U.S. International Trade Commission Investigation No. 332-596

"COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities"

FEMINISTS FOR A PEOPLE'S VACCINE

DAWN FEMINIST

GTPI

Summary

Introduction

Development Alternatives with Women for a New Era (DAWN), represented by Rajnia Rodrigues, and the Brazilian Interdisciplinary AIDS Association (ABIA), represented by Susana van der Ploeg, served as witnesses for the US International Trade Commission number 332-596, COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities.

Between 29-30th April, 2023, they appeared as witnesses before the US ITC Commissioners panel along with other civil society organizations from around the world. According to the Commission, never an investigation process had attracted so much interest from around the world. Activists now hope this effort pushes the US to extend the TRIPS decision as was agreed in June 2022.

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March 29th, 2023

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Oral Statement by DAWN - Development Alternatives with Women for a New Era

I would like to thank the US ITC for hosting this investigation.

I represent DAWN, Development Alternatives with Women for a New Era, a network of researchers and activists from the global South, which hosts the Feminists for a People's Vaccine campaign. The FPV campaign works with 27 feminist civil society organizations for equitable access to COVID-19 diagnostics, vaccines and therapeutics.

This submission argues in favour of immediately and unconditionally extending the WTO TRIPS Decision adopted on June 17th, 2022, to COVID-19 therapeutics and diagnostics.

As a global alliance of feminist CSOs, we have witnessed and received several reports from the ground of the deleterious effects of COVID-19. Specifically its impacts on decades of grassroots mobilization, health campaigning and the rights of women in the global South, that work at the intersections of social markers like **race, ethnicity, class, caste, migrant status, sexual orientation and gender identity**. Many studies show that the brunt of the pandemic is being borne by them. They also happen to be a majority of care workers, health professionals, and informal workers at the frontlines during the pandemic. And now, they continue to be the most affected by the economic crises.

Voluntary licenses, which the pharmaceutical industry claims to facilitate access, are totally inadequate to address the needs of the Latin American region and other developing countries. I speak from Latin America, a region that continues to feel the devastating effects of COVID-19 exacerbated by a lack of timely access to affordable diagnostics and therapeutics.

Let me paint a picture for you of what the pandemic looks like on the ground. COVID-19 is unpredictable and it has changed its contours. But we cannot say COVID-19 is over. Even with vaccination coverage, there still remain many unvaccinated. And even among those vaccinated, diagnostics and therapeutics are a critical need. People with comorbidities, the immunosuppressed and the elderly require testing and treatment to

prevent cases from escalating to severe morbidities and mortalities. Therapeutics are also proven to be effective in treating long COVID. Ideally, they should be affordable, available and accessible to everyone without discrimination, as it happens in the United States, your country.

In Brazil, where I come from, we have seen 37.2 million cases so far, the highest in Latin America. COVID deaths have reached the 700,000 mark. In the last three weeks alone, cases and deaths of Severe Acute Respiratory Syndrome across all states of the country are rising. Of this, 48% of the cases and 83.3% of deaths are attributed to COVID-19. The most affected are children, the elderly population and those with comorbidities. But these numbers are still underreported. Brazil performed 296,000 rapid COVID antigen tests per million as of December, 2022 and ranked 28 out of the 30 countries most impacted by COVID. But this is just Brazil, COVID is affecting Latin America in waves and testing and treatment gaps are seen across the region.

Our Ministry of Health, in March last year, issued an emergency authorization for paxlovid. They were able to purchase 50,000 treatment courses, which arrived only 7 months later. They were inadequate to serve the needs of a universal health care policy. Now, since November 2022, Paxlovid is also available in the private sector for an exorbitant price of USD 700 to almost USD 900, which is unaffordable. The availability and use of these few therapeutics are uneven.

