

Brazil's Fight Against AIDS and Its Implications for Global Health Governance

J.P. Wogart and G. Calcagnotto

Addresses for correspondence: J.P. Wogart (jpwogart@geonet.de), Professor of Economics and Senior Research Associate DUEI, Oesterleystr. 82, 22587 Hamburg, (4940)863-989, Fax: (4940)866-45514

G.Calcagnotto (calcagnotto@iik.duei.de), Senior Research Fellow, Institut fuer Iberoameriakunde, Alsterglaci 8, 22347 Hamburg, (4940) 41478-234, Fax: (4940) 41-478-241

Abstract

The paper traces Brazil's efforts to fight AIDS in the last 20 years. The analysis concentrates on the efforts to combat and prevent the deadly infectious disease through ingenious efforts of private citizens, government agencies, national and international NGOs, which challenged multinational companies, international organizations and foreign governments. While the investigation led to a positive evaluation of the joint efforts in managing the threat, it is made clear that the fight against the HIV/AIDS virus is far from over in Brazil and will have to be strengthened on the local, national and international level.

Introduction

Brazil's fight against the HIV/AIDS virus has become a cause célèbre for antiglobalists, as the country has become one of the leading developing nations to stand up against the industrialized world's trade treaties in general and the patent rights of the international pharmaceutical companies in particular. It is, however, important to separate the myth from the facts as one evaluates the current situation of the AIDS epidemic in that country and examines the efforts of the government and private sector participants to get that deadly infectious disease under control.

This paper traces the interactions, and with it the conflict and cooperative efforts of Brazilian policy-makers, with the representatives of multinational private companies and international public agencies, as well as with national and international NGOs, over the last two decades, and it assesses prospects for conflict resolution in the context of an emerging "global health governance." In the discussion on globalization and ways to "govern" that process, the above expression has been defined as structures and processes necessary to maintain basic global health standards and attempts to move toward the realization of collective goals in the health area at every level of community throughout the world.¹

We start with a short narrative of the outbreak and expansion of AIDS in Brazil and the country's efforts to get an organized response to it. This is followed by examining the development of the pharmaceutical industry in Brazil, with particular emphasis on the role of the multinational companies in the fight against AIDS.

The analysis of the conflict over the pricing of antiretroviral medication leads directly into the interfacing of the multiple international actors in the AIDS drama, with emphasis not only on the government's but also civil society's role in bringing the major issues to the attention of the international community. We conclude with a summary and suggest a framework for studying cooperation and conflict resolution in combating AIDS not only in Brazil but also in other countries affected by the pandemic disease.

Infectious Diseases and Brazilian Government Actions

1. Infectious Diseases: Early Efforts in the Areas of Prevention and Treatment

Brazil has been able to tackle and practically eradicate polio, and it has succeeded in sharply decreasing most of the transmissible diseases, such as cholera, chagas and leprosy. Nevertheless, the country is still confronted by high rates of other transmissible diseases, whose persistence is due to factors which go beyond the health sector. One such hazard is the urban squatter settlements without accompanying infrastructure to provide power, drinking water and sewerage. Another has been caused by the expansion of agricultural frontiers through large infrastructure projects, which has caused massive migration to locations without basic health services.

It is only recently that there has been a remarkable, though not yet consistent, decline of some of those diseases. Among them are viral forms of hepatitis and tuberculosis, which have worried health authorities because of their relatively high incidence rates, their potential evolution to lethal forms and their vast geographic distribution. Some progress has been made in reducing those threats, thanks to improved TBC treatment and hepatitis B vaccination campaigns undertaken at the end of the 1990s.

Malaria and yellow fever are geographically restricted, but represent a threat in selected regions, mainly in the north and northeast of the country. After mass vaccination of 60 million inhabitants between 1998 and 2001, yellow fever's incidence has decreased rapidly, to less than 50 cases. Malaria has been under close investigation in Brazil since the late 19th century by such noted scientists as Oswaldo Cruz and Carlos Chagas. However, the containment is geographically restricted, with large-scale successes only accomplished after engaging in international cooperation exercises. In the 1950s, malaria was still endemic in 84% of the Brazilian territory. In line with the XIV World Conference on Malaria in 1955, Brazil introduced the "National Campaign to Eradicate Malaria." With those measures, the authorities were able to effectively eradicate malaria from the northeast, southeast and the south by the 1970s.

2. The Emergence and Spread of the HIV/AIDS Virus

Among the newly emergent diseases, AIDS has attracted the most attention in Brazil. Since its detection in 1980, it increased steadily until 1997, the year in which over 23,500 new cases were registered (14.8 cases/100,000 inhabitants). From 1980 to 1999, close to 120,000 people died of AIDS, and it became one of the principal death causes for the 20 to 49-year age group. By the year 2000, government agencies estimated that over 600,000 individuals between the ages of 15 and 49 were infected with the HIV/AIDS virus. By then, however, the new measures of universal treatment and prevention increased the survival rate of AIDS-afflicted adults to nearly five years as compared to barely half a year for those patients registered in the 1980s (Risi and Nogueira 2002).

1 An example would be the Millennium Development Goals, three of which specifically aim at improving health, among which the treatment and prevention of AIDS is one. For an introduction into the issue of global health governance, see, among others: Dodgson, R. and N. Drager (2002) and Hein, W. and L. Kohlmorgen (2003).

The spread of AIDS in Brazil can be divided into three phases. The first (early 1980s) was mostly restricted to the great metropolitan centres and its transmission took place through homo- and/or bisexual relations of men. The second phase (late 1980s to early 1990s) witnessed a shift in the transmission mode through the injection of drugs and heterosexual relations, as well as an expansion to all states of the Brazilian federation, with a concentration in the larger towns with 200 to 500,000 inhabitants. The third phase (1996 to 2004 and beyond) was characterized by an increase in heterosexual transmission with a far greater number of infected women and children. The geographical spread of the epidemic has now also reached small municipalities.

The policy responses to AIDS can also be separated into a number of distinct phases (Parker 2003). The initial policy response to HIV/AIDS in Brazil occurred in 1982/83, when the first cases of AIDS were reported and initial programs were mobilized in the State of São Paulo. In 1985/86, the first nongovernmental AIDS-service organizations were founded, and a National AIDS Program was created. Contrary to the early initiatives on the part of the State Secretariat of Health in São Paulo and eleven (of 26) other state governments, that phase was characterized by widespread denial on the part of the federal government. The denial to recognize the seriousness of the disease, combined with a wave of moral panic, fear, stigma and discrimination, was captured vividly in the declarations of several religious leaders.

