2023

TRIPS investigation (332-596)

Technical Report

Technical Report on the Expansion of TRIPS Waiver for COVID-19 Medicines and Tests. Report Submitted to the United States International Trade Commission.

Prof. Dr. Vladimir Fernades Maciel
Prof. Ms. Allan Augusto Gallo Antonio

May. 2023 — Washington, DC

Investigation Number (332-596)

TRIPS investigation

The Brazilian perspective on the TRIPS Waiver Expansion for COVID-19 Drugs and Testing:

Lessons learned from past experiences, current data on reality and possible suggestions for solving the problem.

Prof. Vladimir Fernandes Maciel

Prof. Allan Augusto Gallo Antonio

Mackenzie Center for Economic Freedom, Sao Paulo, Brazil.
It does NOT contains Confidential Business Information (CBI)

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

To the Secretary Barton,

U.S. International Trade Commission,

500 E Street SW, Washington, DC 20436.

The Brazilian perspective on the TRIPS Waiver Expansion for COVID-19 Drugs and Testing: Lessons learned from past experiences, current data on reality and possible suggestions for solving the problem.

- In May 2021, the United States, India, and South Africa proposed a waiver on certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to enable countries to produce generic versions of COVID-19 vaccines, treatments, and diagnostics

- In February 2023, the US International Trade Commission formally announced the opening of its investigation into the benefits of an expansion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) exemption.

- The United States International Trade Commission has requested investigations and research into how an expansion of the TRIPS exemption would affect the market for COVID-19 diagnostics and treatments.

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

- The outcome of the investigation will play a key role in shaping the US position on the matter at the WTO and will likely have a decisive impact on the final outcome of the multilateral negotiations themselves.

- As Brazil is among the top 10 economies in the world and one of the countries that most vaccinated people in absolute numbers, it is believed that the Brazilian experience with compulsory licensing in the past can provide elements for decision-making on which is the best way to proceed.

- Compulsory licensing in Brazil has been slow to produce new medicines, with locally produced medicines more expensive than those manufactured elsewhere.

- The main problems with access to COVID-19 technologies in Brazil are related to healthcare infrastructure, including a lack of testing.

- A TRIPS waiver expansion would undermine R&D for future pandemics and would not make Brazil any more capable of dealing with pandemics.

Some context

The COVID-19 pandemic has created a situation where access to vaccines, diagnostics, and treatments is crucial to contain and prevent the spread of the virus. The issue of intellectual property

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

(IP) rights for COVID-19 vaccines and treatments has been a topic of discussion, particularly in low and middle-income countries.

Proponents of the waiver argue that we are replaying the HIV pandemic in 2000s, with companies withholding Covid IP rights for profit. This is not accurate. There has been a totally different approach from biopharmaceutical companies, often competitors, who dropped many projects in the early stages of the pandemic to collaborate on R&D and share IP for vaccine R&D. Later on, Covid treatments have been made rapidly available to low and middle-income countries at minimal royalties through mechanisms such as the Medicines Patent Pool.

The issue of IP rights for COVID-19 vaccines and treatments has nevertheless been a topic of debate at the international level. According to WTO (2023), in May 2021, the United States, India, and South Africa proposed a waiver on certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to enable countries to produce generic versions of COVID-19 vaccines, treatments, and diagnostics. The proponents of the waiver argue that it is necessary to ensure access to vaccines and treatments for all, particularly in low and middle-income countries. However, opponents of the waiver argue that it will not address the root cause of the problem and may have negative consequences in the long term (ZAMAN, 2022).

It is argued that the current situation is not like the HIV pandemic in the 2000s. In the case of COVID-19, companies have dropped everything to collaborate on research and development (R&D) and share IP for vaccine R&D. For instance, Pfizer and BioNTech partnered with Chinese company Fosun Pharma to develop and distribute their vaccine in China. Similarly, AstraZeneca partnered

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

with the Serum Institute of India to produce its vaccine. Furthermore, COVID-19 treatments have been made rapidly available to low and middle-income countries at minimal royalties through mechanisms such as the Medicines Patent Pool. The Medicines Patent Pool is an UN-backed organization that negotiates with pharmaceutical companies to license their patents and share their IP for certain drugs and treatments in low and middle-income countries. This has enabled the rapid production and distribution of COVID-19 treatments to these countries (WHO, 2022).

