

January 23rd, 2026

To
Mr. Daniel Lee
Assistant U.S. Trade Representative for Innovation and Intellectual Property
United States Trade Representative
600 17th Street NW
Washington, DC 20508 - U.S.A.

Ref.: Public Comments for 2026 Special 301 Submission – USTR-2025-0243

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 2026 Special 301 Review (USTR 2025 0243).

ABPI's intention is to provide an on-the-ground overview of certain aspects of Brazilian IP system that are of special interest to IP rightsholders understanding that comments made will better inform USTR in its following on decisions. We shall present information on what is being done successfully, but also what are areas ABPI believes to be room for improvement towards strengthening Brazilian IP.

Notwithstanding the room for improvements in Brazilian IP laws, it is necessary to highlight that the challenges that Brazil face are typical of a developing country and there is not any prejudice or bias against U.S. companies or interests. The shortcomings in IP protection that still exist in Brazil harm, first and foremost, Brazilian inventors and innovators. Thus, ABPI reiterates its plea, already presented in the previous years¹, that Brazil should be excluded from the 301 Watch List, as the reasons that triggered the inclusion of the country in such list, in 1999, are already long gone.

I. ABPI – A national Association for Intellectual Property

ABPI is a not-for-profit, non-governmental organization, created in 1963 to organize discussions and provide education of IP law and, more recently, it expanded its purpose to encompass advocacy for the improvement of the Brazilian IP system.

¹ <https://abpi.org.br/en/newsletter/abpi-advocates-for-brazils-removal-from-the-ustr-watch-list/>

ABPI currently has approximately 900 (nine hundred) members, amongst them national and international rightsholders, academia representatives and other IP professionals from different areas. It holds no affiliation with any state branch (neither from executive, Congress or judiciary) or party in Brazil, neither supports ideological or political views.

2026 marks the first year of a new board that shall run ABPI for the following 2-year mandate. Its executive committee has 9 members. The association also has 13 regional representatives, in half of Brazilian federative states, and an Advisory Board composed of 30 professionals complete the managing team that is voluntarily dedicated to making ABPI's goals alive².

ABPI's local activities are closely related to the debate and development of Brazilian IP system, being commonly the main entity that engage with different stakeholders from public and private sectors, as well as academia and civil society organizations. Amongst its routine activities, ABPI annually organizes the most representative IP Congress in Brazil, that receives 600 (six hundred) participants in average, both from Brazil and foreign countries. It also maintains 18 commissions that debate different matters of IP and, whenever convenient, generate submissions, comments and questionings to all sorts of initiatives such as bills of law, amendments to BPTO norms or amicus curiae petitions in relevant lawsuits. Furthermore, ABPI organizes and publishes a bimonthly IP Magazine available to its members.

Internationally, ABPI represents Brazil with the AIPPI - the International Association for the Protection of Intellectual Property, the oldest and largest organization dedicated to the strengthening of protection and harmonization of intellectual property law worldwide. Additionally, ABPI is the only Brazilian NGO that has a seat at WIPO – World Intellectual Property Organization, and as such can participate within all initiatives this Organization holds. With such international connections, ABPI exercises a strong advocacy role that regularly cooperate with the USPTO and the U.S. Representations in Brazil.

Bearing in mind its advocacy activities, ABPI presented public comments and joined the USTR public hearing related to investigations initiated into Brazil's acts, policies and practices related to different matters, including IP³. As one of the few Brazilian

² More information on ABPI New Board is available, in English, at <https://abpi.org.br/en/noticias-en/abpi-elects-new-board-for-2026-2027/>

³ As published in July 15 at <https://www.govinfo.gov/content/pkg/FR-2025-07-18/pdf/2025-13498.pdf>

entities engaged with the IP discussions, ABPI feels that it is within its purpose to continue proving USTR with such relevant information.

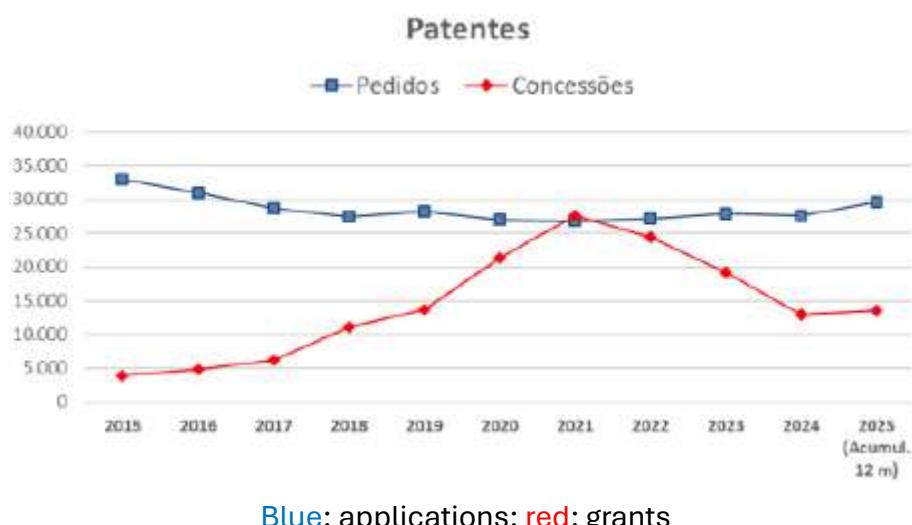
II. Comments on Brazilian Government acts and policies for IP

Since 2020, Brazil has a National Intellectual Property Strategy that administrated by GIPI, a group of different Ministries under the coordination of MDIC (Ministry for Development, Industry and Trade). Civil society organizations are also invited to join discussions and contribute to GIPI and ABPI is proud to be involved since the early days of this policy.

A national strategy orchestrated between various stakeholders is surely evidence of a more mature IP ecosystem.

III. Comments on patent backlog and lack of PTA Protection

As previously reported, in 2018 BPTO adopted measures to accelerate patent analysis, significantly decreasing patent application backlog. However, in the last few years, the number of the BPTO's decisions to grant or reject a patent decreased continuously. The preliminary 2025 IP statistics indicate a small increase number of patent fillings in relation to the previous year (29,557 in 2025, against 27,701 in 2024) but a continuing very low number of grants (13,624 in 2025, and 12,914 in 2024).



It is noteworthy that USA represents the greatest number of foreign patents filed accounting for 23.5% of all new filings, while China is the 2nd largest international originator with 10.5%.

Although measures are being undertaken⁴, ABPI is highly concerned that structural and priority issues, lack of adequate financing and infrastructure might pose a huge challenge to BPTO in keeping up results obtained in the past as well as addressing the relevant periods for patent examination, which are still high terms for some technological fields such as biotechnology and telecommunications.

Due to these concerns, ABPI stands favorably to the adoption of PTA mechanism in Brazil that could alleviate the burden patent holders suffer from insufficient acts from Government to mitigate patent backlog and ultimately deliver the 2-year term of examination that was declared as the objective by the current administration.

It is, however, important to stress that in ABPI's opinion, the desired 2-year term of examination should be counted from the moment that examination is requested by the applicant, and not from the filing date. The applicant always has the option to request examination jointly with the filing, but they should not be obliged to do so. The 18-month secrecy period of the application that exists in Brazil must continue to be an option for the application, as well as the 36-month from filing, for the applicant to request the beginning of the examination.

Furthermore, there should continue to be opportunities for the applicant to present amendments to patent applications, and the current rules for amendments must not be restricted solely to shorten prosecution times.

Another matter of concern is that Brazil lacks a system of PTA – patent term adjustment. Since the 2021 Supreme Court decision to eliminate article 40 sole paragraph that guaranteed minimum term of 10 years for patents in Brazil, patent holders have no judicial option to seek indemnification or adjustment to patent terms due to excessive patent analysis procedure. Only PTA mechanism provided institutionally could bring back the balance to Brazilian patent system, guaranteeing the adequate 20-year period of protection for a patent granted in the country.

⁴ Including expansion of Patent Prosecution Highway, hiring additional patent analysts as well as creating fast track options depending on the field of the invention (e.g. green patents).

Currently in Congress there are different Bills of Law that propose this agenda, by amending the Patent Law to include PTA mechanism. ABPI stands supportive of the proposal currently at the House of Representatives (Bill 5810/2025).

IV. Comments on future of IA regulation

In the end of 2024, Brazilian Senate approved Bill of Law 2338 that aims to regulate artificial intelligence. Since then, the House of Representatives has been analyzing and discussing this Bill within a special commission. During 2025, 31 meetings have been concluded, and more than 160 experts were invited to comment. Special public hearings focused on discussing Bill 2338 copyright provisions that establish the obligation for AI developers to obtain prior authorization and offer mandatory payment for authors so that protected works can be used in AI systems training.

It is worth remembering that Brazil was leading BRICS discussions that were concluded with a joint statement released last July that states that protecting IP rights is imperative⁵. It indicates that a balanced approach is necessary to protect IP and safeguard the public interest, emphasizing the need for adequate copyright protection against unauthorized use “in order to prevent abusive data extraction and privacy violations, while allowing mechanisms for fair remuneration”.

Intense debate is ongoing on this matter, with the organizations representing artistic sectors supporting current provisions. At the same time, ABPI feel that this level of copyright protection could harm AI development in Brazil as well as foreign investment within AI sector. Alternatives should be considered to obtain adequate balanced protection without harming full potential of AI development in the country.

V. Comments on Brazilian fight against piracy and counterfeited goods

Brazil has demonstrated consistent effort in fighting piracy and counterfeited goods. This is evident by the coordinated actions, policies and practices taken recently, after creation of National Council for Piracy Combat and the joint work of different enforcement agents, regulatory agencies, police departments and judiciary branches. It is not unusual to see the launch of major enforcement offensives

⁵ Full statement available in English at https://www.gov.br/mre/pt-br/canais_atendimento/imprensa/notas-a-imprensa/declaracao-dos-lideres-do-brics-sobre-governanca-global-da-inteligencia-artificial#english

against illegal practices, determined to protect intellectual property (IP) owners and foster a fair and innovative environment.

Recent good examples seen to tackle piracy are:

(A) **ADI 3/2025:** change by the Federal Revenue on its interpretation regarding the need of court decision to seize counterfeited goods within Brazilian boarders. The interpretative act issued last December concludes a long-standing demand from ABPI and eliminate different positioning from enforcement agents that will not request court decisions to prevent goods from being authorized into Brazil anymore.

(B) **404 operation:** coordinated by ANATEL (Brazilian Telecom Agency) and different police agencies last November, it removed 535 websites and 01 app from activity, issued 44 police search and seizure warrants and 7 imprisonment orders. The operation was coordinated with Argentina, Ecuador, Paraguay, Peru and the United Kingdom. 404 is the code denomination for initiatives designed by authorities to combat illicit streaming devices (ISDs) and websites, copyright infringement and online piracy⁶.

(C) **Slim operation:** coordinated by federal police with ANVISA (Brazilian Health Surveillance Agency). It targeted criminal activity in preparing, distributing and commercializing weigh-lost drugs, with focus on the ones with 'tirzepatide' compound, sold as 'irregular Mounjaro'. It comprehended 4 states in Brazil, issued 24 police search and seizure warrants and 01 doctor was arrested.

VI. Comments on lack of international harmonization

As known, Brazil does not present within its legal system adequate harmonization with the best practices when it comes to IP rights.

Amongst these gaps, ABPI finds especially problematic the lack of full protection for regulatory data protection (RDP). Contrary to products made to address veterinary purposes or agricultural products, pharmaceutical products for humans lack explicit protection under Federal Law No. 10,603/2022. This creates an inconsistency since all these products are subject to the same regulatory regime.

⁶ Further information as provided by the US Chamber of Commerce available here <https://www.uschamber.com/intellectual-property/how-operation-404-protects-brazils-creative-economy>

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.

Moreover, due to reported lengthy patent examination timelines, higher challenges are imposed for regulated products requiring marketing authorization to launch. For them, innovators face a structural dual challenge: the time required to generate studies and dossiers to satisfy regulatory requirements and the time required for its review. As patent applications are filed early to preserve novelty, these periods accrue while the patent term continues to run.

Brazil also lacks a supplementary protection certificate (SPC) to compensate for mandatory regulatory review. This absence may weaken investment in innovation-intensive sectors, including pharmaceuticals and agricultural technology. Due to that, ABPI supports consideration for adopting a reasonable framework that balances innovation incentives with competition. Ideally, such experience would benefit from safeguards consistent with international practice, including a maximum extension cap and linkage to the first marketing authorization.

We hope the information provided herein is useful in presenting a fair picture of these Brazilian IP matters. ABPI remains available for further collaboration to address critical IP concerns in Brazil.



Peter Eduardo Siemsen
President – ABPI