In the absence of leadership at the national or international levels, responses to the epidemic grew up from the ground, fostered by the representatives of affected communities, such as the emerging gay rights movement, and from the commitment of progressive health professionals and health agencies within state and local governments, who could quickly be enlisted as allies in the fight against AIDS. In the mid-1980s, community mobilization and the formation of AIDS-specific NGOs such as GAPA-São Paulo and ABIA (Rio de Janeiro), together with the pressure of a growing number of state and municipal AIDS programs, provided important incentives for the eventual response at the national level, culminating in the delayed but important implementation of a National AIDS Program in 1985 and 1986.²

With the establishment of the program, a second major phase of the policy response to AIDS can be traced between 1986 through 1990. At the federal governmental level, this period would be marked by a relatively pragmatic and increasingly technical approach to the epidemic. Building on previous state and local initiatives, the development of a national plan for AIDS prevention and control was conceived. However, as the implementation of the National AIDS Program proceeded during the late 1980s, a growing tendency toward centralization in Brasília led to a gradual rise in tensions among AIDS program participants at the lower levels of government.

As increasingly complex and diverse activities began to emerge in different governmental responses to the epidemic, a range of initiatives on the part of civil society began to overcome some of the widespread denial that had characterized the previous period. A larger number of nongovernmental organizations were formed throughout the country, including independent chapters of GAPA in virtually all major Brazilian cities. Those organizations played a major role in calling media attention to the epidemic as well as in placing growing pressure on governmental agencies for a more rapid and aggressive response.

Gradually, diverse religious orders as well as private and public businesses also began to address the growing impact of AIDS at the local level by developing a range of specific initiatives and services aimed at filling the previous vacuum of voluntary actions. As organizations of people living with HIV/AIDS began to form in 1989 and 1990, solidarity became the order of the day, and leaders such as Herbert Daniel emerged as key actors, not only on the national scene but at the international level as well, calling for a response to the epidemic based more on political commitment than on technocratic expertise.

² The Grupo de Apoio a Prevenção da AIDS (GAPA) is the oldest regionally organized NGO to prevent AIDS in Brazil. It has chapters in all major states and cities. The Associação Brasileira Interdisciplinar de AIDS (ABIAS), founded by social scientists in 1986, is aiming at mobilizing Brazilian society to confront AIDS.

A third distinct and disappointing phase can be observed in the 1990 to 1992 period. If 1990 would open with a certain sense of optimism that changes of leadership in the federal government might lead to more effective policy decisions with regard to AIDS, the experience of the two-year period in fact demonstrated the fragility of the accomplishments that had been achieved over the course of the 1980s. Virtually all of the key elements of the National AIDS Program were discontinued during the Collor administration, and a growing antagonism occurred between the National AIDS Program and virtually every other actor involved in responding to the epidemic, which precluded the possibility of collaboration or cooperation across sectors in seeking to develop more effective AIDS-related policies.

While nongovernmental and religious responses to the epidemic continued to grow, the complete lack of an effective dialogue between civil society and the federal government, together with the faltering cooperation between the National AIDS Program and state and municipal AIDS programs, made a sustainable long-term response to the epidemic difficult and called attention to the urgent need to rethink the bases of effective action not only in technical but also in political terms.

A fourth phase in the history of the policy response to the AIDS epidemic in Brazil started in 1992 with the reorganization of the National AIDS Program in the Ministry of Health. Initially, there was a concerted effort on all sides (governmental programs at every level, NGOs, universities) to work together in seeking to rebuild a national response to the epidemic. This collaborative spirit was reinforced and solidified during the process of elaborating a proposal for the first World Bank AIDS Project, at which traditional rivalries and territorial disputes were in large part set aside in favour of cooperation in fighting the disease.³

The spirit of collaboration was reinforced by the National AIDS Program's skilful use of national resources to support a wide range of NGO activities understood as being part of the Bank Project. Shortly after the negotiations with Bank officials, however, a range of administrative problems related to the implementation of the project overshadowed the sense of unity and common purpose that had reigned during 1993 and 1994. In addition, growing tensions between numerous activities by state and municipal AIDS programs on the one hand, and the centralized coordination of the National AIDS Program on the other, hampered further progress.

In spite of various declarations of imminent victory in the war on AIDS, it had been impossible to resolve a range of conflicting policy issues, among others, between the finance and the health ministries. Even some of the less politicized NGOs had become increasingly restless, as the Ministry of Health failed to open new calls for projects or to renew funding for already approved initiatives. The relative transparency that seemed to characterize the elaboration of the World Bank Project had given way to a general lack of transparency concerning the use of funds and the implementation of initiatives, and as the first World Bank Project began to near its conclusion, little clarity seemed to exist concerning the future of combating AIDS.

Since 1996, a new phase in the policy response to HIV/AIDS can be observed with the acquisition and distribution policy of last generation antiretroviral (ARV) drugs to be delivered for free to all AIDS patients. Together with other measures in this period, such as systematization of HIV/AIDS vigilance actions and notifications, intensified prevention, greater participation of organized civil society, and a deeper engagement for human rights, those policies and actions – also fostered by World Bank/Brazilian government joint AIDS-Projects II and III (1998–2006) – can be seen as the main factors for having “avoided 34,000 deaths and 33,000 new AIDS/HIV cases between 1994 and 1999” (Risi and Nogueira 2002). It is this period and the actions the government undertook which

3 José Serra, Minister of Health 1998–2003, has maintained somewhat dryly in an interview: “The Bank's participation was positive for it obliged us to do something well organized to make an efficient management and accounting effort” (Biehl 2004). Actually, the World Bank had financed part of the Brazilian AIDS programs already in 1988 through reallocating \$6.6 million from a general loan against endemic diseases to AIDS support, funds for which were immediately available for disbursement at that time.

will require further analysis, first by looking at the development of the country's pharmaceutical sector and its international links, and then by analyzing global efforts to attack the disease.⁴

Development and Role of the Pharmaceutical Industry in Brazil's Health Sector

1. Recent Developments of Brazil's Pharmaceutical Sector

Brazil is ranked No. 11 when it comes to the output of pharmaceuticals, encompassing 550 factories and laboratories, producing 1.5 trillion units of pharmaceutical products at annual sales averaging US\$5.5 billion during the early 2000s. As one of the large industrializing countries of the south, Brazil has attracted relatively early the most important pharmaceutical companies of the world to establish shop in that country, and there would seem to be a good precondition for a fair degree of competition, since none of the multinationals come even close to holding a 10% market share.⁵ However, the segmentation of the various drug markets for so many different illnesses and their respective remedies, as well as the distribution and transaction system of the industry together with a tight patent system of protection, makes the market determining forces of supply and demand less reliable than in any other industry. As a consequence, the rather strong concentration in the many high-priced niche markets follows the pattern found in the fully industrialized countries, which have required government intervention of one sort or another (Wogart 2004).