It is difficult to make a specific comparison between the numbers of the HIV pandemic in 2000 and the COVID pandemic because they are two different diseases with different transmission rates, severity, and impact on society. However, we can look at some data to get an idea of the scale of each pandemic.

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), the global number of people living with HIV in 2000 was approximately 36.1 million, with 3 million new infections and 2.4 million AIDS-related deaths. In comparison, as of March 2023, there have been over 445 million confirmed cases of COVID-19 worldwide, with over 6 million deaths reported.

It's important to note that the HIV pandemic has been ongoing for decades, while the COVID pandemic is more recent. Additionally, the availability of effective treatments for HIV has improved significantly since the early 2000s, whereas effective treatments for COVID-19 are more recent..

Therefore, since the scale of the COVID pandemic is larger in terms of the number of confirmed cases and deaths. It took a much greater effort from the pharmaceutical industry to contain

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

the harm caused by this pandemic. In this sense, it is important to remember that the pharmaceutical industries faced an important tradeoff, especially with regard to opportunity costs, insecurity and uncertainties inherent in the period of the COVID-19 pandemic.

Brazil's experience with compulsory licensing

The proposed TRIPS waiver aims to temporarily suspend some of the intellectual property (IP) protections under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to facilitate access to COVID-19 vaccines, treatments, and diagnostics. However, the experience of Brazil with compulsory licensing for efavirenz suggests that the effectiveness of a TRIPS waiver in facilitating access to essential medicines may be limited (MARQUES, GUIMARÃES AND STEMBERG, 2005).

In 2007, Brazil issued a compulsory license for efavirenz, which was then patented by Merck, a pharmaceutical company. The license was granted to a Brazilian company, Farmanguinhos, with the aim of reducing the cost of treatment for HIV patients in the country. However, the license was not immediately fulfilled by Farmanguinhos due to the complex technology involved in the production of the drug, which required transfer of technology from Merck. The transfer of technology took two years to process, and when it was eventually fulfilled, the generic products were provided by an Indian company, Hetero Labs, rather than a Brazilian one (RODRIGUES AND SOLER, 2009). Compulsory licensing, in this case, did not lead to rapid access to treatments, necessary in a pandemic situation.

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

Ramani and Urias (Ramani & Urias, 2018) compare the prices of Efavirenz 600mg produced in Brazil after a compulsory licensing in 2007 to the lowest international price of a generic equivalent. They show that, in 2009, when the local production of Efavirenz started, this medicine was 2.6 times more expensive than the cheapest generic version. In 2013, this difference climbed to 6.3. Therefore, from a public health perspective, the local procurement strategy after compulsory licensing issuance was not the most favourable to enabling price reduction.

The experience of Brazil with compulsory licensing for efavirenz also suggests that the real problem is not IP, but the ability of healthcare systems to deliver treatments. Although the compulsory license was issued to reduce the cost of treatment for HIV patients, the drug was not immediately available due to the complex production process and lack of local manufacturing capacity. This highlights the need for investment in healthcare systems to ensure that patients can access the treatments they need, regardless of the cost or the availability of IP protection.

Brazil's experience with compulsory licensing for efavirenz provides important insights into the challenges associated with this mechanism and its potential implications for the proposed TRIPS waiver. One of the key challenges associated with compulsory licensing is the ability of local manufacturers to produce the patented products (CORREA, 2012). As such, investment in healthcare systems is crucial for ensuring that patients can access the treatments they need, regardless of IP protection or licensing arrangements (GERVAIS, 2018).

The economic impact and the implicit social cost

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

Compulsory licensing and TRIPS Waiver Expansion may distort the market in a few ways. Firstly, by allowing the government to issue licenses for the production of patented products, the government effectively takes away the exclusive right of the patent holder to sell their product in the market.

