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A Developing Say Against AIDS

By: Joanna Rydzefski

Introduction and Background:

Lack of access to medicines is a hurdle for many countries around the world, especially developing nations in their attempts to fight serious health problems. The World Trade Organization (WTO) has frequently been scrutinized regarding its impact on access to essential medicines. Created in 1995, the WTO “is the only global international organization dealing with the rules of trade between nations... the goal is to help producers of goods and services, exporters, and importers conduct their business” (Understanding). The WTO created a framework for the protection of physical and intellectual goods. The 157 countries that have entered into the WTO are held to a standard of intellectual property regulations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Ibid). Intellectual property, or “the creations of the mind...used in commerce” is protected from competition and regulated under the TRIPS Agreement, which includes twenty year patents on essential medicines (What, Part). While the main goal of TRIPS is to promote scientific development through patents that guarantee the inventor’s exclusive rights over their product, the repercussions of this monopoly over drug production sparked opposition from developing nations, specifically Brazil and South Africa (Dounis 2011, 3). With the help of human activists, NGO’s, and government support of AIDS programs, Brazil and South Africa addressed their concerns regarding TRIPS through national policies involving the production of generic drugs and parallel importation, respectively.

Developing nations feared that access to essential medicines would decrease due to the increased cost resulting from monopoly control of patented drugs. Price increases restrict the goal of providing affordable medicines to HIV patients, as it is estimated that a price reduction of 95% is necessary for universal affordability of the needed antiretroviral drugs (Beyond 2000, 2).

With the HIV/AIDS epidemic becoming more widespread, Brazil and South Africa acted to combat the WTO's disregard for the greater health implications of TRIPS.

This paper aims to explore how the actions of Brazil and South Africa impacted the scope of the WTO. It argues that the national policies of Brazil and South Africa, which addressed concerns regarding the TRIPS Agreement, led to the Doha Declaration and ultimately to a recognition of trade's impact on the health sector, the importance of multi-sector alliances, and the increased representativeness of the WTO. An analysis of the actions of Brazil and South Africa will be conducted to address the questions of how the World Trade Organization and TRIPS relate to pharmaceutical productivity and how these policies have changed since their enactment in 1995. These countries' impact on international trade, considering their limited voice, will also be analyzed, as compared to the influence of developed nations.

The paper will start by addressing how matters of international trade were conducted prior to the establishment of an international trade organization and why inclusion of intellectual property protection under TRIPS was spearheaded by developed nations. Second, in order to understand why Brazil and South Africa opposed the TRIPS agreement, one must understand their objections. The second section will examine the arguments of developing countries and particularly Brazil and South Africa's concerns and resulting national policies. The third section will focus on the Doha Declaration and will demonstrate how the actions of Brazil and South Africa resulted in the clarification and change of the TRIPS Agreement. Brazil's production of generic drugs and South Africa's policy regarding generic drug importation brought about contestation from developed nations, which questioned the compliance of these policies with regards to TRIPS. The involvement of government, NGO, and human activist response will then be analyzed with regards to their role in supporting unrestricted access to HIV/AIDS treatment.

These actions culminated in the Doha Declaration of 2001, which addressed the compulsory licensing and parallel importation clauses in the TRIPS Agreement (Asegård 2004, 13). As a result, the WTO acknowledged a new role in the health sector and recognized the power of developing nations to have their concerns addressed in an international setting, thus making the WTO more inclusive and representative.

Developments Leading to the WTO and TRIPS Agreement

The creation of the World Trade Organization changed the structure of intellectual property trade by centralizing regulations and adding a dispute settlement board. Previously, intellectual property protections had not been universal, but, “international protection of intellectual property was dependent on the enforcement of national patent laws” (Love 2007, 209). These self-contained laws allowed developing nations, such as Brazil, to produce their own generic drugs, unlike many developed nations with powerful patent laws. Developed nations desired inclusion of intellectual property patents under the WTO because of competition surrounding technological development, the lack of exclusive rights to such developments, and the reduction of trade barriers to developing nations (Correa 2000, 3-4). Developed nations, wanting to maintain these advantages, and developing nations, wanting to protect themselves against injustices, frequently utilized the regulatory dispute board. The dispute settlement system of the WTO made it so that “protagonists would no longer be given the option to adopt dispute panel findings voluntarily” (Ibid, 132). The board’s jurisdiction means that any decision made is applicable to every nation under the WTO and not just merely suggestions (Dispute 2012). Thus, if a developing nation were to win a case at the disadvantage of developed nations, the developed nations would be powerless to change the result and vice versa. Because Brazil and South Africa had taken an active role challenging the influence of the TRIPS Agreement, cases were brought

before country courts and the WTO dispute settlement board by developed nations, who had adamantly pushed for the inclusion of intellectual property protection into this system.

