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Ms. Jennifer Thornton
General Counsel
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Re: 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, 90 Fed. Reg. 34069 (July 18, 2025)

Dear Ms. Thornton:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following submission in response to the request for comments regarding an investigation initiated pursuant to section 302(b)(1)(A) of the Trade Act of 1974, as amended (the Trade Act), to determine whether acts, policies and practices of the Government of Brazil related to intellectual property protection, among other measures, are actionable under section 301(b)(1) of the Trade Act ("Request for Comments"). This timely investigation appropriately focuses on longstanding unfair and discriminatory trade practices in Brazil that have disadvantaged U.S. biopharmaceutical companies for decades and have unreasonably restricted U.S. commerce. It is a critical step toward leveling the playing field and defending American innovation.

PhRMA member companies are devoted to inventing, manufacturing and distributing valuable therapeutics and vaccines that enable people to live longer, healthier and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports high-paying, high-standard and diverse jobs in all 50 states. The U.S. biopharmaceutical industry supports over 4.9 million jobs across the economy, including more than one million direct jobs, and contributes more than $1.65 trillion in economic output on an annual basis.[1] Our sector also continues to be one of the most research-intensive, manufacturing-intensive and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new

[1] TEConomy Partners, "The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates," May 2024, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/D-F/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

medicines.[2] In 2023, U.S. biopharmaceutical goods exports exceeded $101 billion,[3] making the sector the largest exporter of goods among the most R&D-intensive industries.[4]

Innovators and investors in this critical sector depend on strong intellectual property protection and enforcement, health care systems that reward the value of innovation and fair and transparent access to overseas markets. With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new therapeutics and vaccines to patients around the world.

The submission below identifies specific acts, policies and practices in Brazil that are "unreasonable or discriminatory and burden[] or restrict[] U.S. commerce," and thus actionable under section 301(b)(1) of the Trade Act. In particular, Brazil fails to adequately and effectively protect the intellectual property of American innovative biopharmaceutical companies. Brazilian law explicitly omits regulatory data protection (RDP) for biopharmaceutical products despite providing RDP for veterinary, fertilizer and agrochemical products. Further, Brazil is a global outlier regarding its persistently long patent examination backlog, which nearly halves biopharmaceutical patent terms and undermines the innovation cycle intended by patent protection. This situation was worsened by the Brazilian Supreme Court's 2021 decision to eliminate legal provisions that guaranteed a minimum 10-year patent term to compensate, in part, for the country's extensive patent office delays. Last, Brazil imposes tariffs averaging 6.8 percent on pharmaceutical products, compared to 0.2 percent in the United States.

Each of these practices denies fair and equitable opportunities for American biopharmaceutical innovators to introduce their products in the Brazilian market and are not reciprocal to the opportunities afforded to Brazilian innovators in the United States. As such, they meet the definition of unreasonable acts, policies and practices under section 301(d) of the Trade Act. In turn, each of these practices undermine the ability of American biopharmaceutical innovators to compete fairly in the Brazilian market, thereby restricting U.S. commerce.

As the U.S. Trade Representative initiates consultations with Brazil regarding the issues implicated in the investigation, PhRMA urges sustained U.S. government engagement to pursue a durable negotiated resolution to these longstanding issues. PhRMA also urges the Brazilian government to prioritize these negotiations over retaliatory measures, specifically those outlined in Law No. 15.122/2025. That law, published in Brazil's Official Gazette on April 15, 2025, permits Brazil to suspend intellectual property rights—including patents, trademarks and copyrights—in response to any tariffs. These retaliatory measures would impair patient health outcomes by reducing access to innovative treatments, stifle both domestic and foreign investment and deepen trade tensions.

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[2] Research!America, "U.S. Investments in Medical and Health Research and Development, 2016-2020," January 2022, available at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf.

[3] U.S. Bureau of Economic Analysis, International Accounts Products for Detailed Goods Trade Data, available at https://www.bea.gov/international/detailed-trade-data.

[4] ndp analytics analysis of National Science Foundation and Business Research and Development Survey data, 2024.

Resolving Brazil's failure to adequately and effectively protect the intellectual property of American innovative biopharmaceutical companies through negotiations would help create a policy environment that will result in increased innovative product launches in Brazil and, in turn, increased exports of the latest generation of U.S. medicines. Indeed, U.S. biopharmaceutical companies have been important partners in advancing Brazil's public health outcomes by investing in clinical trials, supporting technology transfer, engaging in public-private collaborations and contributing to skilled employment and scientific capacity building.