Another example is the drug baracitinib. Even after approval, the drug is only available in private health care at an unaffordable price of USD 900. Remdesivir, another important therapeutic for COVID, could not be available in the public health system because the cost to the public exchequer would have been over USD 5 billion over the next 5 years. This scenario repeats itself or is even worse across Latin America, a region with one of the highest COVID excess mortality rates.

Universal access to COVID-19 diagnostics and therapeutics are key links to complement vaccination. The TRIPS Decision on June 17th divorced vaccination from diagnostics and therapeutics. By doing so, it jeopardized an integrated public health approach of prevention, testing and treatment for a deadly virus that is mutating.

Our ask is for an extension of the TRIPS decision for the production of life-saving diagnostics and therapeutics for COVID-19. The need of the hour is to advance a public health perspective.

Thank you!

Rajnia de Vito Nunes Rodrigues

Associate of the Feminists for a People's Vaccine Campaign

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Oral Statement by the Working Group on Intellectual Property (GTPI)

I would like to thank the US International Trade Commission for hosting this investigation.

I, Susana van der Ploeg, speak on behalf of the Working Group on Intellectual Property (GTPI) coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA), based in Rio de Janeiro, Brazil. We are a non-profit research and advocacy organization, that brings together civil society organizations, social movements and experts related to the issue of intellectual property and access to medicines in Brazil.

The impact of the pandemic in Brazil has been devastating. In the last week, we reached the mark of seven hundred thousand deaths from COVID-19, but a study by the Federal University of Minas Gerais estimates that this number is underreported by 18%. The virus is still killing people. In the last week, 330 (three hundred thirty) deaths were recorded. Covid is among the top five leading causes of death in Brazil. So we still need to focus on prevention, diagnosis and treatment.

The pandemic has exposed and exacerbated many pre-existing inequalities. The unequal distribution of resources, medical facilities, and access to COVID-19 vaccines, diagnostics, and treatments has resulted in a disproportionate impact on people in developing countries. This can be seen as a form of systemic racism and discrimination. Certain countries and transnational corporations have the power to decide whose life is worth saving.

To address this inequality, there needs to be a coordinated global effort to ensure equitable access to health technologies, including treatments, and diagnostic tools. The availability and affordability of antivirals for the treatment of COVID-19 is a major concern for us. While antivirals like monulpiravir have been shown to be effective in reducing the severity of COVID-19 and improving outcomes for patients, their high cost means that they are not accessible to everyone. In Brazil, where the minimum wage is currently around USD247 (two hundred and forty seven dollars) per month, the cost of monulpiravir at USD324 (three hundred twenty-four dollars) in pharmacies is prohibitive.

Paxlovid, an antiviral medication produced by Pfizer, is now being sold in Brazilian pharmacy chains at a price that is four times higher than the minimum wage. The exorbitant prices charged by pharmaceutical corporations is an obstacle to the access of essential medication.

Compulsory licensing can be an important tool for ensuring access to essential medicines and other health technologies, particularly in cases where intellectual property rights prevent their widespread distribution. It can be used to increase the availability of these products, particularly in cases where they are not affordable or accessible to large segments of the population. Developed countries such as the US have used compulsory licensing (CL) for various purposes, including addressing COVID-related access needs.

We don't need charity, we need equity. And we advocate that the use of voluntary licensing is not an effective strategy for promoting access to medicines, for it is an anti-competitive strategy, and we also highlight that there is no voluntary licensing in Brazil. For instance the agreements signed between the MPP and 35 (thirty-five) manufacturers to produce and supply paxlovid are insufficient, the deal excludes millions of people in developing countries, most Latin American countries, including Brazil, are left out. While a company in Brazil, for example, that signed this agreement will be able to produce the medicine for export, it will not be able to supply Brazil itself to meet local needs.

If the compulsory license offers the possibility of royalties, why are companies interested in the voluntary license? The answer is simple: they don't want competition. They argue that intellectual property is a mechanism to guarantee investments in research and development, but compulsory licensing is a valid mechanism provided in the TRIPS Agreement that ensures financial return to companies.