Concerns of Developing Countries Regarding TRIPS

Brazil and TRIPS

Brazil has repeatedly challenged the restrictions placed on generic drug production under the TRIPS Agreement. Since 1996, Brazil has offered free antiretroviral (ARV) drugs to its citizens. Former president, Fernando Henrique Cardoso, explained how, “Anyone who wanted these drugs... now had a legal right to get them” (Cardoso 2006, 215). The feasibility of this right was hindered because in 1996, Brazil began to implement the full scope of the TRIPS Agreement. Rather than implementing TRIPS under the allowed transitional period, “Brazil’s hurried implementation significantly restricted the state’s generic manufacturing sector, in turn motivating the state to pursue a more adversarial approach” (Ganji 2011, 29). To uphold access to essential HIV medicine, Brazil threatened to use compulsory licensing for drug production. To demonstrate their capability to patent holding, developed nations, Brazil offered “[executives of] multinational pharmaceuticals guided tours in Rio de Janeiro... [demonstrating] not only its willingness to issue compulsory licenses but also its capacity” (Flanagan 2007, 68). If Brazil had lacked the facilities to act on these threats, it would have been disregarded and Brazil would not have been met with such fervent opposition from developed nations.

Brazil threatened to implement compulsory licensing to decrease the price set by patent holding pharmaceutical companies. In 2001, the United States filed a complaint before the WTO because Brazil threatened Merck after the pharmaceutical company refused to reduce its price on an ARV (Lage 2011, 21). The U.S. claimed that Brazil was violating the rights of patent holders and the compulsory licensing clauses of TRIPS. They cited Article 31 of the Agreement, which restricts the enactment of compulsory licensing, stating that countries must first attempt to obtain

a voluntary license from the patent holder, produce drugs for domestic use, and give remuneration (Part). These steps could only be avoided when the situation was considered to be an “emergency”, but at this time there still remained confusion regarding who determined this status and how it was enacted. The need for policy clarification was strengthened by South Africa’s actions.

South Africa and TRIPS

South Africa, adopting TRIPS in 1995, also responded to the Agreement through national health policies. Concurrent with the concerns of Brazil, South Africa feared a lack of access to essential ARV medicines due to an increased cost of patented drugs. In response, South Africa implemented the Medicines and Related Substances Control Amendment Act (MRSCA) in 1997. The amendment gives the Minister of Health the power to authorize compulsory licenses and parallel importation, stating,

“The Minister may prescribe conditions for the supply of more affordable medicines...to protect the health of the public, and in particular may ... prescribe the conditions on which any medicine which is identical in composition, meets the same equality of standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic ... may be imported” (Republic 1997, 11-12).

This policy removed the role of the WTO in authorizing such decisions, thus posing a threat to the patent holders who benefited economically from the monopoly TRIPS created (Fisher 2005, 5-6). Drug inventors and manufacturers were concerned that, if South Africa could decide for itself when to postpone patent implementation, patents would never be enforced and that this would be financially detrimental to their place in the pharmaceutical industry.

When the MRSCA law was created, Article 31 of the TRIPS agreement allowed for the production of generic drugs only under emergency conditions and production was restricted to domestic use. South Africa, unlike Brazil, did not have the capacity to produce drugs

domestically and thus relied on importing generic medicines from other countries. This lack of production power served as a limiting factor in the accessibility to essential ARV medicines and eliminated the option for using compulsory licensing as a bargaining strategy, as Brazil had utilized. South Africa could threaten compulsory licensing, but, because they could not actually produce the necessary amount of drugs for domestic use, parallel importation under the Medicines Act was a bigger worry to developed nations because cheaper generics could still be purchased over their more expensive, patented drugs. The actions of Brazil and South Africa led to overwhelming global activism.

