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Changing global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil

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Abstract

Brazil's large-scale, successful HIV/AIDS treatment programme is considered by many to be a model for other developing countries aiming to improve access to AIDS treatment. Far less is known about Brazil's important role in changing global norms related to international pharmaceutical policy, particularly international human rights, health and trade policies governing access to essential medicines. Prompted by Brazil's interest in preserving its national AIDS treatment policies during World Trade Organisation trade disputes with the USA, these efforts to change global essential medicines norms have had important implications for other countries, particularly those scaling up AIDS treatment. This paper analyses Brazil's contributions to global essential medicines policy and explains the relevance of Brazil's contributions to global health policy today.

Keywords

HIV; AIDS; treatment; Brazil; human rights; trade; access; drugs; essential medicines

Introduction

Globally, 33 million people live with HIV/AIDS (UNAIDS 2008). In 2005, the United Nations committed to providing free and universal access to treatment for all people living with HIV/AIDS in need by 2010 (UNGA 2005). Although the global health community still falls far short of this commitment, in the last five years, the number of people estimated to be receiving highly active antiretroviral therapy (HAART) in developing countries has jumped from 400,000 to three million, or approximately 31% of the people in need (WHO 2008b). Global AIDS deaths have also plateaued, in part due to a large increase in the number of people receiving treatment (UNAIDS 2008). The global commitment to treat all people living with HIV/AIDS and to build health infrastructure towards that end is unprecedented; never before has the global community committed to and implemented health infrastructure to treat a chronic disease.

Global commitments to AIDS treatment can, to a large extent, be attributed to Brazil's efforts. Brazil was the first developing country to begin offering free treatment to AIDS patients. In

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the 1990s, Brazil ignored the World Bank's recommendations not to treat AIDS patients, and to focus instead on preventing new infections because that approach was more 'cost-effective' (World Bank 1993, 1998). Brazil began treating AIDS patients in the public sector in the early 1990s, committed to providing free and universal access to HAART in 1996, and has since made AIDS treatment available to over 180,000 people (Nunn *et al.* 2007).

Today, HIV prevalence in Brazil is 0.5%; approximately 600,000 people live with HIV/AIDS in Brazil (UNGASS 2008). AIDS-related mortality and morbidity have declined dramatically as a result of Brazil's AIDS treatment programmes and vertical (mother to child) transmission has been dramatically reduced since the late 1990s (Marins *et al.* 2003, Hacker *et al.* 2004, Souza-Junior *et al.* 2004, Teixeira *et al.* 2004, Campos *et al.* 2005, Dourado *et al.* 2006). However, HIV prevalence rates are considerably higher in several subpopulations such as injecting drug users (IDUs), commercial sex workers and the urban poor (Dourado *et al.* 2006, Fonseca and Bastos 2007). Additionally, although vertical transmission of HIV has declined, the AIDS epidemic increasingly affects Brazilian women and access to important prevention technologies required to prevent vertical transmission of HIV in Brazil (including HIV test kits and antiretroviral (ARV) prophylaxis) remains problematic in some remote regions. Despite these challenges, Brazil's epidemic has generally stabilised as new infections levelled off in the industrialised, urban southeast where the epidemic has historically been concentrated (Dourado *et al.* 2006).

Brazil is signatory to the 1995 World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Trade Agreement, which introduced intellectual property rules into the multilateral trading system (WTO 1995). TRIPS allows governments or third parties to issue compulsory licenses, which permit use of intellectual property without the consent of the patent holder in cases of national public health emergency, among other limited circumstances (WTO 1995).

The TRIPS Agreement has profoundly influenced Brazil's AIDS programme. In 2000, facing steadily rising costs for its AIDS treatment programme, Brazil took advantage of the TRIPS compulsory licensing clauses; Brazil began threatening to issue compulsory licenses to produce generic copies of patented drugs if pharmaceutical companies did not lower their prices. Although Brazil did not actually issue a compulsory license for an ARV drug until 2007, the controversy received global media coverage, prompted a 2001 WTO trade dispute with the USA, and sparked global policy dialogue about drug prices. Since 2001, Brazil has continued to publicly challenge multinational pharmaceutical companies about drug prices, produced generic drugs locally, threatened to produce generic copies of patented drugs locally and even imported generic drugs under patent in Brazil (Nunn *et al.* 2007). Brazil's actions ultimately resulted in pharmaceutical companies lowering their prices for several ARV medicines in Brazil, and saved Brazil over \$1 billion (USD) in drug costs since 2001 (Nunn *et al.* 2007).