To this end, PhRMA identifies below pragmatic solutions that it urges both the U.S. and Brazilian governments to adopt as part of a binding agreement resulting from this investigation. The proposed solutions address systemic, longstanding and structural challenges facing U.S. innovators in Brazil. They do not capture other unfair and nonreciprocal trade practices, such as compulsory licensing and the weakening of intellectual property protections in trade agreements, that continue to affect patent holders operating in the Brazilian market. PhRMA's forthcoming submission to inform the 2026 National Trade Estimate Report will include a comprehensive summary of ongoing and developing concerns in Brazil.

Key Issues of Concern:

Lack of Biopharmaceutical Regulatory Data Protection (RDP): Consistent with U.S. law and international rules, it is critical that Brazil provide RDP for the confidential data that biopharmaceutical innovators must submit to Brazil's Health Regulatory Agency (ANVISA) to demonstrate the safety and efficacy of a medicine for marketing approval. RDP must protect against both disclosure of test data and, for a reasonable term, unfair commercial use (e.g., third-party reliance on the data). Further, RDP should be available for both small and biologic molecules, and should be granted based on the date of marketing approval in Brazil.

Brazilian Law (10.603/02) provides RDP only to "veterinary pharmaceutical products, fertilizers, bioinputs and pesticides …." The explicit omission of human-use pharmaceutical products creates a discriminatory policy inconsistent with U.S. and international practices. It provides a windfall to third-party entities by enabling improper reliance on an innovator's confidential test data to accelerate marketing approval for competing products without undertaking equivalent research and development expenditures. A recent analysis found that if Brazil introduces RDP for human-use pharmaceutical products, the number of innovative medicines available in the country could increase by 34 to 39 percent (equivalent to approximately 570 additional new treatments) and the number of clinical trials could more than double in the Brazilian market.[5]

Patent Backlog That Halves Biopharmaceutical Patent Terms: Patent backlogs in Brazil directly reduce the value of granted patents and negatively impact the launch of new medicines. The issue is especially significant for U.S. innovators, who file the largest proportion

[5] Copenhagen Economics, "Regulatory Data Protection for Pharmaceuticals in Brazil: How Adopting Regulatory Data Protection Will Impact Patients, Industry, and Brazilian Society," September 2023, available at https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil_092023.pdf.

(approximately 30 percent) of patent applications in Brazil.[6] While complementary initiatives, including expanding the Patent Prosecution Highway, hiring additional personnel and appropriately funding the National Institute of Industrial Property, are important to combat the patent backlog, Brazil must establish a patent term adjustment (PTA) mechanism to compensate for the unreasonable delays in the Brazilian patent examination process.

As highlighted in the Request for Comments, Brazil's patent examination backlog is particularly egregious for biopharmaceutical innovators. According to a recent analysis, the average patent examination timeline for biopharmaceutical patents granted from January 2020 through November 2024 in Brazil was 9.5 years. It is critical for Brazil to establish a PTA mechanism to ensure that innovators are not harmed by undue delays in Brazil's patent examination process. Indeed, Brazil stands in stark contrast to many countries in the region which provide PTA, including Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua.

The need for PTA in Brazil is even more acute following the Brazilian Supreme Court's 2021 decision eliminating the sole paragraph of Article 40 of the Patent Law, which provided a minimum patent term across all sectors to offset Brazil's egregious patent office examination delays. Even worse, the Supreme Court applied its holding retroactively to biopharmaceutical and other health-sector innovator patents – and their patents alone – eliminating overnight thousands of patents and raising significant discrimination concerns.

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PhRMA appreciates the U.S. government's investigation into Brazil's intellectual property and innovation practices, especially regarding the lack of RDP for biopharmaceuticals and the absence of mechanisms to mitigate the excessive patent backlog (i.e., PTA). The discriminatory application of the Supreme Court's Article 40 decision, along with the lack of RDP for biopharmaceutical products, highlights the ongoing discriminatory treatment that biopharmaceutical innovators face in Brazil. Accordingly, we support the Administration's ongoing efforts to ensure that U.S. companies are being treated fairly and that U.S. intellectual property is not being devalued overseas. We look forward to working with the U.S. and Brazilian governments to ensure a binding agreement is reached between the two governments, consistent with Section 301(c)(1)(D) of the Trade Act, to resolve the concerns raised in this submission.

Sincerely,

Ernest Kawka
Deputy Vice President, International

[6] World Intellectual Property Office, Intellectual property statistical country profile 2023 – Brazil, available at https://www.wipo.int/edocs/statistics-country-profile/en/br.pdf.