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Public Citizen 2025 Special 301 Review Post-Hearing Comment

Re: 2025 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing

February 26, 2025

Thank you for the opportunity to submit post-hearing comments on the 2025 Special 301 Review. We would like to take this opportunity to reiterate three key points from our testimony and provide fuller answers to the panel's questions.

I. Health security is national security.

Biosecurity is an articulated priority for the White House. The President's recent Executive Order on the World Health Organization includes a focus on the U.S. biosecurity chain of command,[1] and a credentialed leader has been appointed to the White House office of pandemic preparedness in Gerald Parker.[2]

The United States benefits from a trade agenda that allows trading partners to adapt quickly and in locally effective ways to pandemics to stop their spread. In our view, that means refraining from using U.S. power to deter countries from finding the most expeditious and workable solution to access to medical countermeasures, including for example, locally manufacturing or importing needed tests, treatments or vaccines.

Notably, nearly half of the more than one million U.S. COVID deaths were due to variants. Many of these may have been preventable, including through more rapid and equitable access to medical tools abroad helping curb variant development and transmission.[3]

II. Raising drug prices abroad does nothing to lower them at home.

Treatment rationing due to high prices is a daily reality in the U.S and developing countries.[4] The U.S. and most foreign governments recognize that expansive patent monopolies facilitate manufacturers' high prices. Congress, federal agencies and states, like many U.S. trading partners, are reexamining how to protect health under intellectual property regimes.

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[1] https://www.whitehouse.gov/presidential-actions/2025/01/withdrawing-the-united-states-from-the-worldhealth-organization/

[2] https://www.cbsnews.com/news/trump-head-pandemic-office-gerald-parker/

[3] Jo Walker et al., One Million and Counting: *Estimates of Deaths in the United States from Ancestral SARS-CoV-2 and Variants* (June 22, 2022), https://www.medrxiv.org/content/10.1101/2022.05.31.22275835v1.

[4] KFF, Public Opinion on Prescription Drugs and Their Prices (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ (finding that 82% of adults in the U.S. consider the cost of prescription drugs is unreasonable and about three in ten report not taking their medicines as prescribed because of the cost).

There is no reason to believe that Americans will pay less for medicine if the U.S. government pressures other countries into paying more. Drug corporations are working to maximize revenue in every market, just like any business. A key difference for new pharmaceuticals is that patents insulate them from competition. That allows drug companies to charge Americans and people abroad very high prices, decoupled from research and development costs.

When the U.S. government criticizes developing countries' TRIPS-compliant policies, it deters health-protective practices from taking root. In our view, this practice is inappropriate, and increasingly out of line with U.S. national policy.

III. Progress. Let's not unmake it.

There has been meaningful progress in the Special 301 Report, including increasing recognition of countries' sovereign decisions regarding health and the public interest. We appreciate this progress and reiterate the importance of respecting the rule of law, our trade commitments, and access to medicine all at the same time.

Public Citizen has provided support to countries endeavoring to use TRIPS flexibilities, including compulsory licensing under Article 31.

In February, Colombia began importing the lifesaving first-line HIV treatment dolutegravir, to expand access including for Venezuelan refugees and migrants. It is purchasing the regimen through the Pan American Health Organization, which already provides generic dolutegravir to most of Latin America under a voluntary license with the manufacturer ViiV. However, Colombia was excluded from that license territory.

Public Citizen has supported this process. The government explored the issue at length, over a period lasting more than a year, publishing more than one report and offering several opportunities for public comment and administrative appeal – considerably more due process than is required by TRIPS. Drugmakers challenged the proposal not only administratively and in national courts, but also at the Andean Community's regional intellectual property tribunal.

Colombia's Article 31 government use (or compulsory licensing) of an HIV drug for urgent need exemplifies precisely the original use case for TRIPS flexibilities. Freedom to protect public health in this manner was a core part of the bargain between wealthy and developing countries that allowed the TRIPS Agreement to pass into being. If, after exclusion from a voluntary license and giving exhaustive due process, Colombia is not free to issue a compulsory license without scrutiny for possible trade sanctions through the Special 301 Report, then the guarantees of TRIPS and U.S. commitments to respect them would appear to be not meaningful.