Brazil's policies have also had important impacts beyond the country's borders. Brazil proved that treating people living with HIV/AIDS was possible in a developing country context and has become an example for developing countries scaling up AIDS treatment (Marins *et al.* 2003, Matida *et al.* 2005, Dourado *et al.* 2006). Brazil also established an important precedent for challenging pharmaceutical companies about drug prices, a policy some other countries have subsequently adopted (Ford *et al.* 2007, Nunn *et al.* 2007). Even as Brazil's policies were met with tremendous opposition from the innovator pharmaceutical industry and several governments, to strengthen its efforts to treat all people living with HIV/AIDS, Brazil also made deliberate and concerted efforts to change global health, human rights and trade policies related to access to essential medicines. (The term 'essential medicines' refers to World Health Organisation guidelines for medications that all health systems should make available to their populations.)

Ongoing global health discussions have been influenced by Brazil's actions in many ways, and Brazil continues to play a role in global policy discussions related to access to medicines. Most recently, in May 2008, the World Health Assembly (WHA) passed a resolution which commits to developing novel strategies for research and development for essential medicines and diagnostics for diseases that disproportionately affect developing countries. Opposed by many developed countries, this resolution can be traced to Brazil's and other developing countries' historical efforts to promote improved access to essential medicines. In this paper, we review the impacts of Brazil's efforts at the United Nations Commission on Human Rights (UNCHR), United Nations General Assembly (UNGA), WHA and WTO between 2000 and the present, and explain their historical links and relevance to related efforts to improve access to medicines today.

This article is grounded in empirical data collected over the last three years, including more than 40 in-depth interviews with key informants; reviews of historical documents related to UNCHR, UNGA and WHA resolutions, as well as WTO agreements from 2000 to 2008; quantitative data about Brazilian and global drug prices; and thousands of newspaper articles. We use a chronological narrative approach to explain how and why Brazil has shaped global health, human rights and trade norms related to essential medicines and highlight their evolving implications for global health policy.

Background

The first AIDS case in Brazil was diagnosed in 1983, and by 1988 Brazil had the second highest number of reported AIDS cases in the world, after the USA (Folha de São Paulo 1991). Brazil's commitment to AIDS treatment can be directly related to the country's transition to democracy, including its 1988 Constitution, which includes a clause guaranteeing a right to health and health services for all Brazilians (Brazil 1988).

During the late 1980s and early 1990s, an AIDS movement mobilised in Brazil demanding that the state provide access to prevention and treatment services. Many non-government organisations (NGOs) established in the late 1980s and in the early 1990s proved overwhelmingly important in pressuring the government to adopt progressive AIDS policies. These NGOs framed the poor public policy response to HIV/AIDS as violations of human and citizenship rights, and publicly demanded that the Brazilian government take steps to reduce HIV-related discrimination, enhance prevention efforts, and offer treatment to people living with HIV/AIDS. In 1990, in response to these demands, the Health Ministry committed to providing AIDS treatment, and began producing generic ARV drugs in 1993. Although the courts interpreted the constitutional right to health to include access to AIDS medicines in the early 1990s, AIDS treatment was available only sporadically until the mid-to-late 1990s, primarily because Brazil's Congress and Health Ministry had not appropriated sufficient funds for treatment and Brazil's health infrastructure was fragmentary (Nunn 2008).

In 1996, Brazil's Congress passed Law 9.313, commonly referred to as 'Sarney's Law', (sponsored by then-Senator and former President José Sarney), which guarantees free and universal access to drugs for AIDS treatment for all people living with HIV/AIDS in Brazil (Lei 9.313 1996). Since the mid-1990s, the World Bank also provided over \$500 million in loan support for Brazil's AIDS programmes. The loans forbade spending on drugs for treatment, but Brazil used the loans to subsidise epidemiological surveillance and health infrastructure development, which later facilitated treatment scale up (Nunn 2008). Brazil also began recognising intellectual property rights for pharmaceutical products in 1997, shortly after passing the 1996 Industrial Property Law to comply with WTO intellectual property requirements for middle-income countries (Brazil 1996).

Brazil, obligated by its legal commitments to, on the one hand, provide free and universal access to drugs for AIDS treatment and, on the other, to recognise the intellectual property rights of costly AIDS drugs, faced rapidly rising costs for AIDS treatment in the late 1990s. In 2000, Brazil's Health Minister José Serra began publicly discussing issuing a compulsory license in order to produce several ARV drugs in Brazil's public drug production facilities. Shortly thereafter, in early 2001, the USA filed a WTO trade dispute against Brazil (Buckley 2001).

Anticipating a trade dispute, Brazil commenced an effort to change global norms related to essential medicines. This strategy was adopted in order to facilitate implementation of Brazil's national efforts and included collaborations with other nation states (Serra 2005, Viana 2005). By working to change global norms in international fora, Brazil was able to help normalise its controversial AIDS treatment policies, including its decisions to challenge multinational pharmaceutical companies about ARV drug prices. We explore the implications of the evolution in global essential medicines norms for global health policy.