The interaction between the pharmaceutical multinationals and the Brazilian government as well as the various other actors of the national health sector has been long and arduous. In a country with an endemic inflation between 10% and 100% or more, the authorities have especially been concerned about the pricing of essential goods, of which medicines are considered to be one. Until the end of the 1980s, the industry was heavily protected from imports and subjugated to price controls, which required a lot of negotiations for the firms, forcing them to clearly prove whatever price increases they maintained were based on exogenous cost increases. When inflation abated in the 1990s, that pattern was substituted by a more congenial type of price agreements between the relevant governmental agencies and the industry.

During the times of accelerated inflation, the industry made "operational" losses, some of which were caused by an accountant device called transfer pricing. That situation changed quite dramatically when the government stabilized the currency and liberalized the market for drugs in the mid-1990s. Sales more than doubled, driven mainly by price increases and less by the volume produced and sold, which rose by only 20% between 1991 and 1996 and then remained at that level in the early years of this decade.⁶

There is no doubt that Brazil's renewed external crisis in 1998/99, its devaluation, and with it the slowdown in economic growth, are at least partly responsible for the modest advancement of the industry's sales volume. However, it also stands to reason that the price increases during the 1990s caused consumers and patients to scale back on their purchases. What is clear is that the operational profitability of the pharmaceutical companies improved considerably during that decade, from a negative rate of return to equity of 5% in 1990/91 to over 20% in the mid-1990s and to over 15% in the late 1990s. Compared to all other industrial branches in Brazil, the pharmaceuticals were the most profitable during the decade, a pattern similar to the superior profitability of that industry in developed economies in general and the United States in particular during that period of time (Palmeira/Pan 2003).

4 The latter part of the 1990s also saw the full implementation of Brazil's major health reform, which distributed a significant amount of finances and responsibilities to the states and municipalities. See Finkelman (2002).

5 Among the more important ones are Novartis (6.5%), Roche (6.0%), Aventis (5.65%), Bristol-Myers Squibb (5%), Hoechst Marion Roussel (5%), Pfizer (4.7%), and Ache (4.5%), the only national company among the big ones; see www.tradeport.org/ts/countries/brazil/isa: Brazil – The Pharmaceutical Industry, November 2003

6 Data from the annual reports of the Brazilian pharmaceutical industry's associations ABIFARMA and SINDUSFARMA.

2. The Public Sector's Involvement in the Pharmaceutical Industry

In accordance with the Constitution, Brazil's federal and state governments have created public laboratories to supply drugs for basic healthcare and for some strategic health programs such as the programs against AIDS, malaria and TBC. In the context of macroeconomic structural adjustments programs during the 1980s and 1990s, however, all government agencies had to pursue increasingly stringent market guidelines, which also included the management and finance of public pharmaceutical laboratories. Those policies were sharply criticized by members of the Parliamentary Inquiry Commission on the Pharmaceutical Industry, which rejected the idea of considering drugs more of a merchandise than a "necessary public good" (Brazil, CPI 2000).

In spite of the politicians' criticism and the concerns for improving public health through cheaply produced medications, necessary investments for the improvement and expansion of the public laboratories have not taken place until very recently. As a consequence, the situation of the public laboratories has deteriorated, with the exception of the Fundação para o Remédio Popular (FURP), related to the health ministry of the State São Paulo, and the Farmanguinhos, a production unit of the Fundação Oswaldo Cruz (FIOCRUZ) related to the federal health ministry, operating in Rio de Janeiro. Those two public drug producers have been responsible for about 60% of the sales value of the eight public laboratories in the last few years.

While the public enterprises' share in the market for prescription and over-the-counter drugs has not surpassed 10% of total sales in recent years, within the segment of strategic drugs this share is estimated to be close to 60%. That amount, however, still seems to be insufficient for satisfying the demands of the poorer population. The volume of drugs produced by the public sector firms against hypertension and diabetes are a case in point. Between October 1997 and September 1998, the public labs sold about a fifth of the 620 million units coming from the private pharmaceutical firms. The CPI has estimated that only 44% of the potential patients requiring the medication have full access to these drugs. Even for essential health drugs, the people without access are estimated to reach 40% of the actual purchasers. Following up on those deficiencies, the above cited commission drew the conclusion to rapidly increase the capabilities of public laboratories to produce drugs for the poor.

In addition to not being able to supply sufficient amounts of necessary drugs for the poorer segments of the population, another concern is quality problems of the public labs, as they aim at incorporating the necessary equipment and personnel for developing technologies of drugs that are still protected by patents but are to run out soon. This is also important in the context of WTO negotiations on compulsory licensing for purposes of dealing with national emergencies. The Fundação Oswaldo Cruz in Rio de Janeiro has developed some ARV drugs in support of Brazilian negotiations within the World Trade Organization (WTO), and its laboratories, Farmanguinhos, are currently active in the production of two drugs of the ARV cocktail not yet produced as generics anywhere else in Brazil.

In that context, the federal health ministry established a "Modernisation Program of Public Drug Production" in 2003/04 to overcome the insufficient capital formation of public drug producers. The modernization program has been directed toward six of the above-mentioned eight public laboratories, with its value amounting to a modest US\$26 million. In a first step, it is intended to support the production of four drugs against hypertension and diabetes, as well as increasing the production of anti-AIDS drugs. In the follow-up action, the program entails more labs, more drugs, technological development and quality reinforcement (Palmeira/Pan 2003).

