

September 10, 2025

**PUBLIC DOCUMENT**  
USTR-2025-0043

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

**Re: Post-hearing Comments: 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) submits these post-hearing comments pursuant to the above-referenced Section 301 investigation and the public hearing held on September 3, 2025. Our comments relate solely to the investigation's focus on intellectual property protection in Brazil.

These comments are intended to elaborate on the responses provided during the hearing to the questions posed by the Section 301 Committee and add further context and evidence to the record. As in our original comments, they focus on two longstanding, systemic and discriminatory intellectual property barriers in Brazil that burden or restrict U.S. commerce and harm biopharmaceutical innovation.

### **Lack of Regulatory Data Protection (RDP) for Biopharmaceuticals**

As noted by the Special 301 committee during the hearing, studies have demonstrated the broad benefits that accrue to countries that implement RDP for biopharmaceuticals. For example, in 2023, Copenhagen Economics (CE) analyzed the potential impact of introducing regulatory data protection (RDP) in Brazil.<sup>1</sup> CE's findings, along with the research methodology used, are included in the study.

Modeling data from 53 markets, CE projects that if Brazil introduces RDP for biopharmaceuticals, the number of innovative medicines available in the country could increase by 34 to 39 percent. Additionally, for each innovative medicine introduced, approximately three generic or biosimilar medicines are expected to follow. The report also concludes that the number of clinical trials in Brazil could more than double, resulting in a significant boost in foreign direct investment.

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<sup>1</sup> Copenhagen Economics (2023), Regulatory Data Protection for Pharmaceuticals: How adopting regulatory data protection will impact patients, industry, and Brazilian society, available at [https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil\\_092023.pdf](https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil_092023.pdf).

## Excessive Patent Backlog for Biopharmaceuticals

PhRMA and its members appreciate Brazil's efforts to address the patent backlog through its participation in Patent Prosecution Highway programs and the National Intellectual Property Strategy. However, these efforts—ongoing for over ten years—are subject to unpredictable institutional resourcing. Therefore, we urge the United States Trade Representative to work with its Brazilian counterparts to establish a patent term adjustment (PTA) mechanism in Brazil. PTA mechanisms are not subject to institutional constraints and provide certainty to all patent applicants that they will be compensated for examination delays that are not their fault, preventing unjust losses of exclusivity.

During the public hearing, we noted that the average examination timeline for biopharmaceutical patents granted between January 2020 and November 2024 was 9.5 years. A breakdown of the data, including the methodology used, is provided below:

| YEAR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | NUMBER OF BIOPHARMACEUTICAL PATENTS GRANTED | AVERAGE PATENT PENDENCY (IN YEARS) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|------------------------------------|
| 2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2,020                                       | 10.45                              |
| 2021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2,542                                       | 10                                 |
| 2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 2,374                                       | 9.03                               |
| 2023                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1,929                                       | 8.23                               |
| 2024 (to Nov. 19, 2024)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1,053                                       | 7.52                               |
| Combined                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 9,918                                       | 9.52                               |
| <b>RESEARCH METHODOLOGY</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                             |                                    |
| <p>Osha Bergman Watanabe &amp; Burton LLP began its analysis by identifying the relevant patent classification codes that cover broadly biopharmaceutical inventions, including small molecule and biologic medicines.</p> <p>Generally, Osha found that the relevant classes for biopharmaceutical inventions fall within classification codes A61K or A61P. While some of such inventions are also classified under chapter C, they found that the C classification is a parallel classification that would also bring in a large number of inventions outside of biopharmaceuticals. Thus, they restricted their patent application search to classification codes A61K and A61P. More specifically, they ran the following Boolean search to identify both biopharmaceutical patents granted and patents pending: a61k9* or a61k31* or a61k35* or a61k36* or a61k38* or a61k39* or a61k41* or a61k45* or a61k47* or a61k48* or a61k49* or a61k50* or a61k51* or a61p1* or a61p3* or a61p5* or a61p7* or a61p9* or a61p11* or a61p13* or a61p15* or a61p17* or a61p19* or a61p21* or a61p23* or a61p25* or a61p27* or a61p29* or a61p31* or a61p33* or a61p35* or a61p37* or a61p39* or a61p39* or a61p41* or a61p43*</p> |                                             |                                    |

PhRMA appreciates the U.S. government's attention to the absence of RDP for biopharmaceuticals in Brazil, as well as the ongoing concern regarding the lack of PTA to compensate innovators for undue delays in the patent examination process. We look forward to engaging with both the U.S.

and Brazilian governments to help achieve a resolution that addresses the concerns outlined in our comments.

Sincerely,

A handwritten signature in blue ink, appearing to read 'E. Kawka', with a stylized, cursive script.

Ernest Kawka  
Deputy Vice President, International