Brazil's first forays into changing global policy

During 1999 and 2000, several of Brazil's elected officials and public servants openly discussed the rising costs of AIDS treatment and the possibility of locally issuing a compulsory license in order to produce several patented drugs (Serra 2005, Teixeira 2005, Cardoso 2006). At the 2000 International AIDS Conference in Durban, South Africa, Paulo Teixeira, then Director of Brazil's National AIDS Programme, publicly criticised the US government for pressuring Brazil about its decision to produce generic medicines locally, and alluded to offering African nations assistance with expanding their AIDS programmes (Guedes 2000).

At the same time, other developing countries, including Thailand and South Africa, were facing trade sanction threats from the USA, as well as lawsuits and political pressure from innovator drug companies. In addition, an influential global AIDS movement was emerging that advocated for lowering drug costs and improving access to AIDS treatment for people living in developing countries. The movement also challenged drug companies about their prices while supporting the local production of generic drugs (Smith and Ciplon 2006).

Brazil's efforts to change global health norms related to essential medicines commenced at the WHA¹ in May 2000, when Brazil's delegation introduced a WHA resolution entitled *HIV/AIDS: Confronting the Epidemic*. The proposal sought a WHO-sponsored international price database for essential medicines that would be continuously updated, thereby promoting greater transparency about global drug prices. Also supported by France, Zimbabwe and South Africa, the resolution prompted an aggressive response from the multinational pharmaceutical industry and the US delegation (McNeil 2000, MSF 2000). Although the resolution ultimately failed, it forecasted Brazil's plans to continue to highlight the high costs associated with AIDS treatment in the global policy arena, an effort which escalated in 2001.

2001: a critical year for changing global policy

Brazil's global strategy

In January of 2001, the United States Trade Representative (USTR) launched a formal trade dispute against Brazil at the WTO. The dispute cited Article 68 of Brazil's 1996 Industrial Property Law, which requires that all foreign companies produce their patented products *in Brazil* within three years or else be subject to compulsory license. This clause was initially

¹The WHA is the World Health Organisation's decision-making body and has 192 member delegates from each of the world's nation states.

intended to stimulate development of local industry, but the USA claimed that the Brazilian law was in direct violation of the WTO TRIPS agreement, which guards against protectionist trade measures² (Buckley 2001).

The US trade dispute did not directly address Brazil's AIDS treatment programme or its strategies to threaten to issue compulsory licenses to lower the cost of AIDS treatment. One can speculate whether this was because Brazil's threats to issue compulsory licenses had not actually violated the TRIPS agreement and the public relations dangers of trying to undermine an AIDS treatment programme in a developing country. Nonetheless, the dispute drew global attention to Brazil's AIDS treatment policies.

Brazil's public officials knew they were not likely to win a purely economic battle against the USA. It was in this period that they began in earnest to introduce resolutions at the United Nations Commission and Sub-commissions on Human Rights, and the WHA. Former Brazilian President Fernando Cardoso explained why Brazil accelerated its global strategy to promote its AIDS treatment programme:

At the time, the international political climate was not conducive to AIDS treatment in developing countries. This is why we implemented a Brazilian strategy that included intensive South-South collaboration ... However, just as our strategy interested developing countries, it prompted strong negative reactions from developed countries and the pharmaceutical industry. It seemed logical then, for Brazil to seek global assistance in protecting our national interests. (Cardoso 2006)

Brazilian Health Ministry Diplomat José Marcos Viana described the Brazilian strategy to change global norms related to essential medicines:

We (Brazil) had several pillars in our strategy. One pillar was to defend Brazil's stance on AIDS drugs in several of the UN agencies. We had to defend our position and change international public opinion about these issues, with the press, with NGOs, in every way possible. The UN agencies were a vehicle for changing public opinion about Brazil's stance on AIDS issues and also for changing the legal frameworks to accomplish our objectives. Normally, all of these issues are reserved for the WTO. We decided our most effective line of defence would be to open the discussion to the Commission on Human Rights and the World Health Organization as well. The idea of moving our resolutions through the UN agencies was important for shaping global public opinion in our favour. So we developed a strategy at the World Health Assembly to introduce medicines resolutions. At the Commission on Human Rights, we pushed through that resolution that documented that access to medicines was a fundamental human right.

Our idea was that the Health Ministry, working with Itamaraty (Brazil's Foreign Affairs Ministry), was going to win over international public opinion. Our strategy was *not* to defeat the US government; the balance of power was not in our favour. The only way to win a trade dispute with the US, to convince the American government to change its policies, is to change the American public's opinion, and the opinion of the world. So that was our strategy, at the WHO, at the Human Rights Commission, at the WTO, with other NGOs, with the New York Times and other countries, to convince the American public to support us ... We bought ads in the New York Times, the Washington Post, the Los Angeles times, all the big papers in the US. (Viana 2005)

²Article 27:1 of the TRIPS Agreement reads 'Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.

