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Submission of written comments regarding the Special 301 investigation on Brazil's Acts, Policies, and Practices

Docket ID: [USTR-2025-0043](#)

The Working Group on Intellectual Property (GTPI/REBRIP) and the Brazilian Interdisciplinary AIDS Association (ABIA) respectfully submit the following written comments regarding the Special 301 investigation into Brazil's acts, policies, and practices.

The Working Group on Intellectual Property (GTPI/REBRIP) and the Brazilian Interdisciplinary AIDS Association (ABIA) are Brazilian civil society organizations committed to defending the right to health. ABIA, founded in 1987, is a longstanding observatory of policies related to HIV/AIDS and has coordinated the GTPI since 2003. The GTPI brings together organizations and experts from diverse fields to advocate for access to medicines as a human right and to monitor the intersections between trade agreements and intellectual property rules.

We are participating in the Special 301 process because we are deeply concerned about the impact that heightened intellectual property regimes and inflated medicine prices—imposed on developing countries by the United States Trade Representative (USTR)—will have on access to affordable generic medicines within Brazil's Unified Health System (SUS), as well as on the country's public health sovereignty and capacity for local production.

We believe it is a collective responsibility to ensure that scientific and technological advances benefit everyone—especially the most vulnerable—and do not contribute to preventable deaths or worsen ongoing humanitarian and medical crises. In this context, we have observed the harmful effects of intellectual property (IP), particularly pharmaceutical patents and data exclusivity, on access to life-saving medicines.

We have been working for over two decades documenting and analyzing the impact of intellectual property (IP) on public health in Brazil, particularly concerning the Unified Health System (SUS) and the sustainability of its universal access program for medicines across a wide range of diseases.

Our experience includes observing the health crisis during the COVID-19 pandemic, which led the United States to issue compulsory licenses as a response to the emergency. An initial review by the [Knowledge Ecology International \(KEI\) of 62 COVID-19 related contracts revealed that 59 included authorizations for non-voluntary use of third-party patents under U.S. law \(28 USC 1498\)](#)¹. This legal mechanism allowed the U.S. government to bypass exclusive patent rights for critical countermeasures, such as vaccines, drugs, and diagnostics, without prior negotiation with patent holders, with compensation provided afterward if applicable.

This example highlights how, even in times of crisis, IP regimes can be flexibly managed to prioritize public health, contrasting sharply with the restrictive and

¹ <https://www.keionline.org/37987>



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monopolistic IP practices that often hinder access to medicines in developing countries like Brazil.

This example highlights how, in times of health crisis, IP regimes can be flexibly managed to prioritize public health, contrasting sharply with the restrictive and monopolistic IP practices that often hinder access to medicines in developing countries like Brazil. However, the United States has historically used its significant economic and geopolitical influence to restrict the use of TRIPS flexibilities by other countries, including Brazil and other developing nations.

Despite the flexibilities built into the TRIPS Agreement—such as compulsory licensing and parallel imports—the U.S. government often pressures countries through mechanisms like the Special 301 process and bilateral trade agreements to limit or avoid the use of these safeguards. This coercive approach undermines the ability of sovereign nations to respond effectively to public health emergencies and hinders equitable access to affordable medicines.

It is well documented that monopoly-driven incentives harm the biomedical research and development ecosystem by failing to address less profitable diseases, disregarding public health criteria, limiting the competition necessary for affordable products, and compromising the efficient use of scientific and financial resources. These are political, legal, and commercial barriers that hinder the production, distribution, and access to affordable and appropriate medicines, vaccines, and diagnostics, while also inhibiting patient-driven medical innovation.

The U.S. Trade Representative (USTR) has aggressively pushed for stronger intellectual property (IP) standards on pharmaceuticals—often exceeding the requirements of the WTO's TRIPS Agreement—without adequately considering the negative impacts on medicine access, the right to health, and biomedical innovation. This pressure undermines the legal flexibilities established by TRIPS and reaffirmed by the Doha Declaration, which aim to protect public health.