During the 2025 Special 301 Review public hearing, agency representatives asked three questions about our comments. We paraphrase those questions and answer in greater detail below.

Question one: Do you agree countries must follow procedural policies in TRIPS before issuing compulsory licenses?

Yes. Countries are bound by the procedural requirements of TRIPS Article 31 before issuing compulsory licenses. Article 31 details the steps that must be taken by members considering a compulsory license. These include, under particular circumstances, efforts to obtain authorization by the right holder,

notification of the right holder, adequate remuneration and judicial review, among others. These procedural safeguards were carefully negotiated.

It is inappropriate for the Special 301 Report to seek additional procedural requirements, or to allege a process problem without reference to one of these Article 31 conditions. It would be appropriate for the Special 301 Report to carefully consider TRIPS standards before criticizing a country's policy choices and if it nonetheless decides to include such a criticism, it should clearly articulate an alleged breach of these standards.

Question two: On pages 3-4 of your testimony, you ask that the 301 Committee limit its scope to instances of criminal infringement. Can you clarify your position on whether non-criminal or civil violations of law are appropriate subject matter for Special 301 citation?

The TRIPS Agreement helpfully distinguishes between civil and criminal intellectual property infringements. We believe the latter to be more appropriate for Special 301 attention.

Instead of insisting on policy changes that many believe would harm health and access to medicines, a more appropriate use of Special 301 would be to criticize lax or uneven enforcement of rule of law. Willful trademark counterfeiting and copyright piracy on a commercial scale fall under this category.

It is possible that civil infringement could be so widespread as to amount to a total lack of enforcement, such that they too could implicate the rule of law issues posed by criminal violations and become a reasonable subject for comment in the Special 301 Report.

However, we think it is inappropriate for the Special 301 Report to comment on government policy decisions where a stakeholder interest must be weighed against the public interest, especially when those decisions protect public health. Countries have the sovereign right to balance public interests within the scope of their international obligations, whether that balancing takes place through the judicial branch or through legislative or executive measures. The Special 301 Report should not be used to criticize the valid policy decisions of other countries, including when that policy is the result of civil court decisions.

Question three: The 2024 Special 301 Report found that pharmaceutical patent examination in Brazil takes 9 years; nearly half the patent term. Can you respond to other stakeholder concerns about length of delay being cause for concern?

Variance in review periods is a normal part of patent examination. Indeed, U.S. patent terms already were extended from 17 to 20 years concomitantly with the adoption of the TRIPS Agreement in 1995 in order to accommodate precisely this concern from drugmakers. Extending patent terms beyond that 20-year period due to perceived delays in examination represents a windfall for drugmakers, legislatively, financially and against the public interest in timely access to affordable generics.

We agree that patent offices worldwide should be fully funded and staffed so that examination can proceed efficiently. However, USTR should ensure that it does not seek the adoption of patent term adjustments for patent office or other administrative delays, which are not required under the TRIPS Agreement.

Patent term adjustments can significantly delay market entry of generic medicines and restrict access to affordable treatments. In 2021, the Brazilian Supreme Court ruled a provision of Brazil's Industrial Property Law granting a minimum patent term unconstitutional, citing in its deliberations the right to health and access to medicine.[5] Importantly, the provision of patent terms in Brazil remains TRIPS compliant, providing a 20-year term of protection from the date of filing.

An additional option to promote efficient pharmaceutical patent examination, in addition to staffing and funding patent offices, may be to issue guidance on pharmaceutical patents to examiners. Argentina maintains this practice, however, the Special 301 Report had criticized it for doing so until last year.

[5] *See*, https://www.southcentre.int/wp-content/uploads/2021/06/PB-94-1.pdf