Shaping global health essential medicines norms through trade policy

Brazil's formal efforts to change essential medicines norms through trade policy began in April 2001, when preparing for the November 2001 WTO round of trade discussions in Doha, Qatar. Zimbabwe, which led a group of African countries in the TRIPS Council, requested the council convene a special session related to access to essential medicines. After several trade and intellectual property disputes related to access to AIDS medicines in Brazil, South Africa and Thailand, the TRIPS council met and outlined a proposal to address conflicts related to trade, intellectual property and access to medicines (Abbott 2002, Cannabrava 2006).

In those meetings, Brazil campaigned for greater 'TRIPS flexibilities', or policies that permit more flexibility or leniency in enforcing the TRIPS agreement in developing countries, particularly regarding public health issues. Diplomat José Marcos Viana sheds light on why Brazil became so vocal about TRIPS flexibilities:

Earlier in 2001, José Serra confronted me and said, 'Now there is a World Trade Organisation dispute against us. I want you to find some way that no one can ever file another trade dispute against Brazil, or against any other developing country related to essential medicines'. He was worried that it would happen again. So that was why Brazil got so active at the Doha round of the TRIPS meetings. (Viana 2005)

Serra aimed to change global institutions to protect Brazil's domestic AIDS treatment policies in order to further trade disputes and conflicts with pharmaceutical companies. There was also consensus among other developing countries of the need for greater TRIPS flexibilities in cases of public health emergency. These discussions continued until the November 2001 Doha round of trade talks.

Using human rights to shape essential medicines policy

In May of 2001, Brazil introduced a resolution to the UNCHR³ entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS*. The resolution explicitly cites General Comment 14 issued by the UN Committee on Economic, Social and Cultural Rights (CESCR) in 2000, which (CESCR 2000) specifically recognises HIV/AIDS treatment as a fundamental component of the right to the highest attainable standard of physical and mental health and calls on nation states to make HIV treatment available to individuals living with HIV/AIDS. The USA strongly opposed the resolution but abstained from the vote. Nevertheless, the UNCHR overwhelmingly approved the resolution (52-0, with one abstention) (UNCHR 2001). *Access to Medication in the Context of Pandemics such as HIV/AIDS* was the first international human rights resolution to explicitly address the right to access to medicines. It calls on states to promote access to medicines and medical technologies for pandemics such as HIV/AIDS and to recognise that the right to health includes access to medicines, including drugs for AIDS treatment (UNCHR 2001). (Table 1 lists resolutions and agreements that Brazil either sponsored or supported in international fora in order to promote greater access to AIDS treatment and essential medicines. Note the Table excludes resolutions and agreements that were not ultimately accepted and those in which Brazil was not actively engaged.)

This resolution had important impacts on global policy. Beginning to establish the right to AIDS medicines as part of the human right to health within this political forum enabled Brazil to work in partnership with other countries and build upon its key components in other international fora; subsequent resolutions cited and reinforced its content.

³The UN Commission on Human Rights' historical mandate was to examine, monitor and report on human rights situations and violations worldwide. The institution was historically comprised of 53 member states elected each year. The UN Commission on Human Rights (UNCHR) was replaced by the Human Rights Council in 2006.

One month later in June 2001, the UN High Commissioner on Human Rights issued a report entitled *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, which, among other things, alludes to the Brazilian case to highlight the dilemmas developing countries face in promoting access to essential medicines at affordable prices (UNHCHR 2001). Brazil was highlighted because of its world-renowned treatment policies and efforts to scale up AIDS treatment, and the report helped further legitimise Brazil's efforts to defend its approach to AIDS treatment and efforts to shape global essential medicines institutions (Elliot 2005, Hunt 2006).

In August 2001, shortly after the events noted above, the UN Sub-Commission on Human Rights⁴ approved a resolution entitled *Intellectual Property and Human Rights* without a vote. It's unclear who introduced this resolution, and whether the motivation was actually related to the intellectual property of indigenous populations, but its relevance to Brazil's efforts are clear:

... (the Sub-Commission on Human Rights) Reminds all governments of the primacy of human rights obligations under international law over economic policies and agreements, and requests them, in national, regional, and international forums, to take international human rights obligation and principles fully into account in international economic policy formation. (UNSHCR 2001)

Promoting World Health Assembly (WHA) resolutions to encourage generic drug use and transparent pricing

In May 2001, shortly after adoption of Brazil's resolution at the UNCHR, Brazil introduced the *Revised Drug Strategy* at the WHA. The resolution proposed to expand access to essential medicines and controversially called for the WHO to adopt policies to allow for developing countries to expand access to generic drugs. Linking human rights with access to essential medicines, the resolution stated that developing countries should be permitted to use locally produced generics to uphold their commitments to fulfil the human right to health, and reiterated Brazil's previous request for the WHO to develop an international pricing database (Meyer 2005).

Although there was support from a range of countries and Brazilian Health Minister José Serra campaigned vigorously for this resolution, even delivering a speech at the WHA to lobby for support, ultimately the resolution was not adopted (Berlinck 2001). Brazil, Zimbabwe and other developing countries nevertheless used this opportunity to lobby the WHO to provide technical assistance to developing countries that faced challenges with intellectual property and trade issues impacting access to medicines.