3. The Fight for Price Reductions of ARV Drugs between Brazil and the MNCs

Disputes between Brazilian drug companies and – more importantly – the Brazilian government against the Western-based multinational pharmaceutical enterprises and their respective governments have been going on for decades. As stated above, the major issue was the problem of price adjustments in an economy plagued by inflation and frequent devaluation. That was mainly a domestic issue, which was resolved on location; i.e., with the local representatives of the MNCs. The situation changed, however, when the US Pharmaceutical Manufacturers Association filed

a petition with the US government in 1987, citing Brazil's lack of process and patent protection for pharmaceutical products as an example of unreasonable practice that burdens and restricts US commerce. Since the responsible organization for bilateral trade negotiations is the Office of the United States Trade Representative (USTR), that agency initiated an investigation and requested consultations with Brazil.

Discussions with the Brazilian government were held in early and mid-1988 but did not result in any agreement on the basic issues of patent rights. Immediately afterwards, the president of the United States determined Brazil's policy to be unreasonable and a burden and restriction on US commerce, and he directed USTR to hold public hearings on certain Brazilian export products which would be singled out for additional US import duties. Shortly after that, the president used Section 301 of the Foreign Trade Act and raised tariffs up to 100% for a number of Brazilian paper products, nonbenzenoid drugs, and consumer electronic items.

In 1990, Brazil's president decided to seek and implement legislation which would provide patent protection for pharmaceutical products. That action in turn led the USTR to terminate the tariff measures, but the agency also announced that it would closely monitor Brazil's efforts to pursue and enact the relevant legislation. When Brazil passed a patent law in 1996, it was praised by both the MNCs and the US government. The latter's Information Services commented in the following way: "Previously, Brazil had argued that condoning pharmaceutical patent piracy was necessary to provide affordable medicines for its poorer citizens, but it had come now to a point of view that the country would fare better by modernizing its economy to conform to international standards" (Mossinghoff 2000).

As a consequence of the Brazilian patent law, which was not only enacted a number of years before the WTO had set a deadline, but also seemed to be tougher than prescribed by the International Organization, the major multinational companies responded with a great number of investment plans and commitments for both manufacturing and R & D centres. Just as that new wave of foreign investment was to realize, however, the ongoing trade dispute between Brazil and the United States, which had been revolving earlier around such issues as dumping of steel, soy and other Brazilian export products, started again to concentrate on the intellectual property rights regime of Brazil.

The 2001 release of the USTR Section 301 Report was especially concerned about Article 68 of Brazil's Industrial Property Law, which proposed local production on patented products within three years of patent approval. In case the patent holder did not comply, the government was entitled to override the patent and allow third-party manufacturing of the product. The specific challenge had come in that case from the Brazilian government and an Indian pharmaceutical company which was willing and able to sell a triple-therapy cocktail of anti-AIDS generic drugs to Brazil at a fraction of the price the MNCs were charging.

The USTR-chief, Zoellick, made clear that the American and international concerns were not directed against Brazilian public health policies, but rather to make sure that property rights in general were not infringed upon by national protectionist policies. Those policies were indeed violating Article 27.1 of the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). Brazilian policy-makers, on the other hand, maintained that Article 68 was an integral component of the country's comprehensive anti-HIV/AIDS policy. The way out of the dilemma was that Brazil had another possibility to require "compulsory licensing" of antiretroviral drugs under Article 71 of its patent law, authorizing that type of action in case of a national health emergency. It was consistent with TRIPS, which defines compulsory licensing as a WTO-compatible measure whereby governments can permit the domestic use of a patent without the consent of the patent holder in the type of emergency cases exemplified by the fight against HIV/AIDS.

On June 25, 2001, the US withdrew its WTO complaint against Brazil concerning the local manufacturing of drugs. Instead, it was decided to negotiate that and other disputes through bilateral consultative means. Brazil in turn agreed to notify the US government in advance if it found it necessary to issue a compulsory license under Article 68 of its Patent Law.

Confrontation turned into cooperation two years later, when President Bush agreed with

Brazil's President Lula to jointly assist the two Portuguese-speaking African countries of Angola and Mozambique in combating AIDS. The program is part and parcel of the US government's effort to make a concentrated effort to fight AIDS in the hardest hit countries of Africa and the Caribbean in the context of the recently approved five-year \$15 billion President's Emergency Plan for AIDS Relief (PEPFAR).

With Brazil's accomplishment in carrying out a seemingly successful AIDS program at home and previous cultural and external assistance links with those two nations, it is expected to oversee most of the features of this specific assistance program. One detail will be the transfer of technical knowledge to manufacture generic antiretrovirals and helping to oversee their use in countries whose population lacks adequate healthcare.

Critics have maintained that the Brazilian model cannot be transferred to countries the per capita income of which are still extremely low, as are all the important social indicators, from doctor/patient ratios to functioning hospitals and supportive health personnel (Roger 2003). That certainly seems to be true in the two large Portuguese-speaking African nations.⁷ The critical assessment is shared by Brazil's policy-makers, who have decided to concentrate first on some of the smaller African countries such as the Cape Verde Islands and Guinea-Bissau. The Brazilian coordinator of the anti-AIDS initiative has also maintained that foreign support can only provide one input. At the end of the day, it is up to the governments of each country to get seriously involved. He may have added that even in Brazil, the national government needed a long time before it took the reins in battling the HIV/AIDS virus wholeheartedly. It's the people and the strength and resources and wits of civil society in general, and NGOs in particular, that have been able to play such an important part in taking the AIDS campaign to the forefront in Brazil.

The combination of drugs necessary to alleviate AIDS consists mainly of patented products, for which the respective pharmaceutical companies could and did charge monopoly prices. As a consequence, the Brazilian authorities had negotiated with a number of MNCs for some time. One of the first confrontations took place with Roche. After a number of unsuccessful negotiations, the Brazilian health minister announced in August 2001 that his government would issue a compulsory licence for the production of the antiretroviral drug Nelfinavir (sold under the brand name Viracept by Roche) to a Brazilian manufacturer. Negotiations were resumed and Roche agreed to lower its prices by 40% (Roche Press Release 2001).