For all that's been said and shown, we urge the U.S. government to support the global effort to ensure equitable access to health technologies. Our ask is for an extension of the TRIPS decision for the production of life-saving diagnostics and therapeutics for COVID-19.

Susana van der Ploeg
Coordinator of the Working Group on Intellectual Property (GTPI)

Joint post-hearing submission

In this post-hearing submission, Development Alternatives with Women for a New Era (DAWN), represented by Rajnia Rodrigues, and the Brazilian Interdisciplinary AIDS Association (ABIA), represented by Susana van der Ploeg, are collaborating to give the Commission further information on questions that were raised during the US ITC public hearing investigation number 332-596, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*, held between 29-30th April, 2023.

This post-hearing brief focuses on the Brazilian case as a good example to understand two main issues:

> One, the intellectual property regime is the key reason for a lack of availability, affordability and accessibility of essential drugs, particularly in the context of the COVID-19 pandemic, violating the right to health;
>
> Two, the manufacturing capacity and/or the last mile delivery of diagnostics and therapeutics is NOT the reason for people's lack of access to tests (diagnostics) or treatments (therapeutics). As the Brazilian case demonstrates, a primary barrier is the intellectual property regime.

We make a strong case here for the need to extend the June 2022 TRIPS Decision for the production of life-saving diagnostics and therapeutics for COVID-19, and demonstrate the importance of compulsory license with examples from Brazil during the HIV/AIDS pandemic. Aided with data and background information, we will also show that Brazil's universal healthcare system with services for all, and domestic manufacturing capacity, ensures last-mile delivery.

Brazil: a background

Brazil's Federal Constitution guarantees universal access to health care (UHC) and treatment with 9.1% of GDP spent on healthcare. The Unified Healthcare System (SUS), which delivers comprehensive, equitable and free health care across a country with 'continental' dimensions serves 70% of its 21.6 million population, providing free treatment for chronic diseases and national vaccination programs for the elderly and children. 63% of the country's 6,642 hospitals are private.

After Brazil recognised patents for medicines in 1997, granting the patent holder market monopoly, it resulted in higher prices for drugs that were unaffordable for the government which has a limited healthcare budget. When a drug is under patent, the patent holder has a monopoly on the production, import and sale of the drug, which means that prices can be set at a level that maximizes profits. This way, a critical public health goal of making essential medicines affordable and accessible is compromised. This has led to higher prices for many drugs.

Brazil has a large and diverse population, a well-established healthcare system, and experienced researchers and clinical trial centres. In many cases, the country has been chosen by several pharmaceutical companies as a location for clinical trials of new drugs, vaccines, and treatments. Brazilian public laboratories have joined forces with international institutions to develop and test vaccines and drugs to combat the COVID-19 pandemic, with universities playing a crucial role in research and development for diagnostic kits, drugs, and vaccines. This has contributed to the advancement of medical knowledge and the development of new drugs by pharmaceutical companies, without a concomitant benefit-sharing with Brazil. Despite its participation in Research & Development which has aided the pharmaceutical companies to develop vaccines and drugs, access challenges continue for Brazil, as therapeutics are not readily available at affordable prices.

TRIPS flexibilities and compulsory license (CL): Brazil's fight against the HIV/AIDS pandemic

Compulsory license (CL) refers to a mechanism that allows a government to license the use of a patented medicine to a third party without the consent of the patent holder. However, the patent holder continues to have a right over the patent, including the right to be paid adequate remuneration for the generic version of the products made under CL. Compulsory license ensures that essential medicines are available at affordable prices in a timely manner, especially in developing countries. Countries, however, are free to determine the grounds for granting CL, including what constitutes a national emergency or public interest. This proposition is considered a flexibility and is under Article 31 of the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), which can be invoked to protect and realize the right to health.