A resolution entitled the 2001 WHO Medicines Strategy, which superseded the former WHA Revised Drug Strategy, was ultimately adopted. The *WHO Medicines Strategy* outlined a comprehensive approach to promoting access and rational use of medicines. Lobbying from the Brazilian delegation had a profound impact on the final language of this resolution, which highlighted the links between human rights and access to medicines. The resolution also encouraged states to implement policies that guarantee access to medicines, including medicines for HIV/AIDS, and called on the WHO Director-General to develop a global drug price monitoring system.

By acknowledging access to drugs as a fundamental human right and citing the need to expand access to drugs for AIDS treatment, this WHA resolution further legitimised Brazil's AIDS treatment programme. Having public international debate about drug prices relative to per

⁴The Sub-Commission on Human Rights was a subsidiary body of the Commission on Human Rights, comprised of 26 experts representing the world's different regions.

capita health expenditure also lent legitimacy to Brazil's AIDS treatment institutions and provided momentum for Brazil's efforts to challenge multinational pharmaceutical companies about ARV drug prices.

As a result of the resolution and the growing evidence base for treatment in developing countries, the WHO added ARVs to its Essential Medicines List in 2002, establishing ARVs as part of the minimal standard of medicines that should be made available for all health systems (WHO 2002). These changes in global policy highlighted the importance of treating HIV/AIDS, and provided momentum for the movement to encourage greater transparency about drug prices. These resolutions also led to creation of the WHO-sponsored 'prequalification system' for drug manufacturers to be considered for official WHO product endorsement⁵ (WHO 2006b). WHO also began financing the Management Sciences for Health's (MSH) International Drug Price Indicator Guide, which is published annually and catalogs online drug pricing information for many types of drugs (McFayden 2005). The guide, coupled with MSF's annual 'Untangling the Web of Price Negotiations' (MSF 2002) promoted transparency and policy dialogue about drug prices. Raising quality standards for generic drugs also promoted more affordable global access to high-quality drugs, which has facilitated scale up of global AIDS treatment.

Brazil also sponsored a second WHA resolution in May 2001 entitled *Scaling up the Response to HIV/AIDS*. Specifically, the resolution called for member states to establish health policies which include promotion and distribution of generic drugs for HIV/AIDS treatment. After Brazil engaged in long discussions with the USA, South Africa, Sweden and Thailand, the resolution was somewhat diminished in substance (Pincock 2001). However, the final resolution does refer to the resolutions previously adopted at the UNCHR and WHA and encourages member states to promote use and access to generic medicines for treating HIV/AIDS. Among other things, these efforts helped jumpstart official WHO policy discussions about the impact of intellectual property rights on access to medicines, and helped fuel global political momentum for creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria, now a multi-billion dollar institution that finances prevention, treatment and care for HIV/AIDS, tuberculosis and malaria programmes.

UN General Assembly Special Session (UNGASS): Brazil and the public stage

Due in part to the legitimacy given to Brazil's treatment policies in international fora since January 2001, there was growing international pressure for the USTR to drop its trade dispute with Brazil (Chade 2001, O Globo 2001). In June 2001, the UNGA held a Special Session (UNGASS) on HIV/AIDS. After much global protest from the global AIDS treatment movement and a strong response from the Brazilian government, on 25 June 2001, the first day of the UNGASS, the USTR formally dropped the WTO trade dispute against Brazil (British Broadcasting Company 2001).

During the Special Session, Brazil promoted its AIDS programme and campaigned for text to encourage changes in global essential medicines policy. Brazil introduced resolution text that mentioned the public health challenges associated with intellectual property rights, drug prices, and access to essential medicines in developing countries. Brazilian Health Minister José Serra's speech highlighted Brazil's dramatic decline in AIDS-related mortality, attributing its success to the country's strategy of producing AIDS drugs locally. He also encouraged pharmaceutical companies to adopt differential pricing policies in developing countries, and

⁵The prequalification process is a quality assessment and bioequivalence testing process designed to enhance access to high-quality drugs for AIDS, malaria, tuberculosis and reproductive health. To gain official WHO prequalification status and to be used in any programmes funded by UN agencies, both patented and generic drugs must meet bioequivalence, good manufacturing, laboratory and clinical practices.

urged the General Assembly to commit to providing affordable treatment to all PLWHA (Serra 2001).

The final *Declaration of Commitment on HIV/AIDS* encourages heads of state and government representatives to strengthen health systems and address other factors affecting access to AIDS medicines. Citing the UNCHR resolution *Access to Medication in the Context of HIV/AIDS*, the Declaration of Commitment also reaffirms access to drugs as a fundamental human right. Since this is a political consensus document, it's difficult to tease out Brazil's precise contribution to the final text of the resolution. However, it is clear that without Brazil's political actions and evidence base for treatment, this strong global commitment to AIDS treatment would not have occurred. Furthermore, bolstering the legitimacy of Brazil's treatment institutions, the *Declaration of Commitment* fuelled Brazil's ongoing price negotiations with multinational pharmaceutical companies and efforts to change global essential medicines policy.