This may discourage further investment in research and development of new products, as companies may be hesitant to invest heavily in R&D if their products can be easily copied and sold by competitors. In essence, compulsory licensing and TRIPS Waiver Expansion can create an environment where patent holders are disincentivized from investing in research and development, while governments and generic manufacturers have access to their products without having to pay market prices. This can lead to a reduction in innovation and a slower pace of scientific progress, which can ultimately harm consumers and the economy as a whole.

COVID-19 and Brazil

The COVID-19 pandemic has exposed the weaknesses and challenges of healthcare systems around the world. The issue of access to treatments, vaccines, and diagnostics has been one of the biggest challenges, particularly in low and middle-income countries. While the debate around intellectual property (IP) rights for COVID-19 treatments and vaccines continues, the real problem lies in the ability of healthcare systems to deliver these treatments to those in need.

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

In the case of Brazil, the country has been severely impacted by the COVID-19 pandemic, with a high number of cases and fatalities. The healthcare system has struggled to cope with the surge in cases. While Brazil has made progress in developing and manufacturing vaccines, there have been challenges in delivering them to the population (OLIVEIRA ANDRADE, VIEIRA-MEYER AND FERNANDES, 2020).

One of the key challenges in Brazil has been the lack of adequate testing and contact tracing. Testing has been limited, particularly in rural and remote areas, and the delay in getting test results has hindered efforts to control the spread of the virus. Additionally, the healthcare system has been underfunded and understaffed, which has impacted its ability to provide adequate care to COVID-19 patients (BARRETO ET AL. 2021).

According to the Coronavirus Panel of the Brazilian Ministry of Health, since the beginning of the pandemic until March 7, 2023, 168.964.410 COVID-19 tests have been carried out in the country. It is important to note that this count includes all types of tests (PCR, antigen, serology, etc.) and that some cases may have been tested more than once.This may sound like a high number, but it is important to note that testing rates vary widely across the country.

At the beginning of the pandemic, Brazil faced significant shortages of essential medical supplies, including testing kits and personal protective equipment (PPE), due in part to global supply chain disruptions. This led to delays in testing and a backlog of cases, which in turn hindered efforts to contain the spread of the virus.

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

As mentioned, a second major problem has been the lack of a coordinated national strategy for testing and contact tracing. While some states and cities have implemented their own testing and tracing programs, there has been little coordination or standardization across the country. This has made it difficult to track the spread of the virus and to identify and isolate infected individuals. According to data from the Brazilian Ministry of Health, as of March 2023, the country has only managed to trace the contacts of approximately 25% of confirmed cases. This is significantly lower than the recommended level of at least 80% set by the World Health Organization (WHO).

The lack of access to treatments and vaccines has also been a major issue in Brazil. The government has been criticized for its slow response to procure vaccines and treatments, which has exacerbated the situation.

While the debate around IP rights for COVID-19 treatments and vaccines continues, it is clear that the real problem is the ability of healthcare systems to deliver these treatments to those in need. In the case of Brazil, the challenges in testing, healthcare infrastructure, and procurement have hindered the country's ability to respond effectively to the pandemic.

What should Brazil do?

The debate over the TRIPS waiver has led to discussions on the impact of IP rights on the development of the vaccine and medicine industry in countries like Brazil. Some argue that compulsory licensing and abrogation of property rights will not help in the long-term development of a sustainable industry. Instead, technology transfer through collaboration and investment, which requires IP rights, is believed to be the key.

Market Line (2023) says that Brazil has a significant pharmaceutical industry, but it is largely focused on generic drugs rather than innovative treatments. The TRIPS waiver has been proposed as

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

a way to address the lack of access to COVID-19 treatments and vaccines in low and middle-income countries, including Brazil. However, the waiver will not incentivize innovation and could lead to a decrease in investment in research and development.

In order to address the lack of access to treatments and vaccines, it is important to strike a balance between IP rights and access. The TRIPS waiver is only a temporary solution to address the immediate needs of the pandemic. In the long-term, collaboration and investment in research and development are key to building a sustainable industry.