Since then, similar negotiations under the threat of a compulsory licence have taken place and have been leading to substantial price cuts of other antiretroviral drugs, such as Lopinavir and Efavirenz, as well as an antihepatitis C drug, pegylated interferon. The mood has gone from open conflict to pragmatic negotiations between the multinational pharmaceutical companies and their associations and the Brazilian health authorities. The same can be said of negotiations with the governments of the OECD countries (mainly the US). However, the US and most other governments of the OECD want to have a clear line drawn between the issuing of compulsory licences for medicines of life-threatening infectious diseases and the ones for other patented drugs.

The dialogue among the major contestants has not limited itself to exchanging legal opinions and issuing threats, but has also taken place at more civilized levels, both formally and informally. In addition to discussion with international organizations and the governments in Washington and Brasília, there were among others Brazil's resolution of promoting access to pharmaceuticals at the UN Commission on Human Rights, which was passed by a 52–0 vote and one abstention on April 23, 2001, and there were numerous open forums, where senior representatives of the WTO, the Brazilian government, the MNCs, and the NGOs discussed the major issues of how to balance the need to encourage innovation on the one hand and provide low-cost medication for life-threatening diseases on the other.

⁷ More importantly, in other countries of the continent, many government officials are still not quite ready to realize the danger of the current epidemic sweeping the continent. It took South Africa over five years to start to react in a serious way, and Nigeria is still taxing imported AIDS drugs at 20%.

HIV/AIDS and the Search for Effective Medication and Mediation in the International Arena

1. Curbing AIDS and the Other Infectious Diseases Internationally

According to estimates of the World Health Organization, infectious diseases (IDs) are responsible for the deaths of over 14 million people every year, with the vast majority of them occurring in the poorest developing and transition economies. The causes are manifold and range from poor sanitary conditions to poor nutrition, from lack of doctors, nurses, and hospitals to lack of financial resources to buy medical equipment and drugs.

In the WHO report on "Macroeconomics and Health," the authors identified three types of diseases affecting developing and fully industrialized countries differently, ranging from measles and hepatitis over tuberculosis and AIDS to sleeping sickness and river blindness (Sachs et al. 2001). While the first category has been present in almost all countries of the world, the second includes those infectious diseases which have had the most devastating effects on the working poor in the developing countries. The third type of diseases are exclusively to be found in the south; i.e., mostly in the poorest developing economies of Africa and Asia.

Since the introduction of antibiotics, it seemed that most of the infectious diseases could be brought under control within a few decades. As a consequence, R & D for medicines fighting those and other diseases mainly occurring in the developing countries became less important for pharmaceutical research and have been largely neglected by the major companies.

Two events changed that situation in a fundamental way. First, it turned out that some new strains of TB and other infections became resistant to antibiotics, requiring renewed research into medicines which would be able to fight those tougher bacteria and viruses. Secondly, the rise of the HIV/AIDS virus and its rapid expansion around the world led to multiple efforts to fight it. While the results until today have not yet produced one medicine which can really overcome the HIV/AIDS virus, a cocktail of various drugs have made it possible to soften the impact of the immune weakness and prolong lives for a number of years.

Those drugs were coming out of the research labs of the large international pharmaceutical corporations and were duly patented in the 1970s and 1980s. The first government that challenged the MNCs and their allies was the South African one, whose 1997 Medicines Act was sharply criticized by both the US authorities and the European Commission. When it was then challenged by the large pharmaceuticals in international courts, public outrage and pressure rose to a level which forced the MNCs to reconsider their accusations and finally back down in April of 2001.

As demonstrated above, the issue became even more dramatic in the case of Brazil against the MNCs and the US government in the case of two of the 12 antiretrovirals required by Brazil to effectively treat HIV/AIDS patients. Since the Brazilian government provided the treatments free of charge to every patient in need, the case for lowering the costs of the medicines had become urgent. Had it not been for the price reductions, and with it cutting the treatment costs per person by 70%, the country's health service agencies would not have been able to treat up to three times the patients in 1999 they had been able to during the early and mid-1990s (Neves Motta 2003).

2. The Doha Agreements and TRIPS

As a child of the General Agreements of Tariffs and Trade (GATT), the World Trade Organization (WTO) has been concentrating on reducing the barriers to trade of goods and services, with an emphasis on liberalizing world trade of goods during the early years of its existence. Despite successful efforts by GATT to reduce tariff and nontariff barriers, there have been plenty of distortions constraining trade of almost all agricultural products, which are still highly protected in most OECD countries, the governments of which have also imposed import quotas for a number of industrial products, most notably in the textiles and clothing industries.

The discussions on the economics of the member countries' service sectors became an important topic when the OECD countries looked for a bargaining tool, compensating for their willingness to finally lower their agricultural subsidies, protectionist barriers and other (for example, health-related)

restrictions. In that context the Agreement on Trade-related Aspects of Intellectual Property Rights in 1994 arose, which made members of the WTO agree not only to respect the intellectual property rights of patented products, but also to enact compatible legislation and to build up institutions which would enforce the enacted laws.

Besides the computer and entertainment industry, the pharmaceutical companies had long been fighting for that kind of legislation, since some of the emerging market economies had started to build up their own pharmaceutical industries without paying too much attention to the laws and regulations quite often differently prescribed by their own governments. As late as 1986, over 50 countries were not granting patents on pharmaceutical products at all, including quite a number of fully industrialized economies in Europe (UNCTAD 1996).

While the patents on the more profitable drugs alleviating arthritis, heart failure and lung cancer had been of a far lesser concern and demand in the poorer countries than they were in the advanced ones, the international pharmaceutical companies had realized that middle-income countries and the growing middle classes in the large poor countries like India and China were also increasingly demanding medication treating the same major illnesses facing their counterparts in the north. As a consequence, the US pharmaceuticals pressured their government to build strong (TRIPS plus) intellectual property rights into bilateral international trade treaties, which have been negotiated and implemented in a number of developing countries since the mid-1990s.

A major international reaction was voiced in 2001, when the Commission on Intellectual Property Rights was installed by the then British Secretary of State for International Development to report on Integrating Intellectual Property Rights and Development Policy. That Commission came out with a warning, asking developed countries "to consider the available evidence, imperfect as it is, before further extending IP rights." While the Commission agreed that IP protection of some kind would be appropriate at some stage for developing countries, it maintained that "too often the interests of the producer dominate in the evolution of IP policy, and those of the ultimate consumer are either not heard or heeded" (Commission on Intellectual Property Rights 2002, p.3).