Promoting Brazil's treatment agenda through the World Trade Organisation (WTO) Doha Declaration on public health

Between the UNGASS session and November 2001, the USA, the European Union (EU) and a group of developing countries,⁶ circulated and discussed draft proposals of what would become the *Doha Declaration on the TRIPS Agreement and Public Health*. Brazil played a key role in drafting the developing country position paper that called for greater flexibilities on essential medicines policy in trade regulations. The developing country coalition supported liberal use of compulsory licensing, parallel importation⁷ of pharmaceutical products, and differential pricing across markets. The US delegation aligned with multinational pharmaceutical company interests, opposing the developing country positions, including proposals to permit developing countries to locally define what constitutes 'national public health emergency', and TRIPS flexibilities that would permit compulsory license use in cases of national emergency. The EU adopted a middle ground (Abbott 2002, Serra 2005, Cannabrava 2006).

One completely unexpected event changed the course of the Doha negotiations; in September of 2001, after the attack on the US World Trade Center in New York, when the US faced what was thought to be a bio-terror attack with anthrax bacteria, the US Secretary of Health and Human Services threatened to issue a compulsory license for Bayer's Ciprofloxacin, prompting Bayer to lower its prices. Caught in the awkward position of threatening to issue a compulsory license to induce Bayer to lower its drug prices while trying to restrict compulsory license use in developing countries fighting the AIDS epidemic, the USA ultimately moderated its position (Abbott 2002, Cannabrava 2006). According to several diplomats and experts present in Doha, the final text of the Doha Declaration was negotiated behind closed doors, primarily between the USA and the Brazilian delegation, with the US altering much of the original developing country coalition proposal (Abbott 2002, Love 2005, Cannabrava 2006). The final Doha Agreement affirmed the right of each nation to declare and define what constitutes a public health emergency (WTO 2001). Health Minister José Serra explained how Brazil was able to garner support for TRIPS flexibilities in Doha:

Our efforts to change international law were part of Brazil's work as an sovereign nation, and part of my efforts as Health Minister. We were able to push forward the Doha Agenda because the European Union was divided; Spain, France and Italy were

⁶Developing countries included a group of African nations, which called itself the 'Africa Group', Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela.

⁷Parallel importation occurs when patented drugs are produced and sold in one market and then imported into a second market without authorisation of the patent holder in the second market.

more flexible. Germany, England, the UK were all opposed to TRIPS flexibilities. Of course, the rest of the developing world was not difficult to convince. But the EU position was somewhat ambiguous. And Robert Zoellick, the US Trade Representative, ultimately agreed with the flexibilities. Many NGOs helped publicly support our position. (Serra 2005)

By unambiguously affirming the right of each nation to declare and define what constitutes a public health emergency (WTO 2001), the Doha Declaration clarified some ambiguities of the 1995 TRIPS agreement, which recognised that compulsory licenses can be used in cases of public emergency but did not elaborate on their specific terms of use (WTO 1995). Diplomat Francisco Cannabrava, Brazil's TRIPS negotiator, commented on Brazil's efforts in Doha:

Our objective was not to do away with TRIPS, but we wanted to preserve TRIPS flexibilities. So that was the very specific objective we pursued in Doha. We knew it wouldn't work to change the TRIPS agreement because that was something that would just take too long. The objective was to avoid very strict interpretation of the TRIPS agreement, to get the WTO to recognise publicly that developing countries had a right to issue compulsory licenses for public health needs ... Importation is what we fought for at Doha. We promoted clauses to allow for importation of raw materials, which Brazil needed to make its generics ... We preserved the flexibilities that Brazil needed (Cannabrava 2006).

Since adoption of the Doha Declaration, Brazil continued to use the TRIPS flexibilities to threaten to issue compulsory licenses to produce ARV drugs locally. This had important policy impacts; in late 2001, drug companies Merck and Roche both dropped their prices and, since that time, Brazil has negotiated steep price reductions for several additional ARV drugs. These price negotiations are estimated to have saved the country over one billion dollars between 2001 and 2005 (Nunn *et al.* 2007).

In summary, by the end of 2001, Brazil had achieved its objective of preserving its domestic AIDS treatment institutions through strategic use of global policy fora. However, the impacts of these efforts went much further. The US dropped its trade dispute against Brazil. Moreover, by shaping global policy, Brazil's efforts helped pave the way for other developing countries to follow suit in making drugs for AIDS treatment available to their populations.

Brazil's engagement and policy impacts post-2001

Since 2001, Brazil has worked with other countries to continue to shape global norms related to AIDS and access to essential medicines more generally. This has included efforts at the UNCHR and the WHA. Brazil's efforts have also had direct and indirect impacts on global policy and drug prices.