Reactions to Brazil and South Africa's Policies

There is great inequality between developed and developing countries with respect to technological advancement. According to the United Nations Human Development Program Report from 2000, "It is estimated that industrialized countries hold 97% of all patents, and global corporations 90% of all technology and product patents" (84). It is in the interest of these countries to protect their economic standing and technological advancement, which they aimed to do through the TRIPS Agreement. When developing countries began to act against and question TRIPS, pharmaceutical corporations needed to take action, as "TNPCs [transnational pharmaceutical companies] were not only the major actors in the fight with government officials with developing countries over the price of ARVs, but were also responsible for the introduction and negotiations of the TRIPS Agreement" (Wogart 2009, 141). When developing nations, such as Brazil and South Africa, began to enact policies that developed nations saw as harming their interest, rather than granting equal attainment of the right to human health, developed nations reacted with legal opposition.

Brazil and South Africa capitalized on their unique situations to address the increasing AIDS epidemic. The Brazilian government spearheaded the first actions taken to combat this

rising threat by implementing their national response program. Under Brazilian law, the production of generic medicines was a legal response to protecting the health of its citizens. Brazil's 1996 industrial patent law was the foundation for Brazil's threat of compulsory licensing, which led to a decrease in the cost of pharmaceutical goods. Consistent with the TRIPS Agreement, "Article 71 authorizes compulsory licenses in the case of national health emergencies - it allows the government to authorize local producers to produce generic drugs needed to fight a national health emergency or to import from a generic producer elsewhere, despite patent protection," and does not limit action by defining what constitutes an "emergency" (Wade 2003, 626). The Brazilian government also utilized Article 68 which allows for compulsory licensing, including medicines, to be used without the consent of a foreign patent holder if production within Brazil does not begin within a certain amount of time (Ibid, 627). While the utilization of Article 71 culminated in beneficial negotiations for price reductions with pharmaceutical companies, it was Article 68 that was of bigger concern for the United States specifically. The United States brought a complaint before the WTO Dispute Settlement Board; "On 30 May 2000, the US requested consultations with Brazil in respect of those provisions of Brazil's 1996 industrial property law" (Brazil 2012). The United States questioned whether Brazilian policies regarding AIDS treatment were legal under TRIPS.

Other actors, in addition to Brazilian government, took a stand regarding the treatment and prevention of AIDS. They influenced the continued interpretation of the TRIPS Agreement. Even before the hearing called by the United States, the support for a national treatment and prevention plan was significant. Brazil's efforts were even recognized by the World Bank, which has provided over US\$425 million in loans since 1994 and has "played a key role in subsidizing the [National AIDS Program] NAP, including health infrastructure and human resources

development, HIV/AIDS surveillance, and prevention programs” (Nunn 2009, 1106). The World Bank, knowing where the money was being spent, continued to support the program financially, allowing NAP to have an impact on decreasing the prevalence of AIDS in Brazil. When Brazil’s AIDS treatment program was challenged by the United States, this commitment to decreasing AIDS was mirrored by non-governmental organizations (NGOs). NGOs have consistently advocated for the rights of HIV patients; therefore, the level of support was no different when the law granting such was challenged by the United States. Previously, for example, “NGOs such as *Associação Brasileira Interdisciplinar de AIDS (ABIA)* and *Grupo pela Valorização, Integração e Dignidade do Doente de Aids (Pela VIDDA)* used the courts to gain legal recognition that the right to health... includes rights to prevention, treatment, and care for people living with HIV/AIDS (Nunn 2009, 1105-1106). The idea of a right to health was widely accepted within the country of Brazil due to quick government support against AIDS and a de-stigmatization of the disease. The debate between Brazilian interests and the interests of the United States represented, “global NGOs operating in concert with Brazil and other developing countries to increase the pressure on the US and other developed countries to modify their position” and rejected the complete dismissal of the human right to health (Flannagan 2007, 71). The denial of this human right is exactly what the Brazilian people were arguing against, as “The Brazilian response to AIDS emerged from the demands of civil society groups and developed through active collaboration between the local government of Sao Paulo and NGOs and through support within the official health system” (Wogart 2009, 145). It was the combination of all of these factors that forced the United States to reevaluate its chance of obtaining a favorable verdict from the World Trade Organization Settlement Dispute Board. The U.S. later decided to drop the complaint after negotiating with Brazil, rather than receiving a losing and binding verdict. Then,

“On June 25, 2001, in a joint statement with Brazil, the United States announced that it would withdraw the WTO panel against Brazil” (t’Hoen 2003, 45-46). The realization by the United States that a win was not guaranteed depicts the power behind collective action within a developing country, whose goal could have otherwise been overlooked in favor of the demands of the powerful developed nations and their economic interests. The act of illustrating the power of developing nations with regards to the promulgation of the idea that health is a human right was also reflected in the actions of South Africa.

