, this administrative procedure effectively enables INPI to prevent ANVISA objections from taking effect.

21 Evergreening involves filing ‘new use’ patent claims of an already patented product or process. When successful, the patent term is extended, which delays the generic manufacturer’s entry into the market. A weak examination process might wrongly grant patent protection to a product that does not truly comply with the requirements of novelty, industrial application and/or creative step. This does not mean that all drug patents granted by INPI undergo weak examination processes; it only means that ANVISA becomes responsible for guaranteeing a particularly thorough examination on patents for products important to public health.

The Bolar Exception

A generic drug is identical to the reference drug in terms of active substance, dosage, manner of administration, and pharmaceutical form.²² They are thus interchangeable in terms of safety and health benefit. The global market for generic medicines is US\$55 billion, and growing by approximately 13% a year (Pró-genéricos 2008). In coming years, the generic drugs industry expects that the expiration of patents of several brand medicines will render an additional US\$30 billion in drug sales susceptible to generic competition (Pró-genéricos 2008).

In 1999, Lei 9.787/99 established the legal framework for the production and marketing of generic drugs in Brazil. Subsequently, the Ministry of Health started to prioritize generic medicines when purchasing drugs. Prescription of generic medicines is mandatory within SUS, although private physicians may prescribe branded drugs even when a generic version is available. Currently, there are approximately 541 accredited pharmaceutical companies in Brazil, of which forty-two manufacture generic medicines and generic drugs currently account for almost 14% of unit sales in Brazil (Pró-genéricos 2008).

The introduction of generic versions of branded drugs in the market improves access to medicines because prices are immediately lowered through new competition. As the government spends less to buy the same drugs, it also becomes possible to buy larger quantities and bargain for even better prices (Gadelha, Quental and Fialho 2003, 50, Quental et al. 2008, 623–627). It is therefore important that generic drugs become available in the market as soon as the patent of the branded drug falls into the public domain.

To facilitate this process, national patent regulations may allow for what is known as a Bolar Exception.²³ A Bolar Exception allows third parties to manufacture limited quantities of patented drugs without seeking a license, specifically for drug approval purposes. Because drug approval process can

22 “Generic” drugs should not be confused with “similar” drugs. According to ANVISA, “similar drugs are those that contain the same active agent, the same concentration and pharmaceutical form, and are administered in the same way and with the same dosage and have the same therapeutic result as the reference (or branded drug), but which do not have the same bioequivalence as the proven reference drugs.” A “generic” drug, on the other hand, has been tested by ANVISA to confirm bioequivalence (Agência Nacional de Vigilância Sanitária 2008).

23 The name *Bolar* originates from a lawsuit brought in U.S. courts between *Roche Products Inc.* and *Bolar Pharmaceutical Co* in 1984. It is also known in literature as *early working* of the patent (Love 1997, Correa 2001, Abbott 2002).

be lengthy, without the Bolar Exception, patent periods would be effectively extended beyond the intended period (Correa 2001, 68).

In 2001, Lei 10.196 created a Bolar Exception for Brazil, which was incorporated at Article 43 of the Industrial Property Act. This reform has been effective in speeding up the administrative procedures to enable the immediate entry of generic versions in the pharmaceutical market once patents expire. Even before this reform, however, several individual lawsuits had established such an exception based on a broad interpretation of Article 43. The merit of the 2001 reform is to make the process of securing such an exception less complicated and time-consuming, which ultimately works in favor of public health interests.

The Popular Drugstore Program

Another step taken by Brazil to promote access to medicines is the Popular Drugstore Program – Programa “Farmácia Popular do Brasil” – created by Decree 5.090/04. This measure was originally designed to improve access to essential medicines for patients that use the private health system, as private health insurance policies typically do not cover outpatient drug costs. In practice, however, the program has been widely used by SUS patients when public hospitals fail to provide the medicines on time (Pinto 2008, 130–137).

The program works both through state-sponsored drugstores and private drugstores that choose to participate. The Ministry of Health buys medicines from private and public industries and the participating drugstores resell them at up to 90% below market prices. According to recent government data, the Popular Drugstore Program has: 1) allowed patients to continuously afford necessary medicines; 2) softened the impact of medicines on families’ budgets; and 3) reduced costs of hospitalization caused by the interruption of medical treatments (Ministério da Saúde 2007a).