Brazil's impact on human rights policy related to access to essential medicines

In 2002, the UN Sub-Commission on Human Rights renewed the commitments to AIDS treatment with another resolution entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria*. During 2002–2005, resolutions entitled *Access to Medication in the Context of Pandemics such as HIV/AIDS* and *Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria* were approved by the UNCHR (UNCHR 2002, 2003, 2004, 2005). These resolutions contributed to the development of global human rights standards related to access to essential medicines.

The impact of the Doha Declaration on World Trade Organisation (WTO) policy related to essential medicines

Even in those fora where Brazil has been less engaged since 2001, such as at the WTO, Brazil's previous efforts paved the way for other countries. In the 2003 WTO Cancun negotiations, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003* expanded on the Doha TRIPS flexibilities by allowing countries with insufficient pharmaceutical production capacity to issue compulsory licenses in order to import generic drugs in cases of national public health emergency (WTO 2003). This decision was reaffirmed in the 2005 Hong Kong round of WTO trade agreements (WTO 2005). Although Brazil was far less active in these discussions, had Brazil not been so influential in Doha, public health TRIPS flexibilities are likely never to have materialised. Since 2003, several countries have used these TRIPS flexibilities to issue compulsory licenses in order to import generic medicines (Love 2007).

Global AIDS treatment access and drug prices

Brazil's resolutions have also directly and indirectly impacted global scale up of AIDS treatment and access to essential medicines. The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, which developed in part as a result of the 2001 WHA resolution *Scaling Up the Response to HIV/AIDS* that Brazil introduced, has provided approximately 1.4 million people with AIDS treatment and has also financed hundreds of tuberculosis and malaria programmes (Global Fund 2008). International political momentum for increased global health expenditure also contributed to the creation of the United States' President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, which supplies treatment for another 1.4 million people living with HIV/AIDS in developing countries and supports wide-ranging interventions related to HIV/AIDS (PEPFAR 2008). As a result of these programmes, global AIDS spending expanded from \$300 million to \$10 billion between 1996 and 2008 and US annual spending for overseas development assistance related to HIV/AIDS grew from \$121 million in 1998 to an expected \$8 billion in 2008 (CRS 2004, 2005, 2006, UNAIDS 2006, UNAIDS 2007, Nunn 2008, US Public Law No: 110–293 2008). While these changes certainly cannot be attributed to Brazil's efforts alone, these programmes may not have emerged had Brazil not been so vocal about the importance of global AIDS treatment, proved that AIDS treatment was possible in a developing country, and helped to develop the global policy infrastructure to move these programmes forward.

Additionally, Brazil's demand for active pharmaceutical ingredients (APIs) for use in manufacturing generic drugs in Brazil, along with massive global scale up of AIDS treatment as a result of the Global Fund and PEPFAR, have helped stimulate development and competition within the generic ARV drug industry. Competition and Brazil's price negotiations have contributed to large-scale declines in the cost of AIDS drugs globally (MSF 2007, Nunn *et al.* 2007).

Shaping research and development paradigms for essential medicines

Brazil continues its engagement at the WHA to promote greater access to essential medicines. In 2003, Brazil sponsored an important WHA resolution entitled *Intellectual Property Rights, Innovation, and Public Health* and led a delegation of countries who advocated for a WHO mandate to address intellectual property right issues that impact public health. The resolution, approved by the WHA, created an independent commission to investigate the public health implications of intellectual property protection for developing countries called the Commission on Intellectual Property Rights, Innovation and Public Health (WHA 2003). By linking intellectual property rights, innovation and access to a variety of medical technologies for developing countries, Brazil broadened the public policy discussion related to access to medicines.

In April of 2006, the Commission released its report entitled *Intellectual Property Rights, Innovation, and Public Health*, which finds that intellectual property rights have not stimulated development of new technologies to meet public health needs in developing countries. The Commission was not, however, able to reach an agreement on how to effectively address the paucity of affordable technologies for developing countries through public policy (WHO 2006a). Nevertheless, official acknowledgement by this body that current research and development paradigms have not led to development of appropriate medical and diagnostic technologies for the diseases accounting for large disease burdens in developing countries has further legitimised the global AIDS treatment movement and promoted policy changes to stimulate greater access to essential medicines.

The report also brought momentum to the ongoing debate about global research and development paradigms, particularly for diseases primarily affecting developing countries. In May of 2006, Brazil and Kenya co-sponsored a WHA resolution that called for a working group to develop novel ideas and policy recommendations to address the concerns raised in the report. The resolution, citing all of the aforementioned WHA resolutions sponsored by Brazil since 2001, calls for development of innovative policies for conducting the research and development for drugs and diagnostic products to address the health problems that disproportionately affect developing countries. This resolution created the WHO Intergovernmental Working Group on Innovation, Intellectual Property and Public Health (IGWG), which met in 2006–2008.