Those concerns were also raised by several developing countries, including Brazil and many African governments, stressing the need to support public health needs in the patent issues. The issue at stake was the access to existing drugs and the creation of new ones. On November 14, 2001, the WTO adopted a separate declaration on TRIPS and public health, which opened the way for member countries to fully use the built-in flexibility of TRIPS, including compulsory licensing and parallel importing. At the same time, least developed countries were allowed to delay the introduction and implementation of patent legislation until 2016.

On August 30, 2003, WTO members laid down some further clarifications with regards to pharmaceutical patents and the type of exceptions which were justified under the TRIPS agreement. Among others, the 2003 Doha Declaration has made it possible for nonproducing countries to import pharmaceuticals by issuing compulsory licences. Under the so-called "Bolar" provision, some countries can allow manufacturers of generic drugs to use the patented inventions in order to obtain marketing approval from public health authorities without the patent owner's permission and before the patent protection expires, making it possible for the firm to start producing the drug right after expiration of the patent (Article 30).

Putting the claim into socially responsible language, the idea was to strike a balance "between the long-term social objectives of providing incentives for future invention and creation, and the short-term objective allowing people to use existing inventions and creations" (WTO Fact Sheet 2003). That philosophy is expected to work in the following ways:

- On the one hand, protection of inventions for a fixed period of time should not only give the innovator a reasonable return on a risky investment, but also eventually bring "social" or "external" benefits by providing other researchers to study and improve on the invention and supply society with a constant stream of new innovations and products which will save lives.
- On the other hand, the TRIPS agreement was to provide flexibility for governments to make

exceptions to patent holder rights in cases of emergency, anticompetitive practices, or if the right holder did not supply the invention. As the Doha Declaration states in Article 5c: "National governments have the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

In short, it would seem that the TRIPS agreement and its later elaborations in the areas of pharmaceuticals and public health are seeking a compromise between the wishes of the developed world to internationalize patents and the needs of the developing countries to decide individually how much of the new rules could be accepted and when to use the exceptions in a way which would help the sick and the poor. However, the fight between the pharmaceuticals and their respective associations on the one hand and eager ministers of health trying to provide medicines to their poor populations at lower prices is far from over. The 2005 controversy between the Brazilian government and Abbott Laboratories, to be discussed below, provided just one example (see also Cohen/Lybecker 2005).

The issue of solving the dilemma of simultaneously lowering the costs of life-saving medicines in developing countries and maintaining incentives for innovation and research for drugs and other medical treatment remained on the table of many a meeting between 2001 and 2004. It was on the suggestion of the Brazilian representative to the World Health Organization which led to the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) in February of 2004. The task of the Commission is to advance proposals that would provide better access to medication in developing countries without compromising the intellectual property rights of the research-based pharmaceutical industry.

3. The Role of International NGOs and Private Sector Response

Earlier, international NGOs had actively intervened to support the Brazilian government's stand in the world arena. None was more explicit than Oxfam, which, after analyzing the major issues of the conflict, came out with a number of recommendations (Oxfam 2001). These were, first, the US should cease the case against Brazil at the WTO and stop using "Section 301." Secondly, instead of suing Brazil for violations of patents, the multinational pharmaceuticals producing the patented AIDS medications should issue voluntary licences. Thirdly, WTO member states should agree to bolster health safeguards in the TRIPS agreement and give developing countries greater freedom to decide the duration and scope of pharmaceutical patents as well as allowing countries to require local manufacturing of patented products as part of their national development and health strategy.

The ensuing dialogue among representatives from NGOs, the multinational pharmaceutical companies, Brazilian government representatives and WTO officials came to similar though somewhat less radical conclusions. Sponsored by the Foreign Policy Centre in London, the report of one of those open meetings stated that, "despite dissonance over many of the fundamentals, the seminar opened several doors for potential solutions, among which were the introduction of a tiered patenting system, an increased flexibility of TRIPS for developing countries, and the creation of an international fund to support the consolidation of health systems in those parts of the developing world hardest hit by the AIDS virus" (Walters et al. 2001).

By 2004, two of those proposals had been translated into reality. The Doha Declaration gave a wider and much more flexible interpretation of the TRIPS agreements and the Global Fund against Malaria, AIDS and TB has been installed. In the meantime, within the above-mentioned CIPRH experts of intellectual property rights are rethinking and discussing some of the rules written into the relevant legislations of both the developed and developing countries.

An effective anti-AIDS campaign cannot succeed without a better healthcare system. As a consequence, many developing countries have pledged in their Poverty Reduction Strategy Papers (PRSPs) to improve the infrastructure of their healthcare systems, both by allocating more resources to the

sector and by making the current systems more efficient. In addition, the multilateral institutions as well as many national and international donors have committed an increasing amount of support programs in that area. Part of those efforts have resulted in the creation of the Global Fund to fight AIDS, TB and malaria (GFATM), providing one-off grants to both public and private organizations in countries affected by those three specific diseases.

In addition to multiple government pledges, the Gates Foundation is the No. 1 private sector participant in the Global Fund, in which the major pharmaceutical companies are not yet participating, because the Fund was not ready to accept the industry's suggestion to provide medicines instead of funds. On the suggestion and urging of WHO and UNAIDS, the MNCs have been active for a number of years in sponsoring diverse projects to fight infectious diseases in developing countries, most of which are locally oriented programs in Africa. Other multinational companies in manufacturing and mining have also started anti-AIDS programs in various African countries which go beyond prevention and providing medication to their own employees and their families by becoming engaged in community support against the disease. In Brazil, the important MNCs are all active in the prevention part and some have joined meetings with government health officials, which helps them to coordinate possible action with local and state governments.

In an effort to direct the attention of the MNCs to their "corporate social responsibility," Oxfam and its partners wanted to get a clearer picture of the pharmaceutical MNCs' commitments in the context of benchmarks, which were involving pricing and patents, R & D and the appropriate use of medicines, as well as joint public private initiatives (JPPIs) in 2000. In the context of interpreting the interfacing of the major players in the global health governance scene, it is worthwhile to briefly examine the benchmarks and then evaluate the corporate response and the NGOs' interpretation.

In the hotly contested area of pricing, the NGOs demanded the major pharmaceuticals make clear that the firms supported "substantially lower prices of medicines for developing countries" (Oxfam et al. 2002). In addition, calls were made for greater transparency of firms' pricing procedures. Not surprisingly, answers were not forthcoming, and the majority of the MNCs simply told the interviewers that they did not want to go beyond their mission or policy statements on social responsibility, which they had made available on their respective websites, which – again not surprisingly – had no statements on the specific issues raised by the researchers of Oxfam & Co.