While South Africa did not implement a national AIDS medicine plan, the country took steps toward increasing the availability of generic drugs to lower the cost to the patients, which was an act that was met with opposition from many multinational corporations. Despite the “South African policymakers’ unwillingness to engage in a dialogue on treatment of HIV/AIDS,” the prevalence of other actors working within the community fought for the rights of those infected with HIV/AIDS (Wogart 2009, 148). Even when global actors were able to demonstrate the benefits of providing HIV treatment, the government was unreceptive, such that “The South African government resisted providing anti-retrovirals for pregnant women until 2001, when the courts, ruling in a case brought by the Treatment Action Campaign [TAC], compelled the state to do so” (Gauri 2004, 15). The lack of government support led to a focus on the private sector, such as civil society groups like TAC, for aid and legal assistance. While the actions of South Africa differed from Brazil, promoting access to antiretroviral drugs and upholding the “right to health” was the same for both countries.

South Africa met opposition from pharmaceutical companies who claimed that the Medicines and Related Substances Control Amendment Act violated intellectual property rights regulations. The South African law was contested because it “authorizes two practices that are

controversial (although not explicitly prohibited) under TRIPS” (Lanoszkam 2003, 192). This policy allows for parallel importing and compulsory licensing, which benefit those in need of ARVs but harm the capital intake of the pharmaceutical companies because South Africa would be able to purchase drugs at a cheaper cost. While Lanoszkam claims that these policies were controversial, but not illegal, “In February 1998, the consortium of 40 drug companies, led by the Pharmaceutical Manufacturers' Association of South Africa, filed a suit. Its key legal claim was that the statute... was in violation of South African obligations under TRIPS” (Ibid 2003, 192). The South African case, like the one against Brazil, unified NGOs in support of a right to health message. In response in 2001, “Internationally-recognized NGOs such as Medecins Sans Frontieres, Oxfam, Cptech and ACT-UP pressured TNCPs to withdraw the case [against South Africa]. Even the Bush administration refrained from openly supporting the pharmaceutical industry” (Wogart 2009, 151). These organizations worked together with the South African private sector to pressure the pharmaceutical companies to withdraw their charges. Even U.S. advocacy groups protested and when, “ACT UP began disrupting Vice-President Al Gore's campaign appearances... his position quickly shifted and he announced that he was supportive of compulsory licensing and parallel imports in South Africa” (Flannagan 2007, 71). Because George W. Bush and Al Gore did not back the pharmaceutical industry, the message was sent that the United States' companies would not be supported by their country's government. This lack of support from the companies' base countries illustrated the unpopularity of their actions, not only from the South Africans, but also from their own people country, as the U.S. was not willing to involve itself in the promotion of limiting access to health care. The companies that brought the lawsuit were not considering the effects the verdict of this case would have on health but focused on the economic benefits as, “the industry group framed the matter simply as a

struggle over intellectual property rights. There was no mention of how this might affect the treatment of AIDS” (Lanoszkam 2003, 192). A communal settlement was reached in 2001 which agreed to almost all of South Africa’s demands, but the TRIPS Agreement remained binding (Wogart 2009, 151). This settlement illustrated that South Africa could uphold a national right to health and the desires of its citizens by obtaining concessions from pharmaceutical companies even without the level of government support that was held in Brazil. TAC noted in a statement, “The court case... represented an important victory of activists, poor people and people with HIV/AIDS over corporate abuse of power. This was only possible because of a superbly organized global effort and the dedication of thousands of volunteers” (Treatment 2001). Despite the victories in the developing nations of Brazil and South Africa, there was still fervent debate regarding the overall role of health and its precedence over the economic gain of patent holders.

Doha Declaration

The protests of Brazil and South Africa serve not only to depict the need for policies that allow for countries with limited resources to combat AIDS, but also to identify the ambiguousness of the TRIPS Agreement. Brazil and South Africa were able to make progress in combating AIDS through the use of compulsory licensing and generic importation because of the lack of a clear definition of what was legal under the intellectual property law as it was written. With all of the attention and confusion surrounding the flexibilities within the TRIPS policy, both developed and developing nations called for the policy to be better defined with regards to the access of essential medicines. In 2001 in Doha, Qatar, the World Trade Organization Ministerial Conference “responded to these concerns by adopting the Declaration on TRIPs and Public Health... [and] affirmed the sovereign right of governments to take measures to protect public health, including the use of compulsory licensing and parallel importation” (t’Hoen 2009,

xv-xvi). The Doha Declaration did not change the text of the TRIPS Agreement or alter the intellectual property right regulations, such as lowering the 20 year patent rule, but provided guidance as to how the text could be interpreted to accommodate both the interests of the patent holders and the developing nations' concerns regarding accessing needed medicines (Alsegård 2003, 16). Because the laws and actions of the developing nations of Brazil and South Africa caused such an opinionated public response, the World Trade Organization was forced to pay greater heed to developing nations than in the past. In the Doha Declaration, it is noted, "The majority of WTO members are developing countries. We seek to place their needs and interests at the heart of the Work Programme adopted in this Declaration" (Ministerial 2001). This acknowledgement of the power of developing countries is in stark contrast to the previous regard given them, as exemplified in the pharmaceutical companies' dominance over the initial enactment of TRIPS. Paragraph 6 of the Ministerial Doha Declaration asserts the WTO's obligation to protect human health, thus linking the organization, and all aspects of trade, to a new role in promoting health (Ministerial 2001). Due to the significance of this assertion, the WTO dedicated a separate declaration in support of public health.

The "Doha Declaration on the TRIPS Agreement and Public Health" was the response of the WTO to the growing voice of developing nations, influenced by the actions of Brazil and South Africa. Brazil and South Africa both had national laws that allowed for compulsory licensing, but the confusion regarding TRIPS' Article 31, which lacked a clear definition of what constituted an emergency, caused the United States to question the legality of these countries' policies. Paragraph 5 of the Declaration gives each member country the right to determine what constitutes an emergency and the swiftness with which they react (Declaration 2001). By giving the power to the country instead of the organization, developing nations were thus able to

determine when and how to implement compulsory licensing. The ability to determine such takes the power away from the patent holders, who strongly influence the market, because developing nations can begin to produce generic and, thus, cheaper drugs after deciding, for themselves, that the situation warrants this action. For those countries affected by “Article 31 (f) of TRIPS [which] limits compulsory licensing to uses which are predominantly for the supply of the domestic market,” as challenged in the MRSCA case, Paragraph 6 of the Doha Declaration on Public Health addresses this conflict by recognizing the impact this has on health of developing countries and allows for parallel importation (t’Hoen 2003, 54). Countries are explicitly able to issue compulsory licensing and other health protection policies as a result of the clarification of TRIPS’ Article 8, which did not overtly identify WTO members as having this ability until Paragraph 4 of the Doha Declaration defined this connection in plain text, thus removing the ambiguity of country’s rights (Asegård 2003, 17). Paragraph 4 explains, “We affirm that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health” (Declaration 2001). This clarification reiterated the ability of member countries, under the regulatory policies of the World Trade Organization and its newly defined health role, to decide, create, and enact policies in the best interest of the health of their citizens. The previous concerns addressed under the Doha Declaration significantly impact developing nations as,

“it strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. The declaration ... constitutes a confirmation of the position of countries like South Africa and Brazil which sought to go beyond a narrow interpretation of TRIPS in their search for ways to tackle health crises” (Cullet 2003, 153).

Brazil and South Africa served as the initial voice of developing nations, which culminated in the changed focus of the most encompassing trade organization. By using the system in place to

expose its flaws, these countries were able to push against the traditional imposition of developed countries' corporate interest, which often came at the cost of developing nations, as evident in the fight against AIDS. The progress within the developing world after the DOHA Declaration is exemplified by the fact that between 2001 and 2007, 52 developing nations issued compulsory licenses for the production of generic medicines and utilized other TRIPS flexibilities (t'Hoen 2009, xvi). Access to essential medicines will no longer be restricted, as it was prior to the unification of the TRIPS and WTO mission to protect health.

The creation of the World Trade Organization linked both developed and developing nations into a system of trade. With the developing nations advocating for intellectual property right regulations, the TRIPS Agreement was enacted and patent protections extended to medicines. With the increase in cost that the monopoly perpetuated, lower-income developing nations facing health epidemics were unable to afford essential medicines. In response, the countries of Brazil and South Africa utilized the loopholes in the TRIPS Agreement to produce national legislation allowing for compulsory licensing and parallel importation. The United States and other major pharmaceutical companies reacted, but the public and NGO support of the right to health forced the WTO to re-evaluate its impact on health. The resulting Doha Declaration solidified the WTO as a global health actor and increased the sovereignty of developing nations to act in the best interest of the health of their people.

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