

Mr. Daniel Lee

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600 17th Street NW
Washington, DC 20508

Re: 2024 Special 301 Review
Docket No. USTR–2023–0014

January 30, 2024

On behalf of the Brazilian Intellectual Property Association (ABPI), we appreciate this opportunity to provide written comments to the United States Trade Representative (USTR) as part of its 2024 Special 301 Review to identify countries that deny adequate, effective protection of intellectual property rights (IPR) or deny fair and equitable market access to U.S. persons who rely on intellectual property (IP) protection.

ABPI is a not-for-profit, non-governmental organization, created in 1963 in order to represent, in Brazil, the oldest and largest international organization dedicated to the strengthening of protection and harmonization of intellectual property law worldwide, AIPPI - the International Association for the Protection of Intellectual Property, founded in 1893. ABPI has a strong advocacy role, and we also regularly cooperate with the USPTO and the U.S. Embassy and Consulates in Brazil. Recently, on August 2023, we welcomed in our annual conference Ms. Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (USPTO).

Here are the ABPI written comments, which are as detailed as possible.

Brazil continues to have a very effective legal system to guarantee IP protection and enforcement.

Pirated content and counterfeit goods keep being highly monitored by the Brazilian authorities, who have launched a major offensive against these illegal practices, determined to protect intellectual property (IP) owners and foster a fair and innovative environment. Their efforts result in significant reductions in pirated goods and have strengthened enforcement mechanisms.

Several effective enforcement campaigns against online piracy have been in force for the past years. Cybernetic Authorities have been actively working in close cooperation with national and international authorities to combat illicit streaming devices (ISDs) and piracy. A great example of successful operations in this field are “Operação 404” launched in 2019 and coordinated by the Ministry of Justice and Public Security’s Cybernetic Operations Lab (Ciberlab). Such initiative is aligned with the objectives and guidelines of the National Intellectual Property Strategy, established by the Ministry of Development, Industry, Trade and Services (MDIC), which aims to promote greater security for the intellectual property environment in Brazil.

Coordinated raids in São Paulo and other municipalities have yielded massive hauls of counterfeit goods, with frequent seizures reportedly exceeding tons and totaling hundreds of millions in value. This sustained

crackdown is a potent signal of the Brazilian authorities' active fight against counterfeiting and their dedication to enforcing brand owners' rights across the country.

The Brazilian Judiciary plays a crucial role in protecting and enforcing Intellectual Property Rights in Brazil. Its independence empowers judges to take swift action to prevent IP violations, thanks in part to a highly effective preliminary injunction system. Brazilian judges regularly grant preliminary and permanent injunctions to safeguard IP owners, and often engage in chamber discussions with parties to delve deeper into claims and technicalities towards them. Recognizing the importance of specialized knowledge in IP matters, the judiciary has invested in training programs for judges and facilitated access to resources provided by IP associations like ABPI. This dedication to expertise is further strengthening the judiciary's ability to hear and adjudicate IP cases effectively.

In addition, the Brazilian Patent and Trademark Office (BPTO) carries an independent examination of patent applications and has rules establishing alternatives to expedite examination, such as fast-track examination and the Patent Prosecution Highway Program – PPH. Such priority proceedings are an initiative that contributes very effectively to a more rapid decision. Currently, the BPTO provides more than 20 types of priority proceedings to the applicants. From the moment priority processing is granted, a decision can be reached within less than 8 months, while in regular proceedings it would be reached in not less than 4 years.

Seeking legal certainty, the BPTO usually issues and updates its guidelines for examination, which are in line with many Patent Offices. Furthermore, the BPTO's board of appeals – i.e., the final instance in the procedures before the BPTO – annually issues a compendium of their decisions.

Brazil has recently taken significant steps to access the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. Draft bill 466/22, proposing the country's accession, is currently being considered by the Brazilian legislature and pending only a single processing phase in the Brazilian Chamber of Deputies. The Bill should be forwarded to the Senate for voting. Should Brazil become a member of the Treaty, local institutions can be nominated to become an International Depository Authority (IDA) under the Treaty, significantly reducing the burden on Brazilian companies and institutions that need to deposit biological material for compliance with sufficient disclosure requirements of patent applications in the field of Biotechnology.

In August 2023, the Hague Agreement on the international registration of industrial designs, which simplifies procedures and reduce costs for users of the system, has become effective in Brazil. Accession to the agreement was part of the government's strategic agenda to modernize the Brazilian IP system, which also led to the accession to the Madrid Protocol in 2019. Updated design examination guidelines were published in October 2023 with relevant and long-awaited changes, such as the acceptance of broken lines to disclaim elements or portions of the design.

- Continuing its commitment to robust intellectual property protection, Brazil can further refine its system by addressing the following areas: **Adequacy of the BPTO's internal rules on amendment of applications:** The BPTO has to review its internal rules restricting the applicants' rights to perform amendments during prosecution and file divisional applications. As opposed to the Brazilian IP Law, the BPTO's internal rules state that:

- ✓ BPTO’s Resolution No. 93/2013: it would not be possible to claim – not even in a divisional application – a subject matter not claimed when the examination was requested, even if it does not extend beyond the application’s content initially filed;
 - ✓ BPTO’s legal opinion No. 19/2023: the BPTO’s board of appellate patent examiners should not consider amended claims submitted with an administrative appeal, even if such claims narrow the scope of protection and overcome the grounds for refusal; and
 - ✓ Article 32 of BPTO’s normative instruction No. 30/2013: an applicant could not file a divisional after the rejection even if an administrative appeal against it was filed or the BPTO’s board of appellate patent examiners raises a lack of unity of invention objection.
- **Patent Term Adjustment (PTA):** Brazilian IP Law needs to be modernized to include a provision authorizing the BPTO to adjust a patent term in case the BPTO takes an unreasonable time to grant the patent;
 - **Data Package Exclusivity (DPE):** A crucial gap remains in Brazil's data protection framework: pharmaceutical products for humans lack explicit protection under a federal law. While Federal Law No. 10,603/2022 safeguards data for veterinary, fertilizer, and agrochemical products, this creates an inconsistency, raising concerns about potential discriminatory treatment. Contrary to TRIPS (Article 39), Brazil continues to allow government officials to grant marketing approval for pharmaceuticals to competitors relying on tests and other data submitted by innovators to prove the safety and efficacy of their products. Additional efforts are needed to provide certainty that test data and other data will be fully protected against unauthorized use to secure marketing approval for a fixed period; and
 - **BPTO’s Backlog:** As of 2018, the BPTO adopted measures to accelerate the examination, significantly decreasing the patent application backlog. However, in the last two years, the number of the BPTO’s 1st instance decisions on the merits – i.e., notice of allowance and rejections – decreased:

| Year | Number of decisions |
|------|---------------------|
| 2020 | 30,527 |
| 2021 | 34,237 |
| 2022 | 29,522 |
| 2023 | 21,765 |

We hope the information provided herein is able to demonstrate that Brazil is committed and actively adopting measures to protect and foster American innovation and creativity in our country.

The ABPI remains at your entire disposal for further collaboration with the USTR and other agencies to address critical IP concerns in Brazil.

Please feel free to contact us with questions or for additional information.

Thank you for your consideration.