The industry does not want to be pinned down on such critical issues of pricing, patents and R & D. Nevertheless, there would seem areas of commitment which the NGOs could further explore jointly with the MNCs, as some already have done. Among them are first and foremost the Joint Public Private Partnerships (JPPPs) that have blossomed in the last few years. Oxfam does point out that these newly created "institutions" can be of critical value for developing countries, but the NGOs want to make sure that such issues as transparency and efficiency of the JPPPs will also be addressed once they are fully functioning. Clearly, here the MNCs could – and some of them already do – pledge not only continuous support but also press for increased social governance within those JPPPs.

Another area in which the MNCs have become more forthcoming is the research area, starting from increased funds going into R & D of tropical diseases, some of which are taking place in those countries. Again, the relative expenditures to total R & D are probably quite small, and since they are not published by the industry, critics have to fall back on estimates, which is not very helpful for anybody involved in the debate. Here, public pressure should mount to demand and receive greater transparency.

The final issue of the industry's self-regulation efforts for drug safety would seem another area in which the firms should be able to be more forthcoming and endorse World Health Organization standards of conduct, and not enforce their national standards, which could delay production and distribution of vital antiviral AID drugs to poor countries. On the other hand, a minimum of marketing and drug-safety monitoring of drug companies in countries with notoriously weak regulatory systems should also be a must. The pay-off in terms of long-term customer trust, and with it continuous sales and profits, should be substantial.

The Fight against AIDS and Global Health Governance

The narrative of the Brazilian fight against AIDS has highlighted the incredible amount of actions and interactions that have taken place and that still are occurring among official and unofficial representatives on the local, regional and national levels, and increasingly on an international level. Like in any other country, Brazil's policy-makers have been concerned with balancing their decisions between the need to provide basic health services to the whole population at reasonable prices (or, in emergency cases, for free) and incentives for health providers to be compensated for their research as well as for other investment in human and physical capital.

In way of summary, and considering the question of the extent to which the Brazilian AIDS campaign has led to a most interesting national and international exercise in conflict resolution, one should look more closely at the various policy areas and institutional modes that have been used in the context of the AIDS battle and to what extent those modes can also be applied in resolving issues in other health areas. The following explanations may help in pinpointing the institutional setups that have accommodated the varying demands on the policy-makers to lead that campaign to an at least temporary success story.

A framework developed by social scientists at the University of Cologne in the context of multi-level governing in the European Union would seem to be useful in analyzing the linkages among the various levels of politics affecting AIDS in Brazil (Scharpf 2001). As discussed earlier, a number of conflicting policy areas, supporting innovation and industry on the one hand and consumer protection and welfare on the other, are seen to be moderated and possibly harmonized through different institutional modes and processes. Some are traditional, such as intergovernmental and joint decision-making in international organizations, while others are new, such as the networking of the NGOs and open coordination through such newly created organizations as the private-public partnerships.

While it would seem simple enough to line up the major players on opposite sides of the field, with one group advocating for welfare issues and the other for market incentives, from the moment AIDS became a serious problem in Brazil, requiring fast action, it actually became much more complicated than one could have expected, beginning with the trials and tribulations of the national government and its policy-makers to come to grips with the disease and take action in the 1980s, only to revert then to inaction in the early 1990s. Here, indeed, the network mode provided through the well-organized local NGOs gave the all important push to have federal government agencies finally become fully involved in tackling AIDS in the mid to late 1990s.

Earlier on, joint efforts to confront AIDS on local and national levels were strengthened through an international institution normally known for its preference for hard-nosed projects. But even here, after the strengthening of AIDS awareness and cooperation within the country through the expectation of a World Bank project, renewed mistrust among the major actors prevailed once the project was executed. In short, the fight against AIDS in Brazil was not without hurdles and conflicts already early on, although most participants thought that fighting the disease together should be a must.

Joint decision-making became much easier once another external threat was envisioned, this time not by a new virus but by the multinationals. The conflicting policy goals of private profits vs. public welfare could not be more clearly drawn than as in the Brazilian AIDS case, and it was indeed a classical fight of economic vs. moral values that compelled the MNCs' compromise after they had marshalled government support at the national and international level. In the context of analyzing the interactions between the MNCs and the international organizations, the World Trade Organization moved to the forefront, although that organization had traditionally been involved only in international trade negotiations. With being assigned of responsibility for the liberalization of services, however, the WTO has also become active in developing and implementing an international legal base for strengthening intellectual property rights.

In the context of the prolonged Doha negotiations in 2001 and 2003, the WTO was getting pressure from "the South," which actively participated in and shaped international negotiations, helping developing countries not only to adjust to but also to reinterpret internationally accepted

rules and regulations concerning IPRs in general, and to search for compromises in such vital areas as the supply and pricing of pharmaceuticals in life-threatening diseases in particular.

What about the multinational pharmaceutical industries? Their early denial and later attempts to bring US government and WTO pressure on Brazil did not help them in maintaining their patent-protected prices for developing countries facing the threat of a devastating AIDS epidemic. At the same time, MNCs in general and pharmaceuticals in particular have become active in sponsoring an increasing number of programs, many of which they have implemented jointly with NGOs. That, however, does not answer the question about their future strategy and action. To find satisfactory answers to those questions, in-depth interviews and evaluations by specialist observers of this industry will have to be undertaken.⁸

The current investigation would rather argue that the MNCs may have lost a battle and would have been better off had they realized earlier the rising power of global networks and the new set of institutional realities in the world health arena. They have not, however, lost the fight to protect their profits, which are more seriously challenged on other fronts; e.g., imports of US drugs from Canada at reduced prices and pending law suits following the late revelations of deadly side effects of some of their most successful pain medications. Their influence on the US government, which happens to be the largest contributor to the Global Fund against the major infectious diseases and is engaged in large-scale bilateral efforts to support AIDS programs in many African countries, has remained as strong as ever, making sure that the long-run worldwide profitability of their enterprises will not be seriously undermined as long as their government maintains its power and its outlook.