Through tools like the Special 301 Report and trade agreements, the USTR has consistently pressured countries to adopt measures such as extended patent terms, patent linkage, and data exclusivity, while restricting public participation in patent oppositions and limiting the use of compulsory licenses. These actions delay generic competition, keep medicine prices high, and strain public health programs, especially in developing countries with limited healthcare funding.

In this context, we submit our contribution to the USTR Special 301 investigation of Brazil, emphasizing the need to respect countries' rights to implement TRIPS public health safeguards and balance commercial interests with the fundamental right to life and health.

The Special 301 investigation alleges that Brazil's policies and practices fail to provide adequate and effective intellectual property (IP) protection and enforcement. It seeks information on how these actions may discriminate against or disadvantage American



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workers and businesses connected to the U.S. innovation and creative sectors, as well as other related IP protection measures that could unfairly impact U.S. interests.²

Over the years, the U.S. Trade Representative (USTR) has consistently pressured Brazil through its annual Special 301 Report, challenging Brazil's legitimate public health measures within international law. Notably, Brazil's National Sanitary Regulatory Agency (ANVISA) previously played a crucial role in reviewing the patentability of new biopharmaceuticals—a key safeguard praised for protecting the public health system by preventing low-quality patents on essential medicines. However, this provision is no longer in force. The U.S. government has also pushed for measures that undermine the autonomy of Brazil's Patent Office (INPI) and pressured Brazil to adopt TRIPS-plus provisions—such as data exclusivity, patent term extensions, and patent linkage—that exceed WTO TRIPS obligations and restrict Brazil's policy space to protect the right to health. Importantly, the TRIPS Agreement states that countries are not obliged to implement protections beyond its requirements (Article 1.1).

The USTR's investigation highlights concerns about the average pendency of biopharmaceutical patent applications in Brazil and its effect on patent terms. A patent office's core role is to grant or reject patents based on national laws aligned with international standards.

The USTR's investigation raises concerns about the average pendency of biopharmaceutical patent applications in Brazil and its impact on patent terms. The core role of Brazil's patent office is to rigorously grant or reject patents based on national laws aligned with international standards, a process that must ensure quality given the growing volume and complexity of applications. GTPI/Rebrip/ABIA supports strict examination standards to prevent low-quality patents that restrict competition and access to health products.

Attempts to weaken Brazil's patent examination and thus trivialize the granting of undeserved patents threaten national sovereignty and fundamental rights such as the right to life and health. Pressures to speed up examination times, even at the expense of quality, undermine these rights. Alleged delays often result from strategic actions by patent applicants and do not harm monopolistic interests, which effectively enjoy market exclusivity throughout the application process under Brazilian law (Art. 44, LPI). Therefore, the current duration INPI takes to make decisions does not violate applicants' rights nor generate legal claims.

Moreover, close observation of the delaying tactics used by large multinational conglomerates—the main patent applicants in Brazil—reveals that calls for faster

² OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE [Docket No. USTR–2025–0043] Initiation of Section 301 Investigation: Brazil's Acts, Policies, and Practices Related to Digital Trade and Electronic Payment Services; Unfair, Preferential Tariffs; Anti-Corruption Enforcement; Intellectual Property Protection; Ethanol Market Access; and Illegal Deforestation; Hearing; and Request for Public Comments. July 18, 2015. Available at <https://www.govinfo.gov/content/pkg/FR-2025-07-18/pdf/2025-13498.pdf>.



patent examination serve primarily to dismantle INPI's technical rigor and promote the indiscriminate granting of inappropriate patents.

Furthermore, there is no correlation between reducing INPI's processing time or increasing the number of patents granted and higher innovation rates, stronger legal certainty, increased foreign investment, or industrial growth. Given the surge of frivolous patents and the spread of evergreening practices, the number of patents granted is not an indicator of inventiveness or innovation—especially in developing countries like Brazil, where most patent applications come from large corporations based in wealthy nations.