Brazil's contributions to global essential medicines policy are ongoing; in December 2007, the IGWG recommended that the WHA establish a needs-driven research and development agenda that responds to the health needs of low- and middle-income countries. In May 2008, IGWG proposed a strategy to finance and implement policies to increase the availability, accessibility and uptake of drugs, diagnostic products and vaccines in developing countries (WHO 2007). In spite of considerable opposition from several developed countries, and with strong support from many developing countries, IGWG's recommendations culminated in the 2008 WHA resolution *Global Strategy on Public Health, Innovation and Intellectual Property*. The resolution committed to developing strategies to finance, coordinate and implement a needs-based research and development agenda to respond to the health needs of developing countries⁸ (WHA 2008, WHO 2008a). Although it's difficult to gauge the resolution's long-term policy impacts at this early stage, this WHA resolution may spearhead a fundamental paradigm shift for global research and development for priority diseases in developing countries. This movement, which can be traced to Brazil's 2003 and 2006 WHA resolutions, highlights Brazil's long-term contributions to global essential medicines policy.

Conclusion

Brazil's efforts to preserve its domestic AIDS treatment policies had far-reaching implications for global essential medicines policy. Brazil's reforms improved global transparency about drug prices, affirmed generic drug use to address public health needs, defined access to medicines as a component of the human right to health, promoted incorporation of ARVs into the WHO Essential Medicines List and strengthened TRIPS flexibilities for developing countries. Many of these institutional changes helped pave the way for other countries to begin or expand their national AIDS treatment programmes; today, three million people in developing countries receive drugs for AIDS treatment. Economies of scale for AIDS treatment have also helped stimulate development and competition within the generic ARV drug industry, which has contributed to large-scale declines in the cost of AIDS drugs globally. Perhaps even more importantly, Brazil's efforts have helped shape and promote a global agenda

⁸Although several developing countries tried to include clauses stating that the right to health takes precedence over commercial interests into the resolution, the movement ultimately failed.

to meet the health needs of developing countries, and these discussions continue to impact global essential medicines policy today. These are important and enduring legacies of Brazil's world-renowned AIDS treatment programme.

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Table 1

Brazil's contributions to global essential medicines policy.

Institution	Date	Resolution or agreement	Policy implications
United Nations Commission on Human Rights (UNCHR) ^a	April 2001	Access to medication in the context of pandemics such as HIV/AIDS	Acknowledges that the right to health includes access to medicines, including medicines for HIV/AIDS treatment. Calls on states to promote access to medicines and medical technologies for pandemics such as HIV/AIDS.
World Health Assembly (WHA)	May 2001	WHO medicines strategy	Links human rights and access to medicines at WHA. Encouraged states to implement policies that guarantee access to medicines, including medicines for HIV/AIDS. Led to development of a global drug price monitoring system. WHO added ARVs to the 2002 Essential Medicines List.
World Health Assembly (WHA)	May 2001	Scaling up the response to HIV/AIDS	Endorsed creation of the <i>Global Fund to Fight HIV/AIDS, TB and Malaria</i> . Promoted use and distribution of generic drugs for HIV/AIDS treatment.
United Nations High Commission on Human Rights (UNHCHR)	June 2001	The impact of TRIPS agreement on human rights	Commended Brazil's HIV/AIDS treatment policies and programmes. Highlighted dilemmas faced by developing countries to provide access to medicines at affordable prices while acknowledging intellectual property rights.
United Nations General Assembly Special Session (UNGASS)	June 2001	Declaration of commitment on HIV/AIDS	Reaffirmed access to medicines as a fundamental human right. Encouraged governments to address factors related to provision of AIDS drugs, including pricing. Urged provision of the highest attainable standard of treatment for HIV/AIDS. Encouraged development of domestic innovator and generic drug industries, as consistent with international law.
United Nations Sub-commission on Human Rights	August 2001	Intellectual property and human rights	Reminds governments of the primacy of human rights over other economic policies and agreements.
World Trade Organisation (WTO)	November 2001	Doha Declaration on the TRIPS agreement and public health	Recognised the rights of governments to issue compulsory license in cases of public health emergency. Affirmed governments' right to define what constitutes a national emergency.
World Health Assembly (WHA)	May 2003	Intellectual property rights, innovation and public health	Created an independent commission to investigate the public health implications of intellectual property regulations for developing countries.
World Health Assembly (WHA)	May 2006	Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action	Culminated in a working group to develop strategies and public policies to effectively address the health needs of developing countries. Culminated in creation of the Intergovernmental Working Group on Health (IGWG). IGWG made policy recommendations in 2008 to address the need to develop drugs and diagnostics to address the health needs of developing countries. IGWG's policy recommendations were integrated into the Global Strategy on Public Health, Innovation and Intellectual Property resolution of the 2008 WHA.

^a Renewed and expanded in 2002–2005.