In addition to the economic cost to pharmaceutical companies, the TRIPS waiver will have a perverse effect that will distort market incentives for innovation.

Brazil has already shown potential for innovation in the pharmaceutical industry through partnerships with international organizations and investments in research and development. For example, the country has been involved in the development of a COVID-19 vaccine, the Butantan Institute's CoronaVac, which has been approved for emergency use by the World Health Organization. The government has also invested in the construction of a new production facility for vaccines and biologicals.

Another viable path is to reduce the tax burden not only on medication and COVID tests, but on its entire production chain. Although the federal government may occasionally reduce taxes on the final product, rarely is there a deeper discussion at the state level and the cascading effect of taxes on the productive sector.

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br

References

BARRETO ML, BARROS AJD, CARVALHO MS, ET AL. The COVID-19 pandemic in Brazil: challenges and responses. **The Lancet**. 2021; 397(10278): 10227-2237.

CORREA, C. (2012). **Implications of the Doha Declaration on the TRIPS Agreement and Public Health**. World Health Organization.

GERVAIS, D. (2018). **The TRIPS Agreement: Drafting History and Analysis**. 4th ed. Sweet & Maxwell.

MARKET LINE (2023) **MarketLine Industry Profile: Pharmaceuticals in Brazil**. Pharmaceuticals Industry Profile: Brazil, 1–42.

MARQUES, U. R. Q., GUIMARÃES, V. S., & STERNBERG, C. (2005). Brazil's AIDS controversy: antiretroviral drugs, breaking patents, and compulsory licensing. **Food and Drug Law Journal**, 60(3), 471–477.

MINISTÉRIO DA SAÚDE DO BRASIL. (2023). **Painel Coronavírus.** Retrieved March 2023, from https://covid.saude.gov.br/

NOGUEIRA, TATIANA SIQUEIRA ET AL. **Licenciamento compulsório e acesso ao tratamento do HIV/AIDS no Brasil**. 2013. Tese de Doutorado.

OLIVEIRA ANDRADE R, VIEIRA-MEYER APGF, FERNANDES AC. Health systems' response to the COVID-19 pandemic in Brazil: impacts and challenges. **Ciência & Saúde Coletiva**. 2020; 25(suppl 2): 4573-4584.

Ramani SV, Urias E, 2018,"When access to drugs meets catch-up: Insights from the use of CL threats to improve access to ARV drugs in Brazil", *Research Policy,* 2018, Oct; 47(8): 1538–1552, doi: 10.1016/j.respol.2018.05.008

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/**● e-mail: liberdade.economica@mackenzie.br

RODRIGUES, W. C. V., & SOLER, O. (2009). Compulsory licensing of efavirenz in Brazil in 2007: contextualization. **Pan American Journal of Public Health**, 26(6), 553–559. https://doi.org/10.1590/s1020-49892009001200012

WORLD HEALTH ORGANIZATION (WHO) (2022). COVID-19 technology licensing agreement. **Bulletin of the World Health Organization**, 100(6), 360. https://doi.org/10.2471/BLT.22.010622

WORLD HEALTH ORGANIZATION. (2020). **Contact tracing in the context of COVID-19: interim guidance. Retrieved March 2023**, from https://www.who.int/publications/i/item/contact-tracing-in-the-context-of-covid-19-interim-guidance

WORLD TRADE ORGANIZATION (WTO) (2023). **Waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19**. Accessed on April 1st, 2023. Available at https://www.wto.org/english/tratop_e/trips_e/wavering_IP_e.htm.

ZAMAN, K. (2022). The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence. **European Journal of Risk Regulation**, 13(2), 295–310. https://doi.org/10.1017/err.2021.60

Centro Mackenzie de Liberdade Econômica (CMLE)
Rua Itambé, 135 – Prédio 12 - ● *Higienópolis* ● *São Paulo - SP* ● *CEP 01302-907*
Tel.: + 55 (11) 2766-7034 ● **https://www.mackenzie.br/liberdade-economica/** ● e-mail: liberdade.economica@mackenzie.br