It should also be noted that Brazil's patent office has sought to accelerate patent examinations through modernization, automation, and participation in Patent Prosecution Highway (PPH) programs, which fast-track patents already filed with partner offices. Brazil entered a PPH program with the US Patent and Trademark Office (USPTO) in 2016 and joined the Global Patent Prosecution Highway (GPPH) in 2024. However, these PPH initiatives go beyond Brazil's international obligations and risk further compromising the quality of patent examination by encouraging reliance on decisions from other offices without fully considering Brazil's specific public health and legal context. This can lead to the accelerated granting of inappropriate patents, undermining national sovereignty and public interest protections.

The WTO TRIPS Agreement mandates a patent term of 20 years from the filing date (Article 33) but does not require any extensions. Brazil's Industrial Property Act aligns with this, granting 20 years for invention patents and 15 for utility models (Article 40). Previously, Brazil allowed patent term extensions for delays in patent granting, guaranteeing 10 years from the grant date, but this provision was ruled unconstitutional by the Brazilian Supreme Court in 2021. The U.S. should respect Brazil's sovereignty and court decisions and cease pressuring for patent term extensions.

A study by the Federal University of Rio de Janeiro (UFRJ), coordinated by Professor Julia Paranhos, quantified the financial harm that patent term extensions cause to Brazil's public health system (SUS). Analyzing nine high-cost medicines purchased by SUS, the study found that if Brazil's unique patent extension provision were eliminated, SUS could save between R\$ 1.1 billion and R\$ 3.8 billion. The research showed that from 683 patents granted between 1997 and 2018, over 92% received term extensions. These extensions delay generic and biosimilar competition, keeping prices artificially high. For the nine medicines studied, some generics available internationally cost up to 99% less than what Brazil's Ministry of Health pays.

The study projected savings for SUS under different price reduction scenarios, with the most conservative estimate indicating R\$ 1.1 billion in avoidable costs and the most optimistic scenario reaching R\$ 3.8 billion. To contextualize, SUS's logistics department spent about R\$ 10 billion on medicines from 2014 to 2018, meaning the savings from eliminating patent term extensions could supply medicines for almost a full additional year. This evidence highlights the substantial economic damage that



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patent term extensions cause to Brazil's public health system, undermining access to affordable medicines.³

Brazil remains on the USTR Special 301 Watch List partly due to alleged insufficient protection against unfair commercial use and unauthorized disclosure of test data required for pharmaceutical marketing approval. While Brazil's law criminalizes unfair use of such data in line with WTO TRIPS Article 39.3, it does not grant exclusive rights or "data exclusivity," which the USTR pressures countries to adopt.

Data exclusivity, a TRIPS-plus measure, prevents regulatory agencies from relying on originator test data to approve generics, delaying their market entry—even for off-patent medicines. This forces generic producers to repeat costly and ethically questionable clinical trials or wait for exclusivity to expire. The requirement to repeat clinical trials due to data exclusivity raises serious ethical concerns. Repeating studies already conducted by the original drug manufacturer unnecessarily exposes patients to risks without added scientific benefit, violating ethical principles such as those outlined in the World Medical Association's Declaration of Helsinki. This duplication not only wastes resources but also compromises patient safety and delays access to affordable generic medicines, making the practice both ethically unjustifiable and practically harmful to public health.

These barriers increase generic drug costs, discourage registration, and limit access to affordable medicines.

For all these reasons, GTPI/Rebrip strongly urges the USTR to immediately halt the Special 301 investigation against Brazil. The USTR must stop using this process as a tool to pressure developing countries into adopting IP rules that exceed international obligations, including harmful TRIPS-plus measures like data exclusivity and patent term extensions.

Commercial and trade mechanisms must not be weaponized for political agendas or used as leverage in bilateral disputes. Brazil's response to these unfounded accusations should be to strengthen, not weaken, public health protections—starting with suspending patents that burden the SUS and its people.

Rio de Janeiro, August 18, 2025.

Susana van der Ploeg
Coordinator, GTPI

³ Paranhos, Julia et al. O custo da extensão da vigência de patentes de medicamentos para o Sistema Único de Saúde. *Cadernos de Saúde Pública* 2020; 36(11):e00169719 doi: 10.1590/0102-311x00169719