CL is a very critical and necessary tool that can address inequality and injustices perpetrated by pharma companies and their use of patents on drugs and monopolies for production, import and sale. Companies set prices to maximize profits and their profit strategies can exploit and worsen human despair. When commercial imperatives of pharma companies harm public health and the public interest of a country, governments have an obligation to respond and be accountable to their people by using CL. The enormous benefits of compulsory licensing to the world's larger well-being and health

agenda cannot be minimised. CL is a part of the patent regime that balances public rights and private privileges. It is a win-win for both - countries that issue CLs and pharma companies who are entitled to adequate remuneration. The ethical imperative and political relevance of CL are based on a recognition that affordable access to medicines is an integral part of the right to health. Any patent regime that undermines CLs goes against these rights and results in negative health implications.

In Brazil, the story of affordable and accessible patented antiretrovirals (ARVs) for HIV/AIDS is a story of governments using CLs to increase the reach and access to these life-saving drugs. Supported and enabled by the 2001 UN Declaration of Commitment on HIV/AIDS, which recognized that access to medicines was a fundamental element for achieving the right to health, the Declaration called for the use of all available legal means, including compulsory licensing, to increase access to essential medicines. Here, we elaborate on how Brazil succeeded in making the drug efavirenz a part of a first-line treatment for HIV by issuing a compulsory license.

In 2001, Brazil's Ministry of Health was able to negotiate price reductions of 40 to 70% for drugs nelfinavir and efavirenz, which were held under patent by companies Roche and Merck, respectively. **The Ministry's bargaining position was strengthened by Brazil's existing pharmaceutical manufacturing capacity**. Farmanguinhos, the government's main drug producer, had the ability to produce several antiretrovirals at a low cost and to realistically estimate the production costs for the drugs in question. This capacity was critical in conveying to Roche and Merck that Brazil was serious about using CL, a public health option that is well-documented to be resisted by patent-holding pharmaceutical companies. Before the grant of the CL, the Brazilian government attempted to negotiate a price reduction with Merck. The government noted that Merck was selling efavirenz at cheaper prices, in countries at the same development level, with fewer people in need of treatment than Brazil. Indian generic versions were cheaper than Merck's product. In negotiations, Merck offered a price reduction from US$ 1.59 to US$ 1.10 per dose, which was deemed unsatisfactory by the Brazilian government given the scale of the population in need.

In May 2007, Brazil granted a compulsory license for efavirenz, which was patented by Merck Sharp & Dohme under the so-called pipeline mechanism. **The license covered importing generic versions from India at a third of the price offered by Merck.** The Brazilian Ministry of Health reported estimated savings until 2012 of US$ 237 million. Farmanguinhos, the official pharmaceutical laboratory of the Oswaldo Cruz research Foundation (Fiocruz) produced the first batch of efavirenz in January 2009 at 45% of the price set by Merck before the CL. Farmanguinhos performed its own research activities to reverse engineer the product, and to import small quantities of efavirenz from India. A preliminary injunction filed by Merck to stop the importation was rejected by the Brazilian Court. Brazil thereby surmounted significant challenges that

developing countries regularly face. These included pressures from trading partners and pharmaceutical corporations who threaten countries with trade sanctions and legal actions for attempting to use CL as a life-saving strategy.

The fight against AIDS and the global commitment to increasing access to essential medicines underlined the critical role of compulsory licenses in preventing undue suffering and saving millions of lives while enabling countries to save financial resources. **There is no evidence to suggest that innovation and** Merck's investments in the development of new HIV/AIDS drugs have been hindered as a result of compulsory licensing for efavirenz in Brazil. It is worth noting that Merck continues to innovate and invest in research and development of new drugs to treat HIV/AIDS and Brazil continues to be a market for Merck's products.