In the case of AIDS medication, the demand for the latest string of ARVs being developed by the research-oriented pharmaceutical companies has been strong, both in Brazil and other developing countries, with tension between Brazil and the MNCs raised to a high level in mid-2005. Brazil again fought for substantial price reductions by threatening to issue a compulsory licence. While both national and international NGOs argued and asked the government to proceed and issue that licence, the health ministry preferred to negotiate and the first of the three companies settled for a price reduction rather than have Brazil exercise the harsher option.⁹

At this point in time, negotiations with two further pharmaceutical MNCs are underway, the ARVs drugs (together with that of the earlier price of Abbott's Kaletra) of which would amount to about \$170 million, or close to 70% of its total imports of medications for the disease. That is certainly a significant amount to consider. If it establishes a "public health threat," however, is another question. Beyond the financial problem of paying for the medication, the problems of expanding and strengthening the infrastructure on the regional and local level remain large. Current estimates state that the public health agencies are treating about 170,000 AIDS patients, and hope to reach over 200,000 in 2008. That would still be far less than those being HIV-infected, estimated to be near to 600,000.

In sum, joint action and dialogue between those groups and agencies representing or favouring the incentive of the market system and those within or outside government pursuing the welfare function are ongoing and need to be dealt with on the global, national and local level. While a country study on a very particular illness can only highlight the potential for progress in pursuing a generally accepted framework within the rules and commitments of global health governance, it would seem that the confrontations and disagreements that have eventually led to mutually beneficial cooperation, both within Brazil and between the country and international actors, can provide a useful example of conflict resolution on all three levels of interacting public and private actors.

To what extent that model can be transferred to other countries, and to what extent it can be repeated many more times in Brazil itself, remains to be seen. Moreover, the fight against AIDS remains a tremendous challenge not only for Brazil but even more in many of the poorer developing countries, and requires clearer insights, greater efforts and firmer cooperation than described here to eventually overcome AIDS and other fatal diseases.

⁸ This is part of the second phase of the current research project on Global Health Governance undertaken by the DUEI team in 2005/2006.

References

- Bates, R. 2003. "An AIDS Mirage." www2.techcentralstation.Com. 4/30.
- Biehl, J. 2004. "The Activist State – Global Pharmaceuticals, AIDS, and Citizenship in Brazil." *Social Text* 22(3): 105–32.
- Brazil, CIP, Parliamentary Inquiry Commission on the Pharmaceutical Industry. 2000. *Brasília: Relatório da CPI-Medicamento*.
- Brazil – The Pharmaceutical Industry. 2003. In: www.tradeport.org/ts/countries/brazil/isa.
- Calcagnotto, G. 2003. "Access to Health Services and Pharmaceuticals in Brazil." In: Hein and Kohlmorgen (eds.). *Globalization, Global Health Governance and National Health Politics in Developing Countries: An Exploration Into the Dynamics of Interfaces*. Hamburg: Schriftendes Deutschen Übersee-Instituts: 261–67.
- Cohen, J. C. and K. M. Lybecker. 2005. AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health. *The World Economy* 28.2: 211–230
- Commission on Intellectual Property Rights. 2002. *Integrating Intellectual Property Rights and Development Policy*. London.
- Dodgson R., K. Lee and N. Drager. 2002. "Global Health Governance: A Conceptual Review." Geneva: World Health Organization and London School of Hygiene and Tropical Medicine.
- Finkelman, J. (Org.) 2002. *Caminhos da Saúde Pública no Brasil*. Rio de Janeiro: Editora FIOCRUZ.
- Hein, W. and L. Kohlmorgen (eds). 2003. *Globalization, Global Health Governance and National Health Politics in Developing Countries. An Exploration Into the Dynamics of Interfaces*. Hamburg: Schriftendes Deutschen Übersee-Instituts.
- Mossinghoff, G. 2000. "Case Study: Brazil's Pharmaceutical Industry." U.S. Government Information Service: Introduction to Intellectual Property Rights. In: www.usinfo.state.gov/products/pubs/intelprp/brazil.htm.
- Neves Motta, R. 2003. "O Brasil e a Experiência Bem-Sucedida no Tratamento da AIDS." In Bayma F. and I. Kasznar (eds.). *Saude e Previdencia Social – Desafios para o Terceiro Mundo*. Sao Paulo.
- Oxfam. 2001. "Drug Companies vs. Brazil: The Threat of Public Health." In: www.oxfam.org.uk/what_we_do/issues/health/drugcomp_brazil.htm.
- Oxfam et al. 2002. "Beyond Philanthropy: The Pharmaceutical Industry Corporate Responsibility and the Developing Countries." Oxford, UK.
- Palmeira Lins Filho, P. and Simon S. Koo Pan. 2003. "Cadeia Farmacêutica no Brasil: Avaliação Preliminar e Perspectivas." *BNDES Setorial*. Rio de Janeiro.
- Parker, R. 2003. "Building the Foundations for the Response to HIV/AIDS in Brazil: The Development of HIV/AIDS Policy, 1982–1996." *Divulgação em Saúde para Debate*. Rio de Janeiro, Nr. 27:143–83.
- Risi Jr., J.B. and R.P. Nogueira. 2002. "As condições de saúde no Brasil." In Finkelman: 117–234.
- "Roche and the Brazilian Ministry of Health Reach Agreement for Supply of HIV Drug Viracept." 2001. Roche Press Release, August 31.
- Sachs, J.D. et al. 2001. *Macroeconomics and Health: Investing in Health for Economic Development*. Geneva: Report of the Commission on Macroeconomics and World Health Organization.
- Scharpf, F.W. 2001. "What have we learned? Problem-Solving Capacity of the Multi-level European Policy." Cologne: MPIfG Working Paper, 1.4.
- The Brazilian Health System: A Sector Impact Study*. 1998. Washington, D.C.: World Bank Evaluation Department.
- The TRIPS Agreements and Developing Countries*. 1996. New York: UNCTAD.
- "TRIPS and Pharmaceutical Patents." September 2003. *WTO Fact Sheet*.
- Walters, J. et al. 2001. "Pharmaceuticals and Intellectual Property: Overcoming the Impasse." Foreign Policy Institute, May 2001. www.fpc.org.uk/articles/99.
- Wogart, J.P. 2004. "Role and Responsibility of the Multinationals in the Health Sector: The Pharmaceuticals Confronting Infectious Diseases." Hamburg: German Overseas Institute.