Although the objective of the Program is to widen access to medicines, it has recently been the target of some severe criticisms (Conselho Nacional de Secretários de Saúde 2007, 36). One class action, filed in the state of Sao Paulo, argued that the program violated the constitutional right to health by requiring citizens to pay for medicines, as opposed to receiving them free. A federal judge upheld the claim and ordered all state-subsidized drugstores to offer medicines at no charge (Procuradoria Geral da República 2005). This decision was later overruled by a higher court that considered the Popular Drugstore Program complementary – and not harmful – to public health

policies (Tribunal Regional Federal 2005b). Several similar suits are still underway.

The debate over whether the government can establish a program that provides access to medicines *at some cost* when it should be providing them *at no cost at all* is a healthy one. It compels us to examine root problems of the national public health budget. It would be detrimental, however, for courts to eliminate initiatives such as the Popular Drugstore Program that fall short of the ideal constitutional expectation of free access. The popular drugstores have been effective in expanding access to medicines, especially for Brazilians with lower incomes. All 27 states of the country have operating drugstores – not only in large urban centers but also in rural areas where access to medicines has traditionally been more difficult.

Recent research shows that a growing number of people are completing their medical treatments because they have access to affordable drugs at the popular drugstores when SUS fails to provide them (Pinto 2008, 132). The existence of these drugstores may also be a partial solution the flood of lawsuits filed by individual citizens seeking access to medicines.

Conclusion

In 1988, the Federal Constitution established health care – including access to medicines – as a duty of the State and a right of all. Although wonderful in theory, this ideal has proved difficult to fulfill in practice. Drugs are not always made available, prompting a growing wave of citizen-initiated lawsuits demanding access to medicines. While these suits typically result in victories for the individual plaintiffs, the health care system as a whole loses. The drugs sought by these petitions are often extremely expensive, and the costs of litigation further strain the public health budget.

At the heart of this problem is the rapidly rising cost of medicines. Prior to 1995, public laboratories could produce generic versions of branded drugs without regard for international patents; today less than one-fifth of medicines consumed in Brazil are generics. While still managing to provide access to medicines to most of its population, the Brazilian health care system is rapidly approaching a financial crisis. Recognizing this reality, the nation's highest court has already shown signs of an interest in limiting the scope of the constitutional right of access to medicines. The high cost of patented drugs is thus a key matter to be addressed if the right to health is to be preserved.

Unfortunately, several decisions made in implementing the TRIPS Agreement aggravated this situation even further. Prompted by industry pressure and judicial action, the legislature approved patentability for pharmaceutical products almost immediately, rather than pursuing a more gradual implementation. This resulted in a particularly difficult transition, as new policies designed to control drug costs – such as compulsory licensing, the prior consent mechanism, the Bolar Exception and the Popular Drugstore Program – were introduced only later and still have not been perfected. The 1996 reforms also implemented two measures not required by TRIPS that further increased the price of medicines: the granting of pipeline patents and the prohibition on parallel imports.

The newly implemented cost-cutting measures are not sufficient to control drug expenditures, which continue to rise. Preserving the constitutional right of access to medicines will require further policy reforms to bring the price of medicines down to manageable levels. Toward this end, the authors propose the following concrete recommendations.

First, lawmakers should revise the Industrial Property Act to allow for parallel importation and eliminate the pipeline patent process for medicines. These measures significantly increase the price of medicines, and are not required by the TRIPS Agreement. The Bolar Exception must also be preserved.

Second, the government must ensure that ANVISA plays its intended role in blocking inappropriate patent extensions more effectively. This requires making the patent review procedures more transparent and perhaps also limiting the power of INPI to block ANVISA objections through non-publication.

Third, the government should explore wider use of price negotiations, backed by the threat of compulsory licenses. These have been effective in the specific area of HIV/AIDS treatment. Other drugs, however, also play a significant role in the national health budget and could benefit from similar efforts.

Fourth, the courts should welcome the Popular Drugstore Program. This program has played an important role in promoting access to medicines in Brazil, even if the medicines are not entirely free. In the post-TRIPS era, higher drug costs are inevitable. Insisting on free access to medicines – even for those who can afford to pay at least part of the cost – may not be sustainable.

Finally, the judiciary must begin to take a more holistic look at the dynamics underlying individual petitions. Simply granting every request

causes great financial harm to the overall health system. A more productive approach would be to refocus judicial and legislative attention on the underlying policies that have caused rising drug costs, and the structural reforms needed to address them.

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