Meanwhile, Merck, GileadSciences, and GlaxoSmithKline (GSK) continue to be among the major players in the market for HIV/AIDS treatments and have sold therapies that generate billions of dollars in revenue, with global sales of antiretroviral drugs estimated to exceed US$26 billion annually. It is clear that the pharmaceutical industry's narrative is guided by an attempt to use the TRIPS Agreement solely as an instrument for maximizing private gains and disregarding the commitments to defend the public interest built into the agreement. **However, we cannot allow interpretations of the TRIPS provisions that go against public health.**

Brazil's manufacturing capacity and last-mile delivery

"Real access issues lie in the lack of manufacturing capacity, delay in drug approval and last-mile delivery in developing countries" - a false proposition

In Brazil, there are a number of existing infrastructures for the development, manufacture and for last-mile delivery of health services for COVID-19 vaccines, therapeutics and diagnostics. As one of the largest pharmaceutical markets in Latin America, both multinational and local companies operate in the country. The Brazilian Association of the Pharmaceutical Industry (ABIFINA), reports that around 550 pharmaceutical industries in the country produce a wide range of drugs - from generic medicines to more complex ones such as biologics. These industries are capable of producing a variety of active pharmaceutical ingredients (APIs) and have the capacity to manufacture finished pharmaceutical products.
In addition, Brazil has a strong tradition of vaccine production. The Brazilian National Immunization Program (NIP) is recognized as one of the most comprehensive and effective immunization programs among emerging countries and is comparable to those of developed countries. It was a pioneer in the introduction of the rotavirus vaccine in 2007 and of pneumococcus 10-valent conjugate vaccine and meningococcal C conjugate vaccine in 2010. **These vaccines—and the almost-universal vaccination against**

influenza pandemic H1N1 in 2009—indicate the technical and operational capacity of the NIP and the Ministry of Health. In 2012, the NIP introduced inactivated polio vaccine, hepatitis A vaccine, and tetravalent MMR+ varicella vaccine. National public producers supply more than 90% of the vaccines purchased by the NIP. **This outcome is due to the successful strategies conceived and implemented by the National Vaccine Self-Sufficiency Program[1].**

Brazil provides universal vaccination free of charge for all. It covers wide swathes of the population targeting children, adolescents, the elderly, and indigenous populations. All states of Brazil have established special clinics for the immunization of persons at special risk; specifically those with immunodeficiencies. Some of the clinics that serve marginalized and indigenous populations are located in difficult-to-reach terrains which Brazil has overcome ensuring last-mile delivery. Brazil's capacity to deliver rides on a wide-network of health infrastructure and solid health system buttressed in the Unified Healthcare System, the SUS. It also provides access to most of the vaccines available in the international market. This policy has resulted in the successful global eradication of smallpox and in the elimination of autochthonous cases of polio, measles, and rubella in the country.

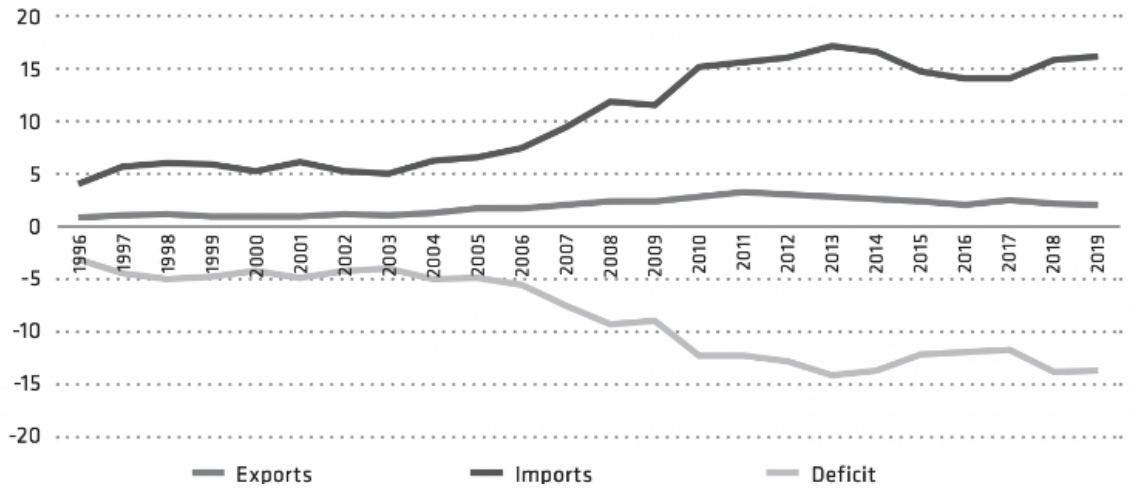
Brazil's robust technical capacity was originally built on complex technologies through technology transfer arrangements. This has led to the development of COVID-19 vaccines by Brazilian biomedical research institutions Fiocruz and Butantan. As of January 27, 2023, Brazil administered over 540 million COVID-19 vaccines, between first, second and booster doses[2]. A strong technical capacity for therapeutics as we discussed earlier, can strengthen both Brazil's needs as well other developing countries with inadequate or no manufacturing capacity. Therefore, the immediate extension of the June 2022 TRIPS Decision to therapeutics and diagnostics is crucial.

The main bottlenecks are rooted in structural asymmetries that lead to Brazil becoming a net importer of intensive technology products. The commitment to universal access to health care in Brazil generates a demand that exceeds the available productive and technological capacity and budget expenditure. After expanding access to health care and medicines in the last 30 years, Brazil has experienced an increase in imports and growing trade deficits due to external dependence. This can be traced to the international dynamics of a patent regime that condemn countries to a state of dependence by excluding and restricting their domestic manufacturing capacity to serve national health needs The Covid-19 pandemic crisis exposed these contradictions starkly. (See Figure 1)

1- *Homma, A., Tanuri, A., Duarte, A. J., Marques, E., de Almeida, A., Martins, R., Silva-Junior, J. B., & Possas, C. (2013). Vaccine research, development, and innovation in Brazil: a translational science perspective. Vaccine, 31 Suppl 2, B54–B60.* https://www.sciencedirect.com/science/article/pii/S0264410X12017355?via%3Dihub

2- https://especiais.g1.globo.com/bemestar/vacina/2021/mapa-brasil-vacina-covid/

Figure 1 | Brazil's health trade balance (1996-2019) - in billions



Source: Gadelha et al (2021)[3]

Further, the arguments that attribute issues of access to the delays by Brazil's regulatory agencies' approvals and other bureaucratic procedures are unfounded. Law 14.006, approved in as early as 2020, authorized the Brazilian government to import and distribute COVID-19 vaccines, medicines and medical supplies that had been approved by foreign health authorities, notably the US Food and Drug Administration (FDA), among others. The law required the national drug regulatory agency ANVISA to observe a deadline of 72 hours to approve them under an emergency use approval procedure. These emergency approval was also seen across other countries of the Latin American region and the world.

Despite the capacity for research, development and distribution of medicines and vaccines that Brazil (and other developing countries) demonstrate, there is a growing trend of inequalities deepening between countries. Developed countries have concentrated their efforts on more advanced technologies and platforms that have higher prices. This either increases or maintains the technological and trade disparity between developed and developing countries.

Brazil's case amply demonstrates that patent regimes that are out of balance, misused or abused, deepen inequality of access to diagnostics and therapeutics. Using WTO's TRIPS flexibilities, like compulsory licenses, allows countries with manufacturing capacities such as Brazil to circumvent anti-health cumbersome intellectual property regimes, while not short-changing pharma companies. Further, with a strong healthcare infrastructure and a network of SUS services, Brazil demonstrates ways and means to bridge the last-mile delivery with access to health for all.

3- *Gadelha CAG, Kamia FD, Moreira JDD, Montenegro KBM, Safatle LP, Nascimento MAC. Dinâmica global, impasses do SUS e o CEIS como saída estruturante da crise. Cadernos do Desenvolvimento 2021; 16:281-302.* [online]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