July 1, 2026

The Honorable Jamieson Greer
United States Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

Re: Comments of the Council for Innovation Promotion on the Proposed Action in the Section 301 Investigation of Brazil's Acts, Policies, and Practices Related to Intellectual Property Protection (Docket No. USTR-2026-0331)

Dear Ambassador Greer:

The Council for Innovation Promotion (C4IP) respectfully submits these comments in response to the United States Trade Representative's (USTR) determination that certain of Brazil's intellectual property practices are actionable under Section 301 of the Trade Act of 1974 and the accompanying request for comments on the proposed action.[1]

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP is chaired by two former directors of the U.S. Patent and Trademark Office (USPTO), Andrei Iancu and David Kappos, who served under Presidents Trump and Obama, respectively. Our board further includes two retired judges from the Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. It also features two distinguished public servants: Lamar Smith, former U.S. Representative for Texas's 21st congressional district and Chairman of the House Judiciary Committee, and Gary Locke, former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China under President Obama.

C4IP supports the Trade Representative's determination that Brazil's acts, policies, and practices with respect to intellectual property protection and enforcement are unreasonable

[1] *Notice of Determination and Request for Comments Concerning Action Pursuant to Section 301: 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,* 91 Fed. Reg. 33,854 (June 4, 2026) (Docket No. USTR-2026-0331) [*hereinafter* Proposed Action Notice].

and burden or restrict U.S. commerce. We write to reinforce that conclusion across the patent and enforcement issues the determination identifies, and to encourage the Trade Representative to pursue durable, intellectual-property-specific commitments as the surest means of eliminating these practices.

I. Brazil Urgently Needs to Address Patent Examination Delay and Build INPI Capacity

USTR's determination correctly identifies the unreasonable length of time Brazil takes to examine patent applications, particularly biopharmaceutical applications, as a serious and longstanding concern. As the Trade Representative found, average patent pendency in Brazil substantially exceeds that of the United States and the other major patent offices, and pendency for biopharmaceutical applications is even longer.[2]

These delays reflect institutional-capacity constraints that Brazil is well positioned to address. Although the National Institute of Industrial Property (INPI) has made meaningful progress in reducing its overall examination backlog, biopharmaceutical applications continue to face the longest waits. Durable improvement will require sustained investment in the office's capacity — including modernization of its information-technology systems, greater flexibility to retain and spend the fees it collects, and the authority to hire the examiners needed to keep pace with demand. C4IP encourages USTR to press Brazil to equip INPI with the resources and autonomy necessary to resolve the biopharmaceutical backlog on a lasting basis.

II. Several Brazilian IP Policies Harm American Biopharmaceutical Innovation

The harm of Brazil's examination delay (particularly acute in this technology sector) is compounded by the absence of any mechanism to restore patent term lost to government-caused delay.[3] Because it is the *effective* term of a patent — not its nominal twenty-year length — that determines the return an innovator can expect to earn, term consumed by delay and left unrestored directly erodes the incentive to undertake the long, capital-intensive research that biopharmaceutical innovation requires; that injury falls hardest precisely where development and review timelines are especially long.

[2] *Proposed Action Notice, supra* note 1, at 33,857 (reporting, based on 2025 WIPO data, average patent pendency of 38.4 months in Brazil, compared to 29.5 months in the United States and 21.5 months across the IP5 offices — 30% and 18% longer, respectively — and biopharmaceutical pendency of at least 54 to 63.6 months and as long as 109.7 months from filing).

[3] *Proposed Action Notice, supra* note 1, at 33,858 (finding that delay harms innovators by reducing effective patent term, "compounded by Brazil's lack of a patent-term-extension mechanism").

Brazil once guaranteed a minimum term measured from grant to offset examination delay, but its Supreme Federal Tribunal struck that provision down in 2021 and applied the ruling retroactively to pharmaceutical and medical-use patents.[4] Subsequently, courts have declined to allow term restoration on a case-by-case basis, and legislative proposals to create a patent-term-adjustment mechanism have not advanced.[5] The result is a structural denial of effective patent term. As USTR's own record reflects, the absence of a patent-term-adjustment mechanism denies fair and equitable opportunities to American biopharmaceutical innovators. And critically, even meaningful progress on INPI's pendency and backlog will not cure this gap: an effective PTA mechanism is needed both to remedy delays already suffered and to compensate for the case-by-case delays that will inevitably persist even as average pendency improves. We urge the Trade Representative to treat the enactment of such a mechanism as a priority objective of U.S. engagement.

Brazil's IP framework leaves a second structural gap. Regulatory data protection (RDP) — the exclusivity that prevents competitors from relying on an originator's costly clinical-trial data to secure their own approvals — is an essential complement to patent rights to support the research-intensive biopharmaceutical industry. Brazilian lawmakers have considered legislation to establish an RDP framework for pharmaceutical products, but no such framework is currently in force, leaving drugmakers without a dedicated framework to protect their regulatory data.[6] This omission is particularly striking because Brazilian law provides RDP for agricultural, veterinary, and pesticide products. The result is a discriminatory framework that affords RDP to other regulated industries but denies it to pharmaceutical products. That places Brazil out of step with the protection afforded in the United States, the European Union, and other major markets.

Brazil's biopharmaceutical market-access policies also raise serious concerns for U.S. innovators. Through its Productive Development Partnerships (PDP) program, Brazil effectively conditions meaningful access to its public-health market on the transfer of proprietary technology and manufacturing know-how to state-backed domestic

[4] Claudio Roberto Barbosa, *The Curious Case of a Stillborn Patent: Patent Office Delays and the Need for a Rational Term-Adjustment System in Brazil,* Kasznar Leonardos (May 21, 2024), https://www.kasznarleonardos.com/en/the-curious-case-of-a-stillborn-patent-patent-office-delays-and-the-need-for-a-rational-term-adjustment-system-in-brazil/.

[5] Ana Paula Brito and Vicente Rosenfeld, *Brazil — Hot Topics in IP 2025: IP Litigation*, Lexology (Mar. 24, 2026), https://www.lexology.com/library/detail.aspx?g=144e0161-3b2c-412c-938e-cb8cc234c7bf; Eduardo Riess, Viviane Kunisawa, *The Administrative 'PTA' Mechanism and the Need for Action by the Brazilian Parliament*, Daniel Law (Feb. 12, 2026), https://www.daniel.com.br/en/articles/the-administrative-pta-mechanism-and-the-need-for-action-by-the-brazilian-parliament/.

[6] *See Life Sciences & Pharma IP Litigation 2026: Brazil*, Chambers and Partners (Jan. 29, 2026), https://practiceguides.chambers.com/practice-guides/life-sciences-pharma-ip-litigation-2026/brazil; Rob Rodrigues and Brenno Telles, *Brazilian Congress Debates Regulatory Data Protection for Pharmaceutical Products*, IPWatchdog (June 5, 2024), https://ipwatchdog.com/2024/06/05/brazilian-congress-debates-regulatory-data-protection-pharmaceutical-products/ (describing May 2024 Brazilian Senate committee hearings on establishing RDP for human-use pharmaceuticals).

manufacturers.[7] Although the program is framed as voluntary, Brazil's considerable role as a purchaser of strategic medicines and its procurement preferences may make participation the only realistic pathway to market for many companies. Requiring U.S. companies to surrender valuable proprietary technology as a practical condition of market access is an unfair and unnecessary barrier that warrants USTR's attention.

III. Brazil Has Robust Standard-Essential Patents Policies, But Some Emerging Challenges Should Be Watched

C4IP notes that standard-essential patent (SEP) enforcement is one area where Brazil has achieved a good balance overall, although some recent developments bear monitoring. In particular, Brazil's courts have traditionally made injunctive relief available to holders of SEPs, reflecting appropriate respect for the right to exclude — the same principle U.S. enforcement authorities have recently reaffirmed as central to a well-functioning patent system.[8]

A few newer developments, however, point the other way. A São Paulo state court has recently introduced a two-phase procedure that would channel SEP disputes toward court-ordered interim payments in lieu of injunctive relief.[9] In addition, there is some indication that Brazilian courts are treating the court where a patent is first asserted as the sole venue for any subsequent litigation over that patent, displacing the ordinary application of Brazil's venue rules. That approach effectively "locks in" the initial forum and creates a race-to-the-courthouse dynamic that can disadvantage patent holders. Moreover, the Administrative Council for Economic Defense (CADE), Brazil's competition authority, has opened an abuse-of-dominance investigation into Ericsson's SEP licensing, raising concern that Ericsson's refusal to license on a territorial (rather than global) basis may harm competitive conditions in Brazil.[10] A judicial framework that substitutes court-administered interim payments for

[7] Rob Rodrigues and Dara Offrede, *Brazil — Updates on the Partnerships for Productive Development (PDPs)*, Kluwer Patent Blog (May 28, 2025), https://legalblogs.wolterskluwer.com/patent-blog/brazil-updates-on-the-partnerships-for-productive-development-pdps/.

[8] *See, e.g.*, DOJ Antitrust Division and USPTO, *Statement of Interest*, Radian v. Samsung, case no. 2:24-cv-1073 (E.D. Tex.) (June 24, 2025), https://www.justice.gov/atr/media/1404506/dl?inline; *see also* Melissa Ritti, *Expert Scrutiny Reshapes Standard-Essential Patent Landscape in Brazil* (May 27, 2026) (describing Brazil's evolving practices in awarding injunctive relief in SEP cases), https://www.mlex.com/mlex/articles/2482610/expert-scrutiny-reshapes-standard-essential-patent-landscape-in-brazil.

[9] Angela Morris, *Brazil Court Unveils Interim Procedure in Acer v Nokia*, IAM (Mar. 26, 2026), https://www.iam-media.com/article/brazil-court-unveils-interim-procedure-in-acer-v-nokia (reporting a São Paulo state court's two-phase framework providing for early review of FRAND comparables and interim payments, without injunctions, in the Brazilian proceedings of the Nokia SEP patent litigation).

[10] Maria Júlia Baumert, *Ericsson, Motorola Pressed in Brazil on Global 5G Patent Dispute Strategies*, MLex (Mar. 9, 2026), https://www.mlex.com/mlex/articles/2450751/ericsson-motorola-pressed-in-brazil-on-global-5g-patent-dispute-strategies (discussing the scope of the current CADE inquiry into the parties); *CADE Investigates Ericsson for Antitrust Violations*, Conselho Administrativo de Defesa Econômica (May 6, 2025), https://www.gov.br/cade/en/matters/news/cade-investigates-ericsson-for-antitrust-violations (reporting that, notwithstanding the parties' global settlement, CADE's Tribunal recommended an administrative inquiry into Ericsson's SEP licensing practices).

the right to exclude, and a competition-law posture that second-guesses a patent holder's licensing and enforcement decisions, each risk eroding the enforcement strength that has made Brazil an effective venue for U.S. and other innovators. C4IP urges USTR to monitor these developments and to encourage Brazil to preserve robust injunctive relief for adjudicated SEP infringement and to respect patent holders' freedom to negotiate licenses on mutually agreed terms.

IV. Brazil Must Take Greater Action to Address Counterfeiting

C4IP agrees that Brazil fails to sufficiently enforce its criminal laws and customs regulations against counterfeit goods. We emphasize one dimension that warrants particular attention: counterfeit and falsified medicines.[11] Beyond the commercial injury to rights holders, counterfeit pharmaceuticals present an acute public-health hazard, and international enforcement data confirm that the trade in illicit and falsified medicines operates at significant scale.[12] Deterrent-level penalties and sustained customs enforcement are therefore not only trade imperatives but public-health ones, and we encourage the Trade Representative to press Brazil on both.

V. Brazil Must Take Greater Action to Address Copyright Piracy

C4IP also supports the determination's finding that Brazil's anti-piracy enforcement is inconsistent and episodic rather than sustained. We highlight the determination's identification of a concrete, verifiable step: Brazil has not acceded to the World Intellectual Property Organization (WIPO) Copyright Treaty or the WIPO Performances and Phonograms Treaty, the treaties designed to extend copyright protection to the digital environment.[13] Accession to these treaties — paired with continuous, year-round enforcement against online piracy — would meaningfully strengthen protection for the American creative industries whose works are widely pirated in Brazil.

VI. Recommended Engagement

Finally, in response to the Trade Representative's invitation for views on U.S. engagement with Brazil in connection with the ongoing Special 301 review, C4IP respectfully submits

[11] See, e.g., José Vitor Santos do Nascimento and Carolinne Oliveira Marquez, Counterfeiting of Medicines in Brazil: A Review (abstract) (Dec. 27, 2025), https://rsdjournal.org/rsd/article/view/50424.

[12] *See, e.g., INTERPOL, Record 769 Arrests and USD 65 Million in Illicit Pharmaceuticals Seized in Global Bust* (June 25, 2025), https://www.interpol.int/en/News-and-Events/News/2025/Record-769-arrests-and-USD-65-million-in-illicit-pharmaceuticals-seized-in-global-bust.

[13] *See* WIPO Copyright Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 2186 U.N.T.S. 121; WIPO Performances and Phonograms Treaty, Dec. 20, 1996, S. Treaty Doc. No. 105-17, 2186 U.N.T.S. 203.

that the practices identified above are most durably eliminated through specific, verifiable commitments, including full funding of INPI in conjunction with efforts to reduce the patent application backlog, enactment of a patent-term-adjustment mechanism, establishment of a pharmaceutical regulatory data protection system, reform of the conditions attached to public-procurement participation, deterrent-level penalties and adequate customs resources directed at counterfeiting, and accession to the WIPO Internet Treaties. C4IP supports the Trade Representative's determination that responsive action is warranted and encourages USTR to structure that engagement so that concrete intellectual property reforms by Brazil are recognized and reciprocated.

C4IP appreciates the opportunity to comment and the Trade Representative's continued attention to the protection of American innovation and creativity abroad.

Respectfully submitted,

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