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Co-Chair

The Honorable David Kappos
Co-Chair

Judge Paul Michel
(Ret.), Board Member

Judge Kathleen O'Malley
(Ret.), Board Member

The Honorable Gary Locke
Board Member

The Honorable Lamar Smith
Board Member

Coke Morgan Stewart
President and CEO

Frank Cullen
Executive Director

**RE: Docket No. USTR-2026-0498: Comments
Regarding Foreign Trade Barriers to U.S. Exports
for 2027 Reporting: Brazil, Canada, China,
European Union, India, Mexico, United
Kingdom, and Vietnam**

October 29, 2026

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

Dear Ambassador Greer and Members of the Trade Policy Staff
Committee:

The Council for Innovation Promotion (C4IP) respectfully submits these comments regarding significant foreign trade barriers maintained by Brazil, Canada, China, the European Union (EU), India, Mexico, the United Kingdom (UK), and Vietnam for consideration in the 2027 National Trade Estimate (NTE) Report. Consistent with the Office of the United States Trade Representative's (USTR) filing instructions, the comments on each country appear as a separate attachment within this single submission, and each attachment may be read on its own.

About C4IP

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 Under Secretaries of Commerce for Intellectual Property and Directors of the U.S. Patent and Trademark Office, Andrei Iancu and David Kappos, who served under Presidents Trump and Obama, respectively. Our Board further includes former Chief Judge Paul Michel and Judge Kathleen O'Malley of the U.S. Court of Appeals for the Federal Circuit, former Secretary of Commerce and Ambassador to China Gary Locke, and former House Judiciary Committee Chairman Lamar Smith.

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C4IP appreciates the opportunity to submit these comments. C4IP looks forward to continuing to work with USTR on these issues and welcomes the opportunity to provide additional information, clarification, supporting materials, or formal presentations regarding any of the concerns discussed above.

Respectfully submitted,

A handwritten signature in black ink, reading "Coke Stewart". The signature is written in a cursive, flowing style.

Coke Stewart
President and Chief Executive Officer
Council for Innovation Promotion (C4IP)

Attachment 1

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: BRAZIL

I. Executive Summary

Brazil is among the largest pharmaceutical, medical-technology, and consumer markets in Latin America. The Office of the United States Trade Representative's (USTR) 2026 Special 301 Report keeps Brazil on the Watch List.¹ The Council for Innovation Promotion's (C4IP) principal concerns, detailed below, span Intellectual Property Protection and Enforcement, Investment Barriers, and Competition Policy: chronic patent-office delay with no mechanism to restore lost term; no regulatory data protection (RDP) for pharmaceuticals; Productive Development Partnerships (PDPs) that condition public-health market access on technology transfer; emerging threats to standard-essential patent (SEP) enforcement; inconsistent counterfeiting and piracy enforcement; and the risk of IP-related countermeasures.²

These barriers reduce the value and enforceability of U.S.-origin IP and, for PDPs, require surrendering know-how as a practical condition of market access. C4IP commends USTR's Section 301 determination that Brazil's IP practices, including patent-examination delay without term restoration and inadequate counterfeiting and piracy enforcement, are actionable, and its July 2026 action.³ C4IP urges USTR to reflect those findings and the concerns below in the 2027 National Trade Estimate (NTE) Report and to seek specific, verifiable commitments in any negotiated resolution.

II. Patent Examination Delay and the Absence of Patent Term Adjustment

Foreign Measure

Delays at Brazil's National Institute of Industrial Property (INPI) and the absence of a patent-term-adjustment (PTA) mechanism following the Supreme Federal Tribunal's 2021 retroactive invalidation, including for pharmaceutical and medical-use patents, of the minimum-term safeguard in Article 40, sole paragraph, of Law No. 9,279/1996.

¹USTR, 2026 Special 301 Report 77 (Apr. 30, 2026), <https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

²Notice of Determination and Request for Comments Concerning Action Pursuant to Section 301: Brazil's Acts, Policies, and Practices, 91 Fed. Reg. 33,854 (June 4, 2026) (Docket No. USTR-2026-0331).

³Notice of Action: Brazil's Acts, Policies, and Practices, 91 Fed. Reg. 45,516 (July 20, 2026) (imposing 25 percent tariffs on imports of Brazil, with exemptions, effective July 22, 2026).

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

USTR's Section 301 determination found that average patent pendency in Brazil substantially exceeds that of the United States and other major offices, and is longer still for biopharmaceutical applications.⁴ USTR's 2026 Special 301 Report cites stakeholder data that pharmaceutical patents granted between January 2020 and November 2025 waited an average of 9.15 years, and notes the effect on effective patent term.⁵ INPI has progressed on its overall backlog, but biopharmaceutical applications still face the longest waits.⁶

Brazil formerly guaranteed a minimum ten-year term from grant to offset examination delay, but in 2021 the Supreme Federal Tribunal struck down that safeguard and applied the ruling retroactively, including to pharmaceutical and medical-use patents in force.⁷ Courts have since declined to restore term case by case, and proposals for a PTA mechanism have not advanced.⁸ Lost term erodes the incentive to invest, and reducing the backlog alone will not close the gap; PTA is needed to remedy past delay and compensate for delay that will persist.

Brazil should resolve these issues through negotiation rather than IP-related countermeasures. Law No. 15.122/2025 authorizes suspending obligations relating to intellectual property rights in response to unilateral measures, which would deter investment and heighten trade tensions.⁹

⁴USTR, supra note 2, at 33,857 (reporting, per 2025 WIPO data, average pendency of 38.4 months in Brazil, versus 29.5 in the United States and 21.5 across the IP5 offices, and biopharmaceutical pendency of 54 to 63.6 months and as long as 109.7 months from filing).

⁵USTR, supra note 1, at 77.

⁶Council for Innovation Promotion, Comments on the Proposed Action in the Section 301 Investigation of Brazil's IP Practices, Docket No. USTR-2026-0331, at 2 (July 1, 2026).

⁷Supremo Tribunal Federal, Ação Direta de Inconstitucionalidade (ADI) 5.529, judgment of May 12, 2021 (Braz.); Claudio Roberto Barbosa, The Curious Case of a Stillborn Patent, 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/>; Constitutional Challenge (ADI) 5529 and Patent Term Adjustment/Extension, Dannemann (2024), <https://www.dannemann.com.br/en/noticias/acao-direta-de-inconstitucionalidade-adi-5529-e-o-ajuste-de-prazo-de-patente>.

⁸Ana Paula Brito & Vicente Rosenfeld, Brazil: Hot Topics in IP 2025, 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/>.

⁹Lei No. 15.122, de 11 de abril de 2025 (Braz.), <https://www2.camara.leg.br/legin/fed/lei/2025/lei-15122-11-abril-2025-797315-norma-pl.html>.

Trade Impact

Unrestored term loss shortens the period in which U.S. innovators can recoup R&D investment and earn licensing revenue in Brazil, discourages early launch, and depresses U.S. investment in Brazilian clinical development and manufacturing.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Brazil, including in any negotiated resolution of the Section 301 action, to enact a PTA mechanism and avoid IP-related countermeasures, and encourage measures to equip INPI to resolve the biopharmaceutical backlog on a lasting basis.

III. Absence of Regulatory Data Protection for Pharmaceutical Products

Foreign Measure

Brazil's regulatory framework governing marketing authorization for pharmaceutical products, which provides no RDP for clinical-trial data submitted to secure drug approval, although Brazilian law extends RDP to agricultural, veterinary, and pesticide products.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

RDP, which prevents competitors from relying on an originator's clinical-trial data to obtain their own approvals, is an essential complement to patent rights. Legislation to establish pharmaceutical RDP has been considered, but none is in force.¹⁰ The gap raises concerns under Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires protection of undisclosed test data against unfair commercial use.

Brazilian law already provides RDP for agricultural, veterinary, and pesticide products, so the omission denies protection to pharmaceuticals alone. USTR's 2026 report makes the same point.¹¹

Trade Impact

The absence of RDP reduces the incentive to conduct clinical trials or launch medicines promptly in Brazil and lets competitors free-ride on U.S.-generated data.

¹⁰Life 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 & 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/>.

¹¹USTR, *supra* note 1, at 77.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, raise the absence of pharmaceutical RDP in bilateral engagement and any negotiated resolution of the Section 301 action, encourage enactment of an RDP framework, and review Brazil's framework for consistency with TRIPS Article 39.3.

IV. Productive Development Partnerships and Forced Technology Transfer

Foreign Measure

Brazil's Productive Development Partnership (PDP) program, administered by the Ministry of Health, and procurement preferences favoring participating domestic manufacturers, including authority to pay up to 15% more than the best import price.

NTE Category

Intellectual Property Protection and Enforcement; Investment Barriers.

Discussion

Brazil's government is the dominant purchaser of medicines, and its PDP program conditions sustained access to that market on transferring proprietary manufacturing technology and know-how, including drug master files and master cell banks, to state-backed manufacturers, with full transfer required within the ten-year supply contract.¹² PDPs have been documented for several biologics, including adalimumab, rituximab, and trastuzumab biosimilars.

PDPs are nominally voluntary, but direct bidding is no realistic substitute: the government may pay up to 15% more than the best imported price for domestic manufacturers, and direct bids are often limited in quantity, price, or duration, making PDPs effectively the only viable path to a long-term relationship with Brazil's public-health system.

Requiring U.S. companies to surrender proprietary technology as a practical condition of market access is an unnecessary barrier; a genuinely voluntary arrangement would let the innovator negotiate on a level playing field and be compensated for any license to its IP and data.

Trade Impact

The PDP program depresses U.S. exports of patented and biologic medicines by incentivizing domestic substitution, transfers know-how to state-backed competitors

¹²Rob Rodrigues & 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/>.

on non-arm's-length terms, and discourages U.S. investment in Brazilian manufacturing and R&D.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, raise the PDP program's effective conditioning of market access on technology transfer in bilateral engagement, and encourage reform of the procurement preferences and contracting terms that make PDP participation the only realistic path to Brazil's public-health market.

V. Standard-Essential Patent Licensing and Competition-Policy Developments

Foreign Measure

Recent Brazilian judicial and competition-authority developments affecting standard-essential patent (SEP) enforcement, including a São Paulo state court's two-phase interim-payment procedure in *Acer v. Nokia*, emerging venue practices in SEP litigation, and the Administrative Council for Economic Defense's (CADE) abuse-of-dominance investigation into Ericsson's SEP licensing.

NTE Category

Intellectual Property Protection and Enforcement; Competition Policy.

Discussion

Brazil's courts have traditionally made injunctive relief available to SEP holders, a principle U.S. enforcement authorities have recently reaffirmed in Statements of Interest filed by the Department of Justice and the USPTO.¹³ Recent developments point the other way. A São Paulo state court has introduced a two-phase procedure in the *Nokia-Acer* dispute that channels disputes toward court-ordered interim payments in place of injunctive relief.¹⁴ Courts also tend to treat the forum where a patent is first asserted as the exclusive venue for later litigation, creating a race to the courthouse. And CADE has opened an abuse-of-dominance investigation into Ericsson's SEP licensing, raising concern that territorial rather than global licensing may be treated as anticompetitive.¹⁵ Each development risks eroding the enforcement strength that makes Brazil an effective venue.

¹³DOJ Antitrust Division & USPTO, Statement of Interest, *Radian v. Samsung*, No. 2:24-cv-1073 (E.D. Tex. June 24, 2025), <https://www.justice.gov/atr/media/1404506/dl?inline>.

¹⁴Angela 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>.

¹⁵Maria 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>; CADE Investigates Ericsson for Antitrust Violations, CADE (May 6, 2025), <https://www.gov.br/cade/en/matters/news/cade-investigates-ericsson-for-antitrust-violations>.

Trade Impact

Diminished SEP enforcement would reduce licensing revenue for U.S. patent holders in Brazil and weaken their leverage to negotiate fair licenses.

Requested USTR Action

USTR should monitor these developments, include them in the 2027 NTE Report, and encourage Brazil to preserve injunctive relief for adjudicated SEP infringement and respect patent holders' freedom to negotiate licenses on mutually agreed terms.

VI. Counterfeiting and Copyright Piracy Enforcement

Foreign Measure

Brazil's enforcement of its criminal and customs laws against counterfeit goods, including counterfeit and falsified medicines, and Brazil's non-accession to the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty.

NTE Category

Intellectual Property Protection and Enforcement; Transparency and Rule of Law.

Discussion

Brazil does not sufficiently enforce its criminal laws and customs regulations against counterfeit goods, as USTR's Section 301 determination also found.¹⁶ USTR's 2026 report finds that counterfeits have surged through smuggling and small parcels and that raids on the Rua 25 de Março market are not followed by deterrent penalties. It cites too few customs officers and lengthy prosecutions, and notes cautious optimism over Receita Federal's December 2025 Ato Declaratório Interpretativo No. 3/2025, which allows customs to seize and forfeit counterfeits without a suit by the trademark owner, though its effect is unclear.¹⁷ Counterfeit and falsified medicines deserve particular attention as an acute public-health hazard operating at significant scale.¹⁸

Online anti-piracy enforcement is similarly inconsistent. USTR's 2026 report finds piracy remains widespread and calls for more consistent, continuous enforcement operations.¹⁹ Brazil also has not acceded to the WIPO Copyright Treaty or the WIPO Performances and Phonograms Treaty, which USTR urges it to join as soon

¹⁶USTR, *supra* note 2, at 33,857-58.

¹⁷USTR, *supra* note 1, at 77.

¹⁸INTERPOL, 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>.

¹⁹USTR, *supra* note 1, at 77.

as possible.²⁰ Accession and continuous enforcement would strengthen protection for American creative industries whose works are widely pirated in Brazil.

Trade Impact

Persistent counterfeiting and piracy displace legitimate U.S. exports, endanger consumers of counterfeit medicines, and depress royalty revenue owed to U.S. rights holders.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Brazil to impose deterrent-level penalties and dedicate sustained customs resources to counterfeiting enforcement, with particular attention to counterfeit medicines, and encourage Brazil's accession to the WIPO Internet Treaties.

VII. Conclusion

C4IP's principal concerns regarding Brazil are patent-examination delay without term restoration, the absence of pharmaceutical RDP, the PDP program's conditioning of market access on forced technology transfer, emerging threats to SEP enforcement, inconsistent counterfeiting and piracy enforcement, and the risk of IP-related countermeasures. Each imposes real costs on U.S. innovators and is capable of concrete, verifiable improvement. C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue its engagement with Brazil, including by monitoring the Section 301 action and any negotiated resolution, to secure durable improvements.

²⁰WIPO 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; USTR, *supra* note 1, at 77.

Attachment 2

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: CANADA

I. Executive Summary

Canada is the United States' closest trading partner and a United States-Mexico-Canada Agreement (USMCA) party whose patent-term and digital-trade frameworks nonetheless fall short of that agreement's requirements. The Council for Innovation Promotion's (C4IP) principal concerns, addressed below, fall within Intellectual Property Protection and Enforcement, Regulatory Practices, and Digital Trade: deficiencies in Canada's patent-term-adjustment (PTA) and patent-term-extension (PTE) frameworks, which fail to fully compensate innovators for administrative and regulatory delay as USMCA requires; gaps in counterfeiting and online-piracy enforcement; and the Online Streaming Act, which raises discrimination concerns under USMCA's digital-trade provisions.

These issues matter because Canada's USMCA commitments were negotiated to give innovative medicines and digital products consistent, predictable treatment across all three parties, and shortfalls in implementation erode that bargain for U.S. innovators and digital-service providers. Because the July 2026 joint review ended without a U.S. decision to extend the agreement, annual reviews now follow through 2036; the Office of the United States Trade Representative (USTR) should use that process, including the 2027 review, to secure Canada's full compliance.²¹

II. Patent Term Adjustment Shortcomings

Foreign Measure

Canada's PTA regulations under the Patent Rules, SOR/2019-251, as amended effective January 1, 2025, implementing Canada's USMCA obligation to compensate patent holders for unreasonable delay between filing and issuance.²²

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

²¹USMCA 2026 Joint Review: United States Declines to Extend Agreement, Triggering Annual Reviews, White & Case (July 2026), <https://www.whitecase.com/insight-alert/usmca-2026-joint-review-united-states-declines-extend-agreement-triggering-annual>.

²²C4IP, Comments in Response to the 2026 Special 301 Review, Post-Hearing Submission, Docket No. USTR-2025-0243, at 5-7 (Feb. 25, 2026); Canada Finalizes Patent Term Adjustment Rules, Smart & Biggar (2024), <https://smartbiggar.ca/insights/publication/canada-finalizes-patent-term-adjustment-rules>.

Discussion

PTA compensates patent holders for time lost to unreasonable delay between filing and issuance. The U.S. system compensates in proportion to administrative delay, and USMCA requires Canada to do the same. Canada has established a PTA system in an attempt to comply, but its regulations still limit inventors' access to and use of PTA.²³

Obtaining PTA in Canada is far harder than in the United States. The USPTO calculates PTA automatically and includes it in the issue notification; Canadian inventors must calculate PTA availability themselves and pay an application fee of up to CAD \$2,570 for the Canadian Intellectual Property Office to evaluate the claim.²⁴ Canadian PTA accrues only if a patent issues more than five years from filing or more than three years from the date examination was requested, whichever is later, while U.S. PTA begins accruing once prosecution exceeds three years from filing. Canada's calculation also subtracts any delay “not directly attributable to the patent office,” whereas U.S. time is less readily subtracted, particularly for overlap, disclaimed terms, or applicant failure to make “reasonable efforts” to respond to USPTO notices. As a result, the effective duration of Canadian PTA can be far shorter than the delay applicants actually experience.

Process barriers compound these limits. Canada has not committed to decision deadlines, and PTA applications may take years to resolve, unlike Certificates of Supplementary Protection (CSPs) applications. Deductions can include periods when even a diligent applicant could not respond to patent office communications, and the Commissioner retains residual discretion to subtract unspecified days, making it difficult to judge whether applying is worthwhile. Applicants also have no redetermination right short of judicial review, while the Commissioner may shorten the term at any time and third parties may challenge it.

Trade Impact

Canada's restrictive PTA framework shortens the effective patent term available to U.S. innovators below what USMCA requires, reducing the period in which they can recoup R&D investment and earn licensing revenue from the Canadian market.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Canada to reform its PTA framework to provide automatic calculation, firm decision timelines, limits on deductions and Commissioner discretion, a redetermination right, and genuinely compensatory adjustment consistent with USMCA, and raise the issue in the annual USMCA joint review process.

²³C4IP, *supra* note 2, at 5-7.

²⁴C4IP, *supra* note 2, at 5-7.

III. Patent Term Extension and Certificates of Supplementary Protection

Foreign Measure

Canada's patent-term-extension (PTE) framework, implemented through CSPs under the CSP Regulations, SOR/2017-165, including the two-year cap on CSP duration, the twelve-month reference-filing requirement, the exclusion of listed ingredient variations, and an exception for manufacture for export.²⁵

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

PTE compensates innovators for time spent awaiting regulatory approval when a medicine is patented but cannot yet be marketed. Canada caps CSPs at two years, an arbitrary limit that may not adequately compensate for longer review periods.²⁶ USTR's 2026 Special 301 Report likewise records stakeholder concerns about the limited duration, eligibility, and scope of protection under Canada's PTE system.²⁷ In FY2024-2025, 15 of the 16 medicines receiving CSPs were issued the full two-year term, indicating that longer extensions may be needed to offset typical regulatory delay.²⁸ The United States (U.S.) and European Union (EU) both allow five-year PTEs despite approving medicines faster than Canada, on average.

Canada also restricts PTE eligibility by requiring that new drug submissions be filed within twelve months of filing in certain reference jurisdictions, including the United States. This removes a company's ability to time filings by resource availability, market prioritization, and clinical strategy, and forces it either to file in Canada on a schedule dictated by its filings elsewhere or to forfeit PTE eligibility, a requirement without precedent among major trading partners. Most significantly, PTE in Canada runs concurrently with PTA rather than adding to it, so patent holders facing both administrative and regulatory delay are not compensated for the total time lost.²⁹ USTR's 2026 report similarly notes stakeholder concern that concurrent extensions for patent-office delay and marketing-approval delay may unfairly undercut compensation for the two separate types of delay.³⁰

CSPs also fall short of full patent protection. They are subject to an exception for manufacture for export, which is inconsistent with restoration regimes elsewhere,

²⁵Certificate of Supplementary Protection Regulations, SOR/2017-165 (Can.).

²⁶CSP Regulations, *supra* note 5.

²⁷USTR, 2026 Special 301 Report 79-80 (Apr. 30, 2026), <https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

²⁸C4IP, *supra* note 2, at 5-7.

²⁹C4IP, *supra* note 2, at 5-7.

³⁰USTR, *supra* note 7, at 79-80.

and Canada automatically excludes new drug submissions involving listed variations of medicinal ingredients, which the U.S. and EU regimes do not.

Trade Impact

Taken together, these deficiencies mean Canadian patent rights for innovative medicines routinely deliver less exclusivity than USMCA requires, limiting incentives for innovation and shortchanging innovators who bear the risks of developing medicines for the Canadian market.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Canada to raise its CSP cap toward five years, eliminate the twelve-month reference-filing restriction and the listed-variation exclusions, provide full patent rights during the CSP term, and provide for PTE to run additively with PTA, consistent with USMCA, and raise the issue in the annual USMCA joint review process.

IV. Online Streaming Act and Counterfeiting/Piracy Enforcement

Foreign Measure

Canada's Online Streaming Act, S.C. 2023, c. 8 (formerly Bill C-11), which subjects foreign streaming services to oversight by the Canadian Radio-television and Telecommunications Commission (CRTC) and imposes financial-contribution requirements on them, and Canada's border, judicial, and online enforcement against counterfeiting and piracy.³¹

NTE Category

Digital Trade; Services Barriers; Intellectual Property Protection and Enforcement.

Discussion

The Online Streaming Act significantly expands government control over the audiovisual marketplace and raises concerns under USMCA Articles 19.4 and 19.5, which prohibit discrimination against digital products based on country of origin.³² The Act subjects foreign streaming services to CRTC oversight, empowering regulators to impose financial-contribution requirements and other obligations historically applied to traditional broadcasters, and the CRTC's resulting contribution decisions have been stayed in court since December 2024. In June 2026, the government announced that it would direct the CRTC to revise those decisions, and in July told the Federal Court of Appeal that it intends to eliminate

³¹Online Streaming Act, S.C. 2023, c. 8 (Can.); Agreement Between the United States of America, the United Mexican States, and Canada arts. 19.4, 19.5 (July 1, 2020).

³²USMCA, *supra* note 11.

the base contribution requirement and replace it with government funding.³³ The replacement design is unsettled, and it must not impose discriminatory obligations on U.S. services that domestic services do not bear.

Separately, USTR's 2026 Special 301 Report keeps Canada on the Watch List and finds that the lack of IP enforcement remains a significant concern, particularly at the border and against online piracy.³⁴ The low number of border seizures and lack of training for border officials suggest that Canadian authorities have yet to take full advantage of their expanded ex officio powers, and rights holders report that courts fail to issue consistent, deterrent-level penalties against those who import, distribute, and sell counterfeit goods. USTR also notes that Toronto's Pacific Mall is listed in the 2025 Notorious Markets List and that online piracy remains very high in Canada, including through piracy devices, apps, and subscription services. Through the annual USMCA joint review process, the United States should insist that Canada use its border authority fully and ensure deterrent-level penalties and effective enforcement against counterfeiting and online piracy.

Trade Impact

Contribution requirements of the kind the Act authorizes impose costs on U.S. streaming services that domestic competitors do not bear, reducing the competitiveness of U.S. digital exports in Canada, while enforcement gaps displace legitimate U.S. exports and depress licensing revenue for U.S. content owners.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, monitor the Online Streaming Act's replacement contribution framework for consistency with USMCA Articles 19.4 and 19.5, and, in connection with the annual USMCA joint review process, press Canada to make full use of its ex officio border powers, train border officials, ensure consistent deterrent-level penalties for importers and sellers of counterfeit goods, and strengthen enforcement against online piracy.

V. Conclusion

C4IP's principal concerns regarding Canada are inadequate patent-term-adjustment and patent-term-extension mechanisms, gaps in counterfeiting and online-piracy enforcement, and the Online Streaming Act's discriminatory treatment of U.S. digital services under USMCA. If Canada does not uphold its USMCA commitments on these points, C4IP recommends that USTR consider the

³³Starting Over: Court Filing Confirms the CRTC's Streamer Contribution Decisions Are Dead, Michael Geist (July 2026), <https://www.michaelgeist.ca/2026/07/starting-over-court-filing-confirms-the-crtc-streamer-contribution-decisions-are-dead-with-a-full-online-streaming-act-reset-to-come/>.

³⁴USTR, *supra* note 7, at 79-80.

full range of tools available to secure compliance.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and use the annual USMCA joint review process to press Canada toward genuinely compensatory protection consistent with its treaty obligations.

Attachment 3

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: CHINA

I. Executive Summary

China remains the most consequential jurisdiction for U.S. IP-intensive industries, both as the world's leading source of counterfeit and pirated goods and as the origin of judicial and regulatory practices that increasingly devalue U.S.-owned patents, particularly standard-essential patents (SEPs). The Office of the United States Trade Representative's (USTR) 2026 Special 301 Report keeps China on the Priority Watch List and finds that reforms to improve IP protection and enforcement remained slow in 2025.³⁵ The Council for Innovation Promotion's (C4IP) principal concerns, addressed below, are: a discriminatory "new drug" definition that disadvantages companies not filing first in China, including for patent term extension and regulatory data protection; weak early patent dispute resolution and enforcement; Chinese courts' assertion of jurisdiction to set global SEP rates without patent-holder consent; structural barriers in patent litigation, including evidentiary burdens and limited judicial transparency; and the scale of counterfeit goods sourced from China and Hong Kong.

Several of these practices, particularly China's assertion of authority over global SEP rates, threaten to set precedents other jurisdictions are already following, and several pharmaceutical concerns bear on commitments China made in the U.S.-China Economic and Trade Agreement (the Agreement).³⁶ USTR should treat them as enforcement priorities and urgent precedent-setting concerns in the 2027 NTE Report.

II. Discriminatory "New Drug" Definition for Patent Term Extension and Regulatory Data Protection

Foreign Measure

China's definition of "new drug" under the Drug Registration Regulation administered by the National Medical Products Administration (NMPA), limited to products not yet approved anywhere in the world at the time of the Chinese filing, as applied to patent term extension (PTE) and regulatory data protection (RDP).

³⁵USTR, 2026 Special 301 Report 50 (Apr. 30, 2026), <https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

³⁶Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China (Jan. 15, 2020), https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf.

NTE Category

Regulatory Practices; Intellectual Property Protection and Enforcement.

Discussion

China defines a “new drug” to include only products not yet approved anywhere else at the time of the Chinese filing, forcing companies to file first in China or forgo regulatory benefits. USTR's 2026 report records right holders' continuing concerns about this definition for PTE and records concerns that NMPA's then-draft data protection measures could limit protection for products first approved abroad.³⁷ The definition matters most for PTE: Article 42 of the Patent Law provides for extension of new-drug patent terms, consistent with Article 1.12 of the Agreement, but amended implementing rules and examination guidelines appear to apply the same new-to-the-world standard, denying extension to most innovative medicines, which are first approved abroad.

NMPA's May 2026 Drug Trial Data Protection Measures show progress toward an RDP framework, providing six years of protection for innovative drugs without fully adopting earlier proposals to exclude products first approved abroad.³⁸ The new-drug limitation nonetheless appears to persist: improved drugs receive only four years, and the transition mechanism may extend protection only to products new to the world. Further concerns include the interaction between the three-year term for first generics and the innovator's own term, and the lack of mechanisms to notify originators of follow-on applications or let them challenge claims of independently generated data. The new-to-China standard used in the RDP measures should also govern PTE.

Trade Impact

These distortions discourage globally sequenced regulatory strategies, deny patent term and data protection to many innovative medicines, and depress U.S. pharmaceutical exports.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, raise China's new-drug definition in bilateral engagement, encourage a new-to-China standard and coverage of all approved indications for PTE, and monitor implementation of the RDP measures.

³⁷USTR, *supra* note 1, at 55, 60.

³⁸National Medical Products Administration, Drug Trial Data Protection Implementation Measures (药品临床试验数据保护实施办法) (May 15, 2026), <https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20260515145324185.html>.

III. Weak Patent Enforcement: Early Dispute Resolution and Preliminary Injunctions

Foreign Measure

China's early resolution mechanism for pharmaceutical patent disputes under Article 76 of the Patent Law and the 2021 NMPA and China National Intellectual Property Administration (CNIPA) implementing measures, and limited access to preliminary injunctions.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices; Transparency and Rule of Law.

Discussion

China's patent-linkage system falls short of the effective early-resolution mechanism China committed to establish in Article 1.11 of the Agreement.³⁹ The nine-month stay is too short to resolve disputes before follow-on approval and excludes biologics; the scope of listed patents is limited; the declarations that trigger an Article 76 action are unclear; and approval is not conditioned on patent expiry when a generic applicant promises not to launch earlier. USTR's 2026 report likewise records these concerns, including the absence of penalties for erroneous certifications.⁴⁰

Enforcement outside the linkage system is similarly constrained. Pre-launch preliminary injunctions against premature follow-on entry are rarely granted in practice,⁴¹ although Article 1.11 of the Agreement calls for expeditious remedies such as preliminary injunctions.

Trade Impact

Premature follow-on entry erodes exclusivity before disputes are resolved and raises the cost of protecting innovative medicines in China.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press China to implement an effective early dispute resolution mechanism consistent with Article 1.11, including adequate stays for chemical and biologic products, broader patent listing, and clear certification rules, and encourage access to pre-launch preliminary injunctions.

³⁹Measures for the Implementation of the Drug Patent Dispute Early Resolution Mechanism (for Trial Implementation), NMPA & CNIPA (July 4, 2021); Agreement, *supra* note 2, art. 1.11.

⁴⁰USTR, *supra* note 1, at 55.

⁴¹USTR, *supra* note 1, at 52, 55.

IV. Global Standard-Essential Patent Rate-Setting Without Patent-Holder Consent

Foreign Measure

The assertion of jurisdiction by China's Supreme People's Court, at an implementer's request, to set global fair, reasonable, and non-discriminatory (FRAND) rates for SEPs licensed through a foreign patent pool, in *TCL Communication Technology Holdings Ltd. v. Access Advance LLC* (2024).⁴²

NTE Category

Intellectual Property Protection and Enforcement; Competition Policy.

Discussion

In *TCL v. Access Advance*, the Supreme People's Court asserted jurisdiction, at an implementer's request, to set global FRAND rates for all SEPs licensed through a foreign patent pool, although the pool does not own all the underlying patents and the individual owners never agreed to have a Chinese court set their worldwide rates.⁴³ USTR's 2026 report observes that Chinese courts appear increasingly interested in exercising jurisdiction over SEP cases, raising concern that China seeks to become the forum for SEP litigation to favor domestic companies.⁴⁴ The determination was sought by the implementer, not the patent owners, who were not parties to the suit, notwithstanding the territorial nature of patents. A Chinese court should not set rates for any owner's patents without that owner's consent, and in no event for patents of other jurisdictions.

Courts elsewhere are taking comparable steps: the United Kingdom (UK) High Court has granted interim license declarations in *Acer*, *Hisense*, and *ASUS v. Nokia*.⁴⁵

Trade Impact

China's assertion of global SEP rate-setting authority reduces licensing revenue for U.S. innovators and creates a template other jurisdictions may adopt.

⁴²*TCL Commc'n Tech. Holdings Ltd. v. Access Advance LLC*, Supreme People's Court of China (2024); China Has Jurisdiction over SEP Rates for Foreign Patent Pools, Kangxin Partners (2024), <https://en.kangxin.com/html/2/215/217/24655.html>; Access Advance and TCL: A Submission to the Shenzhen Court, China IPR (Nov. 4, 2024), <https://chinaipr.com/2024/11/04/access-advance-and-tcl-a-submission-to-the-shenzhen-court/>.

⁴³*TCL Commc'n*, supra note 8.

⁴⁴USTR, supra note 1, at 56.

⁴⁵UK High Court Issues Interim RAND License Declaration in *Acer*, *Hisense* and *ASUS v. Nokia*, Cleary Gottlieb (2025), <https://www.clearygottlieb.com/news-and-insights/publication-listing/uk-high-court-issues-interim-rand-license-declaration-in-acer-hisense-and-asus-v-nokia>.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press China to refrain from setting FRAND rates for any owner's patents without that owner's consent, and never for patents of other jurisdictions, and continue to highlight this practice in multilateral discussions of SEP licensing norms.

V. Litigation Barriers and Limited Judicial Transparency

Foreign Measure

China's patent-infringement litigation procedures, including the absence of formal discovery, elevated pleading and evidentiary requirements under the Supreme People's Court's 2020 Provisions on Evidence in Intellectual Property Civil Litigation, and its practices on publication of patent-related judicial decisions.⁴⁶

NTE Category

Transparency and Rule of Law; Intellectual Property Protection and Enforcement.

Discussion

Patent-infringement suits in China are burdensome because procedure lacks formal discovery and imposes elevated pleading and evidentiary requirements.⁴⁷ USTR's 2026 report identifies similar obstacles, including lengthy delays, courts' reported unwillingness to issue preliminary injunctions, and burdensome invalidity proceedings.⁴⁸

China also publishes only limited, selected judicial decisions, and USTR's 2026 report notes that online uploads have declined for five years.⁴⁹ This hinders assessment of whether U.S. rights holders face discriminatory treatment.

Trade Impact

Elevated evidentiary burdens and limited transparency raise the cost of enforcing U.S. patents in China, discourage meritorious claims, and make it hard to verify consistent treatment of U.S. rights holders.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press China to adopt

⁴⁶Provisions of the Supreme People's Court on Evidence in Civil Procedures Involving Intellectual Property Rights (2020); China's Supreme People's Court Releases Provisions on Evidence in Intellectual Property Civil Litigation, China IP Law Update (Nov. 2020), <https://www.chinaiplawupdate.com/2020/11/chinas-supreme-peoples-court-releases-provisions-on-evidence-in-intellectual-property-civil-litigation/>; China Looks to Address Discovery Shortcomings, Managing IP, <https://www.managingip.com/article/2a5cg1ajlz4h7boenzk74/china-looks-to-address-discovery-shortcomings>.

⁴⁷SPC Evidence Provisions, *supra* note 12.

⁴⁸USTR, *supra* note 1, at 52, 55.

⁴⁹USTR, *supra* note 1, at 57.

discovery or evidence-production mechanisms adequate to support infringement claims, and encourage full publication of patent-related judicial decisions.

VI. Counterfeit Goods Sourced from China and Hong Kong

Foreign Measure

China's enforcement of its criminal and customs laws against the manufacture and export of counterfeit goods, including through e-commerce channels.

NTE Category

Intellectual Property Protection and Enforcement; Digital Trade.

Discussion

China remains the world's leading source of counterfeit and pirated goods, as USTR's 2026 report again finds.⁵⁰ China and Hong Kong together accounted for over 87 percent of the value of counterfeit and pirated goods seized by U.S. Customs and Border Protection in fiscal year 2025.⁵¹ USTR further reports that counterfeit medicines remain widespread and that sales have migrated to e-commerce and social-media platforms with slow takedowns.

Trade Impact

The scale of counterfeit goods from China and Hong Kong displaces legitimate U.S. exports, imposes interdiction costs on U.S. Customs and Border Protection, and erodes trust in U.S. brands.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report and continue to press China to strengthen criminal and customs enforcement against counterfeit manufacturing and export, including against e-commerce platforms that facilitate counterfeit sales.

VII. Conclusion

C4IP's principal concerns regarding China are its discriminatory new-drug definition for patent term extension and regulatory data protection, weak early patent dispute resolution and enforcement, Chinese courts' assertion of jurisdiction to set global SEP rates without patent-holder consent, structural barriers to fair and transparent patent litigation, and the scale of counterfeit goods. Several, particularly global SEP rate-setting, carry precedential consequences beyond China. C4IP also encourages USTR to monitor closely other issues not addressed here:

⁵⁰USTR, *supra* note 1, at 52-53.

⁵¹U.S. Customs and Border Protection, Intellectual Property Rights (IPR) Seizures Dashboard (Apr. 1, 2026), <https://www.cbp.gov/newsroom/stats/intellectual-property-rights-ipr-seizures>.

parallel CNIPA invalidation proceedings and repetitive invalidation petitions, mandatory joint IP ownership under China's human genetic resources rules, and the lack of notice to applicants of third-party observations during patent prosecution.

Attachment 4

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: EUROPEAN UNION

I. Executive Summary

The European Union (EU) is a global standard-setter for intellectual-property policy, so its legislative and regulatory choices on biopharmaceutical patents, compulsory licensing, and standard-essential patents (SEPs) carry implications well beyond Europe. The Office of the United States Trade Representative's (USTR) 2026 Special 301 Report places the EU on the Watch List and finds that the provisional agreement on the General Pharmaceutical Legislation (GPL) "raises serious concerns."⁵² The Council for Innovation Promotion's (C4IP) principal concerns, addressed below, fall within Intellectual Property Protection and Enforcement, Competition Policy, and Regulatory Practices: the GPL, which shortens baseline regulatory data protection (RDP), conditions restoration of the full period on burdensome criteria, and expands patent-infringement exemptions; expanded compulsory licensing and proposed supplementary protection certificate (SPC) changes; the pending litigation over the withdrawn SEP Regulation proposal; and the review of the Intellectual Property Rights Enforcement Directive (IPRED), which could curtail injunctive relief for patent infringement.

These issues matter to U.S. exporters, investors, and innovators because the EU's role as a norm-setter makes its choices on RDP, compulsory licensing, and SEP governance likely to influence other jurisdictions, compounding harm to American innovators beyond the European market. C4IP urges USTR to address these concerns in the 2027 National Trade Estimate (NTE) Report and to press for reconsideration of the provisions of greatest concern while these processes remain unresolved.

II. General Pharmaceutical Legislation Reforms and Reduced Regulatory Data Protection

Foreign Measure

The EU's revised GPL, provisionally agreed in December 2025 and not yet formally adopted, which shortens the baseline period of RDP for new medicines, conditions restoration of the full period on additional criteria, and broadens patent-infringement exemptions for generic and biosimilar developers.⁵³

⁵²USTR, 2026 Special 301 Report 83 (Apr. 30, 2026),

<https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

⁵³Council of the European Union, Position at First Reading on the Regulation Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use, Doc. 7105/2/26 REV 2 (Sept. 28,

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

The GPL weakens RDP, the exclusive right a company holds over the clinical data required to approve a medicine, which takes enormous investment to generate.⁵⁴ USTR's 2026 report finds that, once adopted, the GPL will reduce protection against unfair commercial use of undisclosed test data and will condition restoration of the protection term on criteria such as conducting clinical trials in multiple Member States or seeking EU market authorization within 90 days of first global submission. Stakeholders describe these as market-entry conditions beyond an innovator's control or otherwise unreasonable. Such conditions tie IP protection to local activity rather than to the innovation itself and risk encouraging other jurisdictions to follow.⁵⁵

The GPL also broadens patent-infringement exemptions, allowing generic and biosimilar developers to take certain regulatory and commercial steps during the brand drug's patent term. USTR's 2026 report finds that the legislation would extend the Bolar exemption to commercial activities, which could undermine a patent owner's right to prevent commercial activities by follow-on competitors during the term of a patent and any associated SPC and, absent an effective notification mechanism, make preemptive injunctive relief difficult to obtain.⁵⁶ Under the final compromise text, the exemption would reach health technology assessment, pricing and reimbursement approvals, and procurement-tender submissions, which often signal an imminent follow-on launch.⁵⁷ Together, these changes diminish the value of patent rights, discourage investment in the European market, and shift more of the global cost of drug development onto U.S. companies and consumers.

On September 28, 2026, the Council adopted its first-reading position. Parliament's final vote is expected this autumn, followed by publication and a transitional period expected to run through 2028, so USTR still has a window to urge the EU to

2026), <https://data.consilium.europa.eu/doc/document/ST-7105-2026-REV-2/en/pdf>; Council of the European Union, Press Release, Pharma Package: Council and Parliament Reach a Deal on New Rules for a Fairer and More Competitive EU Pharmaceutical Sector (Dec. 11, 2025), <https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>.

⁵⁴Council of the European Union, *supra* note 2, recital 71.

⁵⁵USTR, *supra* note 1, at 83.

⁵⁶USTR, *supra* note 1, at 83.

⁵⁷Council of the European Union, Directive on the Union Code Relating to Medicinal Products for Human Use, Doc. 6367/26, recitals 63-64 (Feb. 24, 2026), <https://data.consilium.europa.eu/doc/document/ST-6367-2026-INIT/en/pdf>.

reconsider the provisions of greatest concern before they bind all Member States.

Trade Impact

Reduced baseline RDP, harder-to-meet restoration conditions, and expanded patent-infringement exemptions will shorten effective exclusivity for U.S. biopharmaceutical innovators in the EU, weaken the incentive to launch there, and shift a disproportionate share of global R&D costs onto U.S. companies and consumers.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press the EU bilaterally to reconsider the RDP and patent-exemption provisions of greatest concern before the GPL's transitional period ends, and consider designating the EU for heightened monitoring.

III. Compulsory Licensing and SPC Measures

Foreign Measure

Regulation (EU) 2025/2645 on compulsory licensing for crisis management, adopted as part of the EU's 2023 Patent Package, which establishes a new Union-level power to grant compulsory licenses without the rightsholder's consent. It entered into force in January 2026 but will not operate in practice until an implementing regulation establishes an advisory body.⁵⁸ This section also addresses related SPC measures, including the Biotech Act proposal and the pending SPC reform proposals.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

The Regulation creates a Union-wide compulsory license, granted by the Commission rather than a court and layered on top of the 27 national regimes, that authorizes use of patented inventions without the rights holder's consent.⁵⁹ Licenses may issue once a crisis or emergency mode is declared under a Union legal act, but the triggering instruments are broad, and their activation rests with EU political institutions. The framework raises questions under Article 31 of the World Trade Organization (WTO) TRIPS Agreement, including individual-merits review, adequate remuneration, and independent judicial review, and the need for a new

⁵⁸Regulation (EU) 2025/2645 of the European Parliament and of the Council of 16 December 2025 on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006, OJ L, 30.12.2025, ELI: <http://data.europa.eu/eli/reg/2025/2645/oj>; ECTA Member Voice: Regulation (EU) 2025/2645 on Compulsory Licensing for Crisis Management, ECTA (Apr. 1, 2026), <https://ecta.org/en/latest-news-detail/news-973/ecta-member-voice-regulation-eu-20252645-on-compulsory-licensing-for-crisis-management/>.

⁵⁹Regulation (EU) 2025/2645, *supra* note 7.

mechanism is questionable given the success of voluntary licensing during the pandemic. USTR's 2026 report also records stakeholder concerns with related SPC measures, including pre-grant opposition proposals and the 2019 manufacturing waiver.⁶⁰

The proposed Biotech Act would add a 12-month SPC extension for certain biotechnology medicines only if, among other conditions, trials are conducted in more than two Member States and a manufacturing step occurs in the EU, tying IP protection to local activity.⁶¹ In September 2026, a Parliament committee backed retaining the extension and broader biosimilar stockpiling before SPC expiry.⁶²

Trade Impact

Expanded compulsory-licensing authority reduces the certainty of exclusive rights for U.S. patent holders in the EU, discourages long-term R&D investment in sectors where EU market access matters, and, given the EU's influence as a regulatory model, may encourage similar measures elsewhere.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, raise concerns about whether the Regulation's implementation will respect TRIPS Article 31 safeguards, urge the EU to construe the crisis triggers narrowly, and press the EU not to condition SPC extension on local activity or weaken SPC manufacturing-waiver safeguards.

IV. Withdrawn SEP Regulation Proposal

Foreign Measure

The Commission's 2023 proposal for a centralized administrative body to set SEP licensing terms, COM(2023) 232, which the Commission withdrew in 2025 but which remains the subject of an action brought by the European Parliament before the EU courts.⁶³

⁶⁰USTR, *supra* note 1, at 83.

⁶¹European Commission, Proposal for a Regulation to Establish Measures to Strengthen the Union's Biotechnology and Biomanufacturing Sectors (European Biotech Act), art. 27 (Dec. 16, 2025).

⁶²European Parliament Committee on Legal Affairs Backs Biosimilar Stockpiling Before Expiry of Pharmaceutical Protection, Agence Europe (reporting committee vote of Sept. 7, 2026), <https://agenceurope.eu/en/bulletin/article/13934/13/european-parliament-committee-on-legal-affairs-backs-biosimilar-stockpiling-before-expiry-of-pharmaceutical-protection>.

⁶³Proposal for a Regulation on Standard Essential Patents, COM(2023) 232 final (Apr. 27, 2023), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0232>.

NTE Category

Intellectual Property Protection and Enforcement; Competition Policy; Standards, Testing, Certification and Licensing.

Discussion

In 2023, the Commission proposed a centralized administrative body to set SEP licensing terms, which would have displaced market-based licensing negotiations without demonstrable justification. The Commission withdrew the proposal in 2025, but the European Parliament challenged the withdrawal in November 2025 (Case C-727/25), and a decision is unlikely before 2027.⁶⁴ If the court annuls the withdrawal, the proposal could return to the legislative process. Given its likely harm to standards innovation and its potential as a precedent elsewhere, it warrants continued monitoring.

Trade Impact

A revived SEP Regulation would depress licensing rates available to U.S. SEP holders in the telecommunications and connected-device sectors, reduce returns on standards-development R&D, and encourage similar administrative rate-setting elsewhere.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report and monitor the pending litigation and any revival of the proposal.

V. IPRED Review and Availability of Injunctive Relief

Foreign Measure

The Commission's review of the IPRED, including a Commission-commissioned study, published in early 2026, on IPRED's divergent application across Member States, which could inform revisions limiting injunctive relief for patent infringement.⁶⁵

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

⁶⁴Case C-727/25, European Parliament v. European Commission, Action Brought on 14 November 2025, OJ C/2026/89 (Jan. 5, 2026), <https://eur-lex.europa.eu/eli/C/2026/89/oj/eng>; see also EU SEP Regulation Battle Escalates: Parliament Brings Commission Before EU Court, Linklaters (Nov. 2025), <https://techinsights.linklaters.com/post/102lw3e/eu-sep-regulation-battle-escalates-parliament-brings-commission-before-eu-court>.

⁶⁵European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Follow-up Study on the Application of the Directive on the Enforcement of Intellectual Property Rights, Publications Office of the European Union (2026), <https://data.europa.eu/doi/10.2873/9680583>.

Discussion

The Commission's study finds significant divergence in how Member State courts apply IPRED's remedies and notes that national courts often conduct only limited proportionality assessments in patent injunction cases.⁶⁶ Revisions informed by the study could limit injunctive remedies for patent holders, similar in effect to the U.S. Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, which held that courts must apply a four-factor test before issuing a patent injunction rather than treating it as the presumptive remedy.⁶⁷ U.S. courts have read *eBay* more broadly than warranted, substantially curtailing injunctions and limiting small innovators' recourse against calculated infringement by larger competitors. The Department of Justice and USPTO have recently sought to correct this through Statements of Interest explaining that strong injunctive remedies are critical to a well-functioning patent system.⁶⁸

If the EU weakens injunctions through IPRED revision, it would repeat a mistake the United States is now working to correct and could set a damaging precedent given the EU's influence on other jurisdictions.

Trade Impact

Weakened injunctive relief under a revised IPRED would reduce the leverage U.S. patent holders rely on to negotiate fair licenses in the EU, lower the expected return on patent enforcement in Europe, and risk encouraging other jurisdictions to adopt similar standards.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, monitor the IPRED review closely, and share the recent U.S. experience correcting the overbroad application of *eBay* so that the EU does not repeat it.

VI. Conclusion

C4IP's principal concerns regarding the EU are the GPL's reduction of baseline RDP and expansion of patent-infringement exemptions, the expansion of compulsory-licensing authority and proposed SPC changes that would condition extension on local activity and loosen manufacturing-waiver safeguards, the pending litigation over the withdrawn SEP Regulation proposal, and the IPRED review's potential to curtail injunctive relief. Given the EU's global influence and

⁶⁶European Commission, *supra* note 14.

⁶⁷*eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), <https://supreme.justia.com/cases/federal/us/547/388/>.

⁶⁸Statement of Interest of the United States, *Collision Commc'ns, Inc. v. Samsung Elecs. Co.*, No. 2:23-cv-00587-JRG (E.D. Tex. Feb. 27, 2026), <https://www.justice.gov/atr/media/1429386/dl?inline>; Statement of Interest, *Radian Memory Sys., LLC v. Samsung Elecs. Co.*, No. 2:24-cv-1073 (E.D. Tex. June 24, 2025), <https://www.justice.gov/atr/media/1404506/dl?inline>.

the spillover effects of these policies, they warrant USTR's sustained attention.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue bilateral engagement with the EU while these processes remain unresolved.

Attachment 5

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: INDIA

I. Executive Summary

India is a major pharmaceutical manufacturing hub and an increasingly important market for U.S. innovators in biopharmaceuticals, technology, and creative content. The Council for Innovation Promotion's (C4IP) principal concerns, addressed below, fall within Intellectual Property Protection and Enforcement and Regulatory Practices: the restrictive patentability standard of Section 3(d) of the Patents Act, which denies protection to many clinically valuable incremental pharmaceutical innovations; the continued absence of regulatory data protection (RDP) and adequate trade-secret protection; a pre-grant opposition system that, despite the Patents (Amendment) Rules, 2024, still contributes to delay and uncertainty in prosecution; persistent, though improving, delays in patent litigation; and recent Delhi High Court decisions permitting biosimilar market entry despite an unexpired, valid originator patent and setting aside a standard-essential patent (SEP) royalty award. The Office of the United States Trade Representative's (USTR) 2026 Special 301 Report keeps India on the Priority Watch List and finds a continued lack of progress on many long-standing IP concerns.⁶⁹

These issues matter because India's restrictive patentability and enforcement environment directly affects U.S. biopharmaceutical companies' incentives to invest in clinical development, file patents, and launch new medicines in India, notwithstanding the reform steps USTR recognizes, including the Patents (Amendment) Rules, 2024. USTR should continue to measure India's IP framework against the standard of predictable, enforceable protection.

II. Restrictive Patentability Standard Under Section 3(d)

Foreign Measure

Section 3(d) of India's Patents Act, 1970, which bars patents on new forms of known substances absent a demonstrated significant enhancement in therapeutic efficacy.⁷⁰

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

⁶⁹USTR, 2026 Special 301 Report 61 (Apr. 30, 2026),

<https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

⁷⁰The Patents Act, 1970, No. 39 of 1970, § 3(d) (India), as amended by the Patents (Amendment) Act, 2005, <https://www.wipo.int/wipolex/en/text/128091>.

Discussion

Section 3(d) bars patents on new forms of known substances absent a demonstrated significant enhancement in therapeutic efficacy.⁷¹ In practice, it denies protection to many incremental pharmaceutical innovations, including new formulations, delivery mechanisms, and combination therapies, that benefit patients even where they do not meet India's heightened efficacy threshold. The provision narrows protection below the Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS) general patentability standard and creates a sector-specific barrier aimed at the pharmaceutical industry.

Because Section 3(d) is substantially more restrictive than the standards applied in the United States and other major markets, it discourages the incremental innovation on which much of modern pharmaceutical development depends and reduces the predictability of protection for improved formulations in India. USTR's 2026 Special 301 Report states that the United States continues to monitor the restriction on patent-eligible subject matter in Section 3(d) and its impacts, and finds that the procedural and discretionary invocation of patentability criteria has led to significant application delays and rejections across sectors.⁷²

Trade Impact

Section 3(d) narrows the patent protection available to U.S. pharmaceutical innovators in India, discourages investment in incremental-innovation research for the Indian market, and permits earlier generic competition against improved formulations than a TRIPS-consistent standard would.

Requested USTR Action

USTR should include this issue in the 2027 National Trade Estimate (NTE) Report, raise Section 3(d)'s treatment of incremental pharmaceutical innovation in bilateral engagement with India, and review the provision's consistency with India's TRIPS obligations.

III. Absence of Regulatory Data Protection and Trade-Secret Gaps

Foreign Measure

India's regulatory framework for pharmaceutical marketing authorization, which provides no RDP and inadequate protection for trade secrets submitted in connection with drug approval.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

⁷¹Patents Act, supra note 2, § 3(d).

⁷²USTR, supra note 1, at 61.

Discussion

India provides no RDP and inadequate trade-secret protection for pharmaceutical products, undermining incentives to conduct clinical trials or launch new medicines there. This gap raises concerns under Article 39.3 of the TRIPS Agreement, which requires members to protect undisclosed test data submitted to approve pharmaceutical products against unfair commercial use.⁷³ USTR's 2026 report records stakeholder concern about whether India effectively protects such data against unfair commercial use and unauthorized disclosure.⁷⁴ It also finds that no civil or criminal laws in India specifically address trade-secret protection, that criminal penalties are not expressly available, that civil remedies reportedly are difficult to obtain and lack deterrent effect, and that stakeholders have highlighted requirements to disclose source code for telecom equipment undergoing certification.

The Law Commission of India recommended sui generis trade-secret legislation in March 2024,⁷⁵ and the Department for Promotion of Industry and Internal Trade consulted industry in 2025, but no such legislation has been adopted.⁷⁶ Without RDP and effective trade-secret protection, competitors can rely on an originator's clinical-trial data to secure approval without bearing the cost of generating it, which discourages innovators from running trials or launching new medicines in India.

Trade Impact

The absence of RDP reduces the incentive for U.S. companies to generate clinical data for Indian approval or to launch promptly, lets follow-on competitors free-ride on U.S.-generated data, and depresses U.S. pharmaceutical exports and licensing revenue tied to India.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, encourage India to adopt a functioning RDP framework and effective trade-secret protection, and review India's framework for consistency with TRIPS Article 39.3.

IV. Pre-Grant Opposition System and Patent Litigation Delay

Foreign Measure

India's pre-grant opposition system under Section 25(1) of the Patents Act, 1970, as modified by the Patents (Amendment) Rules, 2024, which lets third parties challenge applications at early stages of examination, and the pace of patent-

⁷³Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, 1869 U.N.T.S. 299.

⁷⁴USTR, *supra* note 1, at 61, 63.

⁷⁵Law Comm'n of India, Report No. 289, Trade Secrets and Economic Espionage (Mar. 2024), https://delhihighcourt.nic.in/files/2025-05/reports/289_lcir_part_1.pdf.

⁷⁶USTR, *supra* note 1, at 63.

infringement litigation outside India's fast-track forums.⁷⁷

NTE Category

Intellectual Property Protection and Enforcement; Transparency and Rule of Law.

Discussion

India's pre-grant opposition system, though intended to promote patent quality, allows third parties to challenge applications repeatedly at early stages, frequently producing protracted proceedings and repeated review cycles that delay meritorious patents and create prosecution uncertainty for applicants, including U.S. biopharmaceutical and technology companies.⁷⁸ USTR's 2026 Special 301 Report likewise finds that applicants face long waits for grants, excessive reporting requirements, and frequent, protracted pre-grant opposition procedures, and encourages India to continue reforms to reduce patent pendency.⁷⁹

The Patents (Amendment) Rules, 2024, issued on March 15, 2024, took a welcome step by requiring the Controller to assess whether an opposition is maintainable before it proceeds.⁸⁰ Gaps remain, however. Section 25(1) still allows any person to oppose before grant, and the 2024 Rules do not appear to require a legitimate interest, set a filing deadline, or limit serial challenges.

Despite improvement in fast-track forums, trial duration varies widely elsewhere in India, and timelines outside those forums remain lengthy and unpredictable. USTR's 2026 report welcomed the 2024 establishment of additional Intellectual Property Divisions at the High Courts, bringing the total to four, and encourages the allocation of resources for education and staffing.⁸¹

Trade Impact

Prosecution delay from repeated pre-grant oppositions, combined with unpredictable litigation timelines outside fast-track forums, raises the cost and uncertainty of obtaining and enforcing patents in India and discourages U.S. companies from seeking timely protection there.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, encourage India to build on the 2024 Rules by streamlining pre-grant opposition procedures, including a legitimate-interest requirement and time limits for filing, to prevent abuse of

⁷⁷The Patents Act, 1970, No. 39 of 1970, § 25(1) (India), <https://www.wipo.int/wipolex/en/text/128091>.

⁷⁸Patents Act, supra note 9, § 25(1).

⁷⁹USTR, supra note 1, at 61.

⁸⁰The Patents (Amendment) Rules, 2024 (India) (issued Mar. 15, 2024), <https://www.wipo.int/wipolex/en/legislation/details/23105>.

⁸¹USTR, supra note 1, at 62.

repeated challenges, and encourage continued expansion of fast-track patent litigation forums nationwide.

V. Delhi High Court Decisions and Patent Enforcement Predictability

Foreign Measure

The January 12, 2026, decision of the Division Bench of the Delhi High Court in *Zydus Lifesciences Ltd. v. E.R. Squibb and Sons, LLC*, overturning a preliminary injunction and permitting Zydus to market a nivolumab biosimilar notwithstanding Bristol Myers Squibb's then-unexpired Indian patent,⁸² and its May 18, 2026, decision in *K.K. Bansal v. Koninklijke Philips Electronics N.V.*, setting aside a royalty and damages award for standard-essential patents (SEPs).⁸³

NTE Category

Intellectual Property Protection and Enforcement; Transparency and Rule of Law.

Discussion

In *Zydus Lifesciences Ltd. v. E.R. Squibb and Sons, LLC*, the Division Bench reversed a preliminary injunction that had blocked Zydus from launching its nivolumab biosimilar, ZRC-3276, finding that biosimilarity alone did not establish infringement and that the public interest in lower-cost access favored lifting the injunction with the patent due to expire within months. Zydus was ordered to file audited accounts of its sales until expiration.⁸⁴ Decisions of this kind weaken confidence in patent protection and risk signaling to follow-on manufacturers that market entry may proceed despite unresolved disputes, undermining the expectation that a valid, unexpired patent will be enforced. USTR's 2026 Special 301 Report compounds the concern: it notes that India has no system to notify a patent holder before a follow-on product is marketed, and that pharmaceutical stakeholders question whether India has an effective mechanism for early resolution of patent disputes.⁸⁵

Standard-essential patent (SEP) enforcement faces similar uncertainty. In *K.K. Bansal v. Koninklijke Philips Electronics N.V.*, Philips had enforced DVD-standard patents against Indian manufacturers and obtained a decree for fair, reasonable, and non-discriminatory (FRAND) royalties and damages. In May 2026, the Division Bench set the award aside, finding that Philips had not proved essentiality and that

⁸²*Zydus Lifesciences Ltd. v. E.R. Squibb and Sons, LLC*, FAO(OS) (COMM) 120/2025 (Del. High Ct. Div. Bench Jan. 12, 2026), <https://indiankanoon.org/doc/104456244/>.

⁸³*K.K. Bansal v. Koninklijke Philips Electronics N.V.* (Del. High Ct. Div. Bench May 18, 2026), <https://indiankanoon.org/doc/183478356/>.

⁸⁴*Zydus Lifesciences Ltd.*, *supra* note 14.

⁸⁵USTR, *supra* note 1, at 61.

its patent rights were exhausted under Indian law.⁸⁶ Philips has sought special leave to appeal. The Supreme Court heard the matter on October 27, 2026, and listed it for arguments on December 1, 2026. Because the case bears on how Indian courts set and review SEP royalties, its outcome may have global implications for rate setting.

Trade Impact

Reduced predictability in enforcing valid patents against biosimilar entry discourages U.S. biopharmaceutical companies from relying on Indian patent protection, weakens the incentive to launch innovative biologics in India, and risks a precedent other follow-on manufacturers may exploit. Uncertainty over evidentiary and exhaustion standards likewise complicates SEP holders' ability to recover FRAND royalties from implementers.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, raise the predictability of injunctive relief for valid patents in bilateral engagement, encourage India's judiciary to apply consistent standards to requests to enjoin infringing biosimilar entry, encourage India to establish a system for notifying patent holders before follow-on products are marketed, and closely monitor the Supreme Court's review of the Philips SEP decision, which may have global implications for rate setting.

VI. Conclusion

C4IP's principal concerns regarding India are the restrictive patentability standard under Section 3(d), the absence of regulatory data protection and adequate trade-secret protection for pharmaceutical products, continued delay from the pre-grant opposition system despite the Patents (Amendment) Rules, 2024 and from litigation outside fast-track forums, and reduced predictability in patent enforcement illustrated by recent Delhi High Court biosimilar and SEP decisions. C4IP recognizes that India has taken steps to improve its IP framework, including the Patents (Amendment) Rules, 2024 and additional High Court IP Divisions that USTR has welcomed, but significant deficiencies remain.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue its engagement with India toward effective, predictable, and reliable IP protection.

⁸⁶K.K. Bansal, *supra* note 15.

Attachment 6

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: MEXICO

I. Executive Summary

Mexico is a treaty partner under the United States-Mexico-Canada Agreement (USMCA) and a major market and manufacturing partner for U.S. biopharmaceutical and other IP-intensive industries. While the Office of the United States Trade Representative's (USTR) 2026 Special 301 Report moved Mexico from the Priority Watch List to the Watch List, it noted concerns that the Council for Innovation Promotion (C4IP) also highlighted in its 2026 Special 301 comments recommending that Mexico remain on the Priority Watch List.⁸⁷ Those concerns, addressed below, fall within Intellectual Property Protection and Enforcement and Transparency and Rule of Law: incomplete patent linkage; the scope and consistent implementation of the April 2026 regulations, including their treatment of new uses and clinical-trial time; the lack of notice to patent holders before generic or biosimilar approval; and enforcement gaps against counterfeiting and piracy, including the lack of criminal prosecutions and of ex officio authority for border officials.

These issues matter because Mexico's USMCA commitments were negotiated to set a predictable, enforceable floor of IP protection among the three parties, and implementation gaps undermine that bargain for U.S. innovators. The July 2026 joint review ended without a U.S. decision to extend the agreement, which triggers annual reviews through 2036; those reviews, including the one now being prepared for 2027, give USTR a recurring opportunity to assess Mexico's compliance and help lock in the progress Mexico has made.⁸⁸

II. Incomplete Patent Linkage Implementation

Foreign Measure

Mexico's patent-linkage system governing the relationship between patent status and marketing authorization for generic and biosimilar pharmaceuticals, and

⁸⁷USTR, 2026 Special 301 Report 86 (Apr. 30, 2026), <https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>; C4IP, 2026 Special 301 Comments, Docket No. USTR-2025-0243, at 12-13 (Jan. 28, 2026).

⁸⁸USTR, Ambassador Greer Issues Statement on the USMCA Joint Review (July 1, 2026), <https://ustr.gov/about/policy-offices/press-office/press-releases/2026/july/ambassador-greer-issues-statement-usmca-joint-review>.

Mexico's commitments under USMCA Chapter 20 (Intellectual Property Rights).⁸⁹

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

USTR's 2026 report credits Mexico's October 2025 inclusion of use patents in the Industrial Property Gazette as addressing one aspect of the early-resolution concern, but states that other concerns remain and that the United States continues to be concerned about the lack of an effective system for early resolution of potential pharmaceutical disputes.⁹⁰ An effective linkage system keeps regulators from approving a generic or biosimilar that would infringe an unexpired patent and gives the patent holder a meaningful chance to enforce its rights before infringing competition reaches the market, as Mexico's USMCA commitments contemplate.⁹¹ Mexico's implementation has not yet given U.S. patent holders that opportunity consistently: they still lack a clear right to notice and to present facts to Mexican Institute of Industrial Property (IMPI) before approval, and the listing of use patents needs a durable legal framework.⁹²

Trade Impact

Incomplete linkage exposes U.S. patent holders to premature generic and biosimilar competition in Mexico, eroding the value of U.S.-origin pharmaceutical patents in a major regional market and discouraging early launch and continued R&D investment.

Requested USTR Action

USTR should include this issue in the 2027 National Trade Estimate (NTE) Report, acknowledge Mexico's progress, press Mexico to complete an effective patent-linkage system, including secondary regulations that formalize the listing of use patents and give patent holders notice and an opportunity to respond before approval, and review its implementation for consistency with Mexico's USMCA commitments, including through the annual USMCA joint review process.

III. Implementation of Regulatory Data Protection and Patent Term Extension

⁸⁹Agreement Between the United States of America, the United Mexican States, and Canada, ch. 20 (July 1, 2020), <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between>.

⁹⁰USTR, *supra* note 1, at 86.

⁹¹USMCA, *supra* note 3, ch. 20.

⁹²C4IP, *supra* note 1, at 3, 13.

Foreign Measure

Mexico's April 2026 amended regulations on pharmaceutical test-data protection and patent term extension, including the scope of their coverage, following a period in which requests for regulatory data protection were reported to be rejected or inconsistently granted.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

USTR's 2026 report notes that, in April 2026, Mexico issued amended regulations providing protection against unfair commercial use and unauthorized disclosure of test data for pharmaceutical and agricultural chemical products, and establishing a system of patent term extensions for unreasonable marketing approval delays.⁹³ C4IP welcomes these steps, which respond directly to long-standing concerns. The regulations were published on April 24, 2026, and took effect the next day, but the Ministry of Health has 180 days to complete its regulatory and administrative adjustments. The decree does not specify how the “unreasonable delay” that qualifies a patent for extension will be calculated, and it provides no new funding.⁹⁴ The priority now is careful, consistent implementation. Before the amendments, drugmakers' requests for data exclusivity were often rejected or inconsistently granted,⁹⁵ and inconsistent application would undermine the predictability the new rules are meant to provide and the incentive to generate clinical data for Mexican approval, raising concerns under USMCA and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 39.3.⁹⁶

Scope is the first open question. The amended regulations protect data for five years only for a “new molecule,” meaning a substance with no prior Mexican registration.⁹⁷ That may exclude important innovations, including new uses of known molecules, and the regulations do not clearly say. Clarity on scope is essential to the predictability the reforms are meant to deliver.

Patent term extension raises a related question. As described, it compensates only for unreasonable health-authority delay, counted from the filing of the marketing authorization application, and is capped at five years.⁹⁸ Clinical-trial time appears

⁹³USTR, *supra* note 1, at 86.

⁹⁴Decreto por el que se reforman y adicionan diversas disposiciones del Reglamento de Insumos para la Salud, D.O.F., Apr. 24, 2026 (Mex.), https://dof.gob.mx/nota_detalle.php?codigo=5785957&fecha=24/04/2026.

⁹⁵C4IP, *supra* note 1, at 5.

⁹⁶Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights art. 39.3, Apr. 15, 1994, 1869 U.N.T.S. 299.

⁹⁷Decreto, *supra* note 8, arts. 2(XV), 167 Bis.

⁹⁸Decreto, *supra* note 8.

to fall outside its scope, unlike U.S. practice, which credits half the testing phase.⁹⁹ That may not fully address Mexico's USMCA commitment on unreasonable curtailment of patent term.¹⁰⁰

Trade Impact

If the new rules are applied unpredictably or read narrowly, U.S. companies will have less incentive to invest in clinical trials supporting Mexican approval and in new uses, follow-on competitors may rely on U.S.-generated data without the certainty RDP should provide, lost patent life will go uncompensated, and pharmaceutical exports and licensing revenue tied to Mexico will suffer.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, recognize the April 2026 regulations as significant progress, urge Mexico to clarify the scope of data protection, including for new uses, and to consider crediting clinical-trial time toward patent term extension, as U.S. practice does, and monitor their implementation closely to ensure that test-data protection and patent term extensions are applied clearly and consistently, consistent with USMCA and TRIPS Article 39.3.

IV. Notice Failures to Patent Holders and Counterfeiting and Piracy Enforcement

Foreign Measure

Mexico's regulatory notification practices for generic and biosimilar approvals, and its border, administrative, and criminal enforcement against counterfeit and pirated goods, including the lack of ex officio authority for border officials and the absence of reported criminal IP prosecutions.

NTE Category

Intellectual Property Protection and Enforcement; Transparency and Rule of Law.

Discussion

Mexico does not give patent holders proper notice before a generic or biosimilar product is marketed, depriving them of the chance to assess and, where appropriate, enforce their rights before a potentially infringing product reaches the market.¹⁰¹ This compounds the incomplete linkage described above, because patent holders may not learn of an approaching generic or biosimilar entry in time to seek relief.

⁹⁹35 U.S.C. § 156(c)(2).

¹⁰⁰USMCA, supra note 3, art. 20.46.

¹⁰¹C4IP, supra note 1, at 3, 13.

USTR's 2026 report finds that Mexico continues to suffer from widespread importation, manufacture, sale, and transshipment of counterfeit goods, that the Notorious Markets-listed El Santuario, Mercado San Juan de Dios, and Tepito continue to flourish, that IMPI's administrative actions are limited by budget cuts and staffing reductions, and that criminal investigations and prosecutions appear to be non-existent, with the Attorney General's Office reporting no IP enforcement statistics in six years and reportedly imposing an internal ban on seeking search warrants in IP cases.¹⁰² USTR welcomes the March 2026 IMPI-ANAM (National Customs Agency of Mexico) coordination agreement as a step toward addressing the lack of ex officio authority for border officials and the December 2025 appointment of a specialized IP prosecutor, and encourages Mexico to restore enforcement funding, improve coordination, prosecute more IP cases, and impose deterrent-level penalties. Through the annual USMCA joint review process, USTR should press Mexico to follow through, because counterfeit goods undermine legitimate trade, harm rights holders in all three USMCA countries, and erode confidence in the agreement.

Trade Impact

Inadequate notice and weak criminal, administrative, and border enforcement reduce the practical value of IP rights for U.S. companies in Mexico, discourage reliance on Mexican regulatory and enforcement processes, and depress exports, licensing revenue, and investment tied to IP-intensive products.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Mexico to adopt an effective pre-marketing notice requirement, secure ex officio authority for border officials, restore enforcement funding, prosecute more IP cases, and impose deterrent-level penalties, and use the annual USMCA joint review process, including the 2027 review, to secure full implementation of Mexico's IP commitments.

V. Conclusion

C4IP's principal remaining concerns regarding Mexico are incomplete patent linkage, the need for clarity on the scope and consistent implementation of the April 2026 data-protection and patent-term-extension regulations, including for new uses and clinical-trial time, inadequate notice to patent holders, and weak criminal, administrative, and border enforcement against counterfeiting and piracy. C4IP recognizes, as USTR's 2026 Special 301 Report does, that Mexico has taken meaningful steps forward, and believes continued engagement can consolidate that

¹⁰²USTR, *supra* note 1, at 86-87.

progress as the annual USMCA review process continues.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue its engagement with Mexico to secure full implementation of its USMCA intellectual-property commitments.

Attachment 7

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: UNITED KINGDOM

I. Executive Summary

The United Kingdom (UK) is a close U.S. ally with a longstanding, market-based approach to standard-essential patent (SEP) licensing. The Council for Innovation Promotion (C4IP) welcomes the UK Government's October 13, 2026, response to its 2025 SEP consultation that it will not introduce a Rate Determination Track or a United Kingdom Intellectual Property Office Intellectual Property Office (UKIPO) essentiality-checking service, will make no legislative change on injunctive relief, and will make provision of SEP information voluntary.¹⁰³ These decisions reflect the UK's long record of constructive engagement with its trading partners on trade and IP concerns. Two issues remain, both within Intellectual Property Protection and Enforcement, Competition Policy, and Standards, Testing, Certification and Licensing. First, UK courts' use of “interim licenses” and platform-licensing declarations draws global SEP disputes into UK proceedings without the patent holder's consent, as in *Acer, Hisense & ASUS v. Nokia* and *Tesla v. InterDigital*. Second, the Government's follow-on measures, and any future move to mandatory disclosure, should remain voluntary, balanced, and non-binding. Because those measures are still being designed, timely U.S. engagement offers a low-cost opportunity to keep the UK's market-based approach intact.

II. Interim Licensing Practices and Global SEP Rate-Setting Without Consent

Foreign Measure

UK courts' use of “interim licenses” and platform-licensing declarations in SEP disputes, as illustrated by *Acer, Hisense & ASUS v. Nokia Technologies Oy*, [2025] EWHC 3331 (Pat), and *Tesla, Inc. v. InterDigital Patent Holdings, Inc.*, [2026] UKSC 27 (July 27, 2026).¹⁰⁴

NTE Category

Intellectual Property Protection and Enforcement; Standards, Testing, Certification and Licensing.

¹⁰³Intellectual Property Office, Government Response to the Consultation on Standard Essential Patents (Oct. 13, 2026), <https://www.gov.uk/government/consultations/consultation-on-standard-essential-patents-seps/outcome/government-response-to-the-consultation-on-standard-essential-patents>.

¹⁰⁴*Tesla, Inc. v. InterDigital Patent Holdings, Inc.*, [2026] UKSC 27 (July 27, 2026), <https://supremecourt.uk/cases/judgments/uksc-2025-0058>; Press Summary, <https://caselaw.nationalarchives.gov.uk/uksc/2026/27/press-summary>.

Discussion

UK courts increasingly use interim licenses and platform-licensing declarations to draw global SEP disputes into the United Kingdom, constraining patent holders' ability to enforce their rights elsewhere. In December 2025, the Patents Court in *Acer, Hisense & ASUS v. Nokia Technologies Oy* granted implementers an interim reasonable and non-discriminatory (RAND) license declaration in a dispute over SEPs essential to the H.264/AVC and H.265/HEVC video-coding standards.¹⁰⁵ As in Chinese courts, the implementers, not the patent owners, initiated the proceedings.

On July 27, 2026, the Supreme Court held in *Tesla v. InterDigital* that Tesla has a real prospect of establishing that the only fair, reasonable, and non-discriminatory (FRAND) license available for InterDigital's UK SEPs is a global license through Avanci's platform, and that Tesla may seek declarations against InterDigital and Avanci without joining every participating SEP owner.¹⁰⁶ The decision expands UK courts' claimed authority over global SEP licensing. It parallels the extraterritorial rate-setting of Chinese courts, such as the Supreme People's Court's 2024 decision in *TCL v. Access Advance*, and compounds the harm to U.S. patent holders.¹⁰⁷ The Government's October 2026 response does not address these practices, so the concern remains, and the courts' approach will largely determine whether UK SEP jurisdiction stays market-based.¹⁰⁸

Trade Impact

UK courts' assertion of authority over global SEP licensing rates without patent-holder consent reduces licensing revenue for U.S. innovators in wireless and connected-device sectors and risks setting worldwide terms to which U.S. patent holders never agreed.

Requested USTR Action

The Office of the United States Trade Representative (USTR) should include this issue in the 2027 National Trade Estimate (NTE) Report, raise concerns about UK courts' use of interim licenses and platform-licensing declarations in bilateral engagement, and monitor *Tesla v. InterDigital* following the Supreme Court's remand.

¹⁰⁵*Acer, Hisense & ASUS v. Nokia Technologies Oy*, [2025] EWHC 3331 (Pat); UK High Court Issues Interim RAND License Declaration in *Acer, Hisense and ASUS v. Nokia*, Cleary Gottlieb (Dec. 19, 2025), <https://www.clearygottlieb.com/news-and-insights/publication-listing/uk-high-court-issues-interim-rand-license-declaration-in-acer-hisense-and-asus-v-nokia>.

¹⁰⁶*Tesla*, supra note 2.

¹⁰⁷*TCL Commc'n Tech. Holdings Ltd. v. Access Advance LLC*, Supreme People's Court of China (2024); China Has Jurisdiction over SEP Rates for Foreign Patent Pools, Kangxin Partners (2024), <https://en.kangxin.com/html/2/215/217/24655.html>.

¹⁰⁸UK IPO, supra note 1.

III. Government Follow-On Measures and Preserving the Market-Based Approach

Foreign Measure

The UK Government's October 13, 2026 response to the UKIPO's 2025 SEP consultation, including its follow-on measures.¹⁰⁹

NTE Category

Intellectual Property Protection and Enforcement; Competition Policy; Standards, Testing, Certification and Licensing.

Discussion

C4IP welcomes the Government's decisions not to introduce the Rate Determination Track proposed in the UKIPO's 2025 consultation, under which non-judicial specialists would have set royalty rates for an SEP holder's entire global portfolio, or an IPO essentiality-checking service. C4IP also welcomes the decisions to make no legislative change on injunctive relief and to make provision of SEP information to the IPO voluntary and prospective.¹¹⁰ These decisions preserve the market-based licensing framework and avoid a troubling precedent in which a national forum could license a foreign company's entire portfolio without consent.

Several follow-on measures warrant attention so that the UK's market-based approach is not further limited. The Government will work with the judiciary on an early, court-anchored evaluation process, and states that it would not create a standalone rate-setting forum. C4IP welcomes that statement. Options under consideration include a stay of proceedings and costs consequences for non-engagement. Any such process should remain voluntary and should not pressure patent holders into early evaluation that constrains enforcement elsewhere. The Government will also develop non-binding FRAND licensing and good-faith negotiation guidelines. These should apply even-handedly to implementers and patent holders, to avoid shifting FRAND toward an administratively guided model.

The Government may consider mandatory disclosure or sanctions if future evaluation shows significant non-compliance with voluntary provision of SEP information. Any transparency measures should not burden SEP holders without matching obligations on implementers. The Government will also assess the feasibility of a voluntary, non-binding IPO-led FRAND opinion service. USTR should monitor that process to ensure any such service does not determine liability or impose a binding global rate.

¹⁰⁹UK IPO, *supra* note 1; see also Intellectual Property Office, Consultation on Standard Essential Patents (2025), <https://www.gov.uk/government/consultations/consultation-on-standard-essential-patents-seps>.

¹¹⁰UK IPO, *supra* note 1.

Trade Impact

Follow-on measures that acquire normative weight, or pressure patent holders into early evaluation or disclosure, could shift bargaining leverage toward implementers in negotiations touching the UK market, even without formal regulatory force.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, acknowledge the Government's October 2026 decisions, and encourage the UK to keep its FRAND guidelines, any early determination process, and any opinion service voluntary, non-binding, and balanced, and to keep SEP information voluntary rather than moving to mandatory disclosure or sanctions.

IV. Conclusion

C4IP commends the UK Government's October 2026 decisions, which reflect the UK's longstanding record of constructive engagement on trade and IP concerns. Two concerns remain: UK courts' use of interim licensing and platform-licensing declarations to assert global SEP rate-setting authority, and the design of the follow-on measures, including any move to mandatory disclosure. Because those measures are still being developed, near-term engagement offers a genuine opportunity to prevent lasting harm.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue its constructive engagement with the United Kingdom to encourage alignment of these measures with market-based licensing principles.

Attachment 8

Comments Regarding Foreign Trade Barriers to U.S. Exports for 2027 Reporting: VIETNAM

I. Executive Summary

Vietnam is a fast-growing export and investment destination and an increasingly significant market for U.S. IP-intensive industries, including pharmaceuticals, entertainment, and consumer goods. The Office of the United States Trade Representative's (USTR) 2026 Special 301 Report identified Vietnam as a Priority Foreign Country.¹¹¹ The Council for Innovation Promotion's (C4IP) principal concerns, detailed below, fall within Intellectual Property Protection and Enforcement, Regulatory Practices, and Investment Barriers: widespread counterfeiting amid a sharp decline in enforcement; large-scale online piracy that recent convictions have failed to deter; gaps in the biopharmaceutical IP framework, including patent-grant delays, limited patent enforcement, the absence of patent term restoration, and uncertain implementation of regulatory data protection and patent linkage; and provisions of the 2025 IP reforms that warrant monitoring despite genuine progress elsewhere in that legislation.

These issues matter because Vietnam's \$30 billion-plus e-commerce market, its role as a base for piracy operations with global reach, and its growing manufacturing and investment ties to U.S. companies give IP gaps there consequences well beyond its borders. C4IP recognizes Vietnam's recent reforms as encouraging first steps and urges USTR to evaluate Vietnam on concrete, verifiable improvements. C4IP's July 2, 2026, comments in USTR's Section 301 investigation develop these concerns and are incorporated by reference here.¹¹²

II. Counterfeiting and the Decline in Enforcement

Foreign Measure

The enforcement practices of Vietnam's market-surveillance and customs authorities against counterfeit goods sold through physical markets, e-commerce platforms, and livestream commerce, and the administrative-penalty regime applicable to e-commerce violations.

¹¹¹USTR, 2026 Special 301 Report 43 (Apr. 30, 2026), <https://ustr.gov/sites/default/files/files/Press/Releases/2026/2026%20Special%20301%20Report.pdf>.

¹¹²Council for Innovation Promotion, Comments Re: USTR Section 301 Investigation of Vietnam's Acts, Policies, and Practices Related to IP Protection and Enforcement, Docket No. USTR-2026-0364 (July 2, 2026), https://c4ip.org/wp-content/uploads/2026/07/C4IP-Comments-Re_-USTR-Section-301-Investigation-of-Vietnam-IP-Practices.pdf.

NTE Category

Intellectual Property Protection and Enforcement; Digital Trade.

Discussion

Counterfeit goods, both local and imported, remain openly sold in Vietnam's physical markets and increasingly through e-commerce and livestream commerce, including fraudulent listings for counterfeit milk, food, and supplements that pose health and safety risks.¹¹³ Vietnam's e-commerce market passed \$30 billion in 2025, and authorities handled more than 23,400 counterfeit cases that year, mostly on e-commerce platforms and social media, spanning cosmetics, apparel, footwear, electronics, and, of particular public-health concern, supplements and medicines.¹¹⁴ Enforcement has uncovered large operations, including a Hanoi warehouse holding roughly 2,000 counterfeit handbags and repeated raids on hubs such as Saigon Square,¹¹⁵ and authorities have prosecuted large fake-milk operations.¹¹⁶

Enforcement has also gone backward. USTR's Section 301 initiation notice and its 2026 Special 301 Report both find that violations involving IP-infringing goods and goods of unknown origin or inferior quality fell by roughly 50% in 2025 from 2024, despite multiple campaigns.¹¹⁷ The report attributes the decline to the 2025 government reorganization, which restructured the Market Surveillance Agency and moved most of its enforcement work to local authorities, leaving gaps that counterfeit sellers have exploited. Independent reporting is consistent: detected market violations were roughly 31.8% lower in 2025, and the responsible agency acknowledged that restructuring disrupted personnel and management continuity while e-commerce penalties remained too low.¹¹⁸ The reorganization eliminated and streamlined ministries.¹¹⁹ At the border, USTR adds, Vietnam Customs has had ex officio authority to suspend procedures for suspected counterfeit goods since 2022

¹¹³USTR, *supra* note 1, at 44-45.

¹¹⁴Growing E-Commerce Market Sees Tougher Fight Against Counterfeits, Vietnam+ (Dec. 24, 2025), <https://en.vietnamplus.vn/growing-e-commerce-market-sees-tougher-fight-against-counterfeits-post334831.vnp>.

¹¹⁵Vietnam Cracks Down on 23,000 Market Violations in 2025, Vietnam+ (Dec. 18, 2025), <https://en.vietnamplus.vn/vietnam-cracks-down-on-23000-market-violations-in-2025-post334511.vnp>.

¹¹⁶Hiếu Mạnh, The Blame Game: Who Is Responsible for Việt Nam's Counterfeit Crisis?, The Vietnamese Mag. (July 8, 2025), <https://www.thevietnamese.org/2025/07/the-blame-game-who-is-responsible-for-viet-nams-counterfeit-crisis/>.

¹¹⁷Initiation of Section 301 Investigation and Request for Public Comments: Vietnam's Acts, Policies, and Practices Related to IP Protection and Enforcement, 91 Fed. Reg. 33,285, 33,286 (June 3, 2026).

¹¹⁸Vietnam+, *supra* note 5.

¹¹⁹USDA Foreign Agric. Serv., GAIN Report No. VM2025-0009, Vietnam: Government Restructuring (Mar. 13, 2025), https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Vietnam+Government+Restructuring+-+Major+Changes+and+Expected+Impacts_Hanoi_Vietnam_VM2025-0009.pdf.

but has rarely used it, and has no such authority over goods in transit.¹²⁰

Trade Impact

Declining enforcement displaces legitimate U.S. exports of branded consumer goods, apparel, electronics, and pharmaceuticals in Vietnam's e-commerce market, exposes consumers in Vietnam and in transshipment markets to unsafe counterfeit food, supplements, and medicines, and erodes U.S. brand owners' ability to rely on the Vietnamese market while enforcement capacity is rebuilt.

Requested USTR Action

USTR should include this issue in the 2027 National Trade Estimate (NTE) Report, press Vietnam to restore and exceed pre-reorganization enforcement levels, close coordination gaps among its consolidated agencies, use Customs' ex officio authority, and encourage a shift from low-deterrence administrative penalties toward civil and criminal remedies for e-commerce counterfeiting.

III. Online Copyright Piracy and Inadequate Criminal Deterrence

Foreign Measure

Vietnam's criminal-enforcement regime for online copyright infringement, including the penalties imposed in its first criminal copyright convictions and the pace of subsequent criminal referrals.

NTE Category

Intellectual Property Protection and Enforcement; Digital Trade.

Discussion

Vietnam remains one of the world's most significant sources of online piracy. USTR's 2026 report finds that Vietnam has the highest incidence of online piracy in the Asia-Pacific region, high levels of music piracy, and ranks eighth worldwide for certain mobile video-game piracy, and that it hosts English-language infringement sites and a locally operated cyberlocker serving a global audience.¹²¹ The report cites MegaCloud, which reportedly delivers more than 46,000 movies and 16,000 TV series to over 260 pirate sites, and MyFlixerz, which drew more than 622 million visits in August 2025. Vietnam's government estimates that more than 400 Vietnamese websites stream tens of thousands of films without authorization, and industry survey data indicate roughly two-thirds of internet users aged 16 to 44 regularly pirate music.¹²² Vietnam was also the base for some of the largest piracy

¹²⁰USTR, *supra* note 1, at 45; C4IP, *supra* note 2, Part I.

¹²¹USTR, *supra* note 1, at 43-44.

¹²²Vietnam's Domestic Film Piracy Problem Underlines the Country's Wider Copyright Problem, Lexology (Nov. 26, 2025), <https://www.lexology.com/library/detail.aspx?g=edb88c5a-bea5-4b92-9548-e2da35aec6a2>; Ernesto Van der Sar, Rightsholders Brand Vietnam an Online Piracy Haven & Demand Action, TorrentFreak

services ever taken down, including Fmovies.¹²³

The core problem is weak deterrence. Vietnam's first criminal copyright convictions came in 2024, including against the operator of BestBuyIPTV, a platform on USTR's Notorious Markets List for five consecutive years, but courts imposed only a suspended sentence and modest fines, with similarly light penalties on associated operators three months later.¹²⁴ USTR's 2026 report makes the same point about Fmovies: over prosecutors' objections, the court imposed suspended sentences and criminal fines of about \$2,700 and \$770, and USTR urges more criminal cases and penalties at the higher levels Vietnamese law allows. It also cites unclear criminal thresholds under the 2015 Penal Code amendments, uncertainty over handling digital evidence and domain names, and continued reliance on administrative enforcement, with right holders facing informal pressure to pursue administrative complaints. USTR acknowledges recent takedowns, including Y2Mate and 11 other stream-ripping sites in 2025 and Xoilac TV and R*phim in 2026, and hopes the uptick in prosecutions continues.¹²⁵ Vietnamese authorities, however, did not begin a further round of criminal referrals until May 2026, immediately after the Priority Foreign Country identification, and none has yet produced a conviction, suggesting that enforcement has been reactive to U.S. pressure.¹²⁶

Trade Impact

Weak criminal penalties for commercial-scale piracy depress licensing and subscription revenue for U.S. film, music, and video-game rights holders, allow Vietnam-based piracy operations to keep serving a global audience that includes U.S. consumers, and undermine legitimate U.S. digital-content services in Vietnam.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, press Vietnam to impose deterrent-level penalties for commercial-scale piracy, and encourage significantly more prosecutions of piracy operators.

(Feb. 5, 2024), <https://torrentfreak.com/rightsholders-brand-vietnam-an-online-piracy-haven-demand-action-240205/>.

¹²³Todd Spangler, Fmovies, a Massive Internet Piracy Ring, Is Shut Down by Police in Vietnam, *Variety* (Aug. 29, 2024), <https://variety.com/2024/digital/news/fmovies-shut-down-piracy-vietnam-police-1236114171/>.

¹²⁴Espe Angelica A. de Leon, Vietnam's First Criminal Sentence for Online Copyright Infringement, *Asia IP* (May 23, 2024), <https://asiaiplaw.com/article/vietnams-first-criminal-sentence-for-online-copyright-infringement>; ACE Commends Vietnamese Court and Local Law Enforcement for Second Conviction of Illegal Streaming Service Operators, *Alliance for Creativity & Entm't* (July 26, 2024), <https://www.alliance4creativity.com/statement/ace-commends-vietnamese-court-and-local-law-enforcement-for-second-conviction-of-illegal-streaming-service-operators/>.

¹²⁵USTR, *supra* note 1, at 44, 46.

¹²⁶Criminal Proceedings Launched Against Copyright Infringement, *Vietnam+* (May 16, 2026), <https://en.vietnamplus.vn/criminal-proceedings-launched-against-copyright-infringement-post342899.vnp>; C4IP, *supra* note 2, Part II.

IV. Gaps in Vietnam's Biopharmaceutical IP Framework

Foreign Measure

Vietnam's biopharmaceutical IP framework, including patent-grant delays, weak enforcement, no patent term adjustment (PTA) or restoration, no operative patent linkage despite CPTPP commitments, new pre-grant challenge procedures, and uncertain implementation of regulatory data protection under Article 128 of the IP Law and Circular No. 32/2026/TT-BYT.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

Discussion

Innovators continue to report lengthy waits for patent grants in Vietnam, despite the examination reforms discussed in Part V. Vietnam has no effective patent enforcement mechanism and does not adjust patent terms to offset grant delays, shortening the term actually available. The 2022 IP Law amendments were meant to close these gaps but appear to fall short, and they added pre-grant opposition and stronger third-party observations on top of post-grant challenges, increasing uncertainty for applicants.¹²⁷

Vietnam's regulatory data protection (RDP) regime has been limited and not automatic: it has reached only a “new active ingredient” not marketed anywhere in the world for more than twelve months before the Vietnamese filing, and protection has had to be requested.¹²⁸ Article 128 of the IP Law now sets five years of protection on paper, and Circular No. 32/2026/TT-BYT, effective October 1, 2026, folds it into the revised drug-registration rules to block approval of follow-on products that rely on protected data absent the innovator's consent.¹²⁹ Its value depends on implementation, including whether protection attaches automatically on approval. USTR's 2026 report likewise finds that Vietnam lacks an effective system for protecting test data against unfair commercial use and unauthorized disclosure.¹³⁰

¹²⁷Amendment to Vietnam IP Law: Notable Changes Concerning Patents and Industrial Designs, Mondaq (2022), <https://www.mondaq.com/trademark/1238662/amendment-to-vietnam-ip-law-notable-changes-concerning-patents-and-industrial-designs> (discussing Articles 112a and 131a).

¹²⁸Circular No. 05/2010/TT-BYT, arts. 3, 6 (Viet.) (Mar. 1, 2010), <https://www.wipo.int/wipolex/en/text/447861>; Pharmaceutical Data Exclusivity in Southeast Asia, Tilleke & Gibbins (July 14, 2025), <https://www.tilleke.com/wp-content/uploads/2021/08/Tilleke-Pharmaceutical-Data-Exclusivity-in-Southeast-Asia-2025.pdf>.

¹²⁹Circular No. 32/2026/TT-BYT (Viet.) (July 29, 2026); see Vietnam's New Drug Registration Regulations to Reduce Administrative Burden, Tilleke & Gibbins, <https://www.mondaq.com/vietnams-new-drug-registration-regulations-to-reduce-administrative-burden/1829146>.

¹³⁰USTR, *supra* note 1, at 46.

Vietnam also lacks an effective patent-linkage mechanism. Although it committed under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) to tie marketing approval to patent status, it has not implemented an operative system, and neither its 2025 IP Law overhaul nor its 2025 Law on Pharmacy reforms introduced one.¹³¹ Article 128 and the new Circular add notice for patent holders, including disclosure of follow-on applications five months ahead of approval, but notice alone is not the linkage CPTPP Article 18.53 contemplates. Nor does Vietnam restore patent term lost to regulatory review, despite long approval timelines. Article 131a merely waives certain patent fees for the delay period, leaving the term unchanged.¹³²

Trade Impact

Grant delays, the lack of PTA and restoration, weak enforcement, and new pre-grant challenges erode effective patent life and add uncertainty. With the RDP and linkage gaps, they shorten effective exclusivity for U.S. biopharmaceutical innovators, discourage early submission of regulatory dossiers and clinical data, and weaken incentives to launch new medicines promptly in Vietnam.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report and raise these gaps in bilateral engagement, including under the U.S.-Vietnam Trade and Investment Framework Agreement, urging meaningful RDP, effective patent enforcement and linkage, and patent term restoration and adjustment consistent with Vietnam's international commitments, and review Vietnam's implementation of its CPTPP linkage commitment.

V. Recent IP-Law Reforms: Welcome Progress and Provisions Warranting Scrutiny

Foreign Measure

Vietnam's 2025 amendments to its Intellectual Property Law, effective April 1, 2026, including expanded compulsory-licensing authority for provincial-level bodies and a new exception permitting use of copyrighted works for AI training.

NTE Category

Intellectual Property Protection and Enforcement; Regulatory Practices.

¹³¹CPTPP Obligations Alter Vietnam's IP Landscape, Tilleke & Gibbins (Apr. 23, 2019), <https://www.tilleke.com/insights/vietnam-investment-review-cptpp-obligations-alter-vietnams-ip-landscape/16/>; Vietnam's Newly Amended IP Law Takes Effect, Baker McKenzie (Apr. 1, 2026), <https://www.bakermckenzie.com/en/insight/publications/2026/03/vietnams-newly-amended-ip-law-takes-effect>.

¹³²Dung Vu, Patent & Design Updates from Vietnam: January 2024, Lexology (Jan. 23, 2024), <https://www.lexology.com/library/detail.aspx?g=66964e01-aa09-4e4e-9462-531e68bc515b>; C4IP, *supra* note 2, Part III.

Discussion

Vietnam has taken positive steps. The 2025 reforms introduced fast-track substantive patent examination and shortened standard examination from eighteen to twelve months.¹³³ If implemented effectively, these changes could improve the environment for innovation and investment.

Two cautions are warranted. First, the reforms took effect only on April 1, 2026, so their significance depends on implementation and should be judged by measurable outcomes. Second, the same law expanded compulsory-licensing authority, including by authorizing provincial-level bodies to grant compulsory licenses in sectors such as healthcare, energy, and essential goods, a new risk for patent holders that warrants close monitoring.¹³⁴ The law also adds a copyright exception for AI training under conditions the government will set, which could undermine voluntary licensing markets and diminish the value of works created by American copyright owners.¹³⁵ USTR's 2026 report adds a process concern: stakeholders objected to short public-comment periods on the draft IP Law and implementing decrees, one lasting only 24 hours, and USTR urges Vietnam to give interested parties a meaningful opportunity for input.¹³⁶

Trade Impact

Broader compulsory-licensing authority creates uncertainty for U.S. patent holders weighing investment and commercialization in Vietnam, and an AI-training exception without adequate safeguards could reduce licensing revenue for American copyright owners whose works are used to train AI systems there.

Requested USTR Action

USTR should include this issue in the 2027 NTE Report, acknowledge Vietnam's progress on patent-examination timelines, and monitor the compulsory-licensing authority, the AI-training exception, and their implementing regulations to ensure they do not undermine U.S. rights holders, including by pressing for meaningful stakeholder consultation.

¹³³Supplementing Regulations to Strengthen the Examination Timeframe for Patent Applications in Vietnam, ASL Law (Apr. 9, 2026), <https://aslgate.com/supplementing-regulations-to-strengthen-the-examination-timeframe-for-patent-applications-in-vietnam/>; Yen Vu et al., Vietnam's 2025 Amended IP Law: Major Reforms Effective from April 2026, Rouse (Jan. 19, 2026), <https://rouse.com/insights/news/2026/vietnam-s-2025-amended-ip-law-major-reforms-effective-from-april-2026>.

¹³⁴Vietnam's IP Law Amendment, Mirandah Asia (Apr. 6, 2026), <http://www.mirandah.com/vietnams-ip-law-amendment/>.

¹³⁵Vietnam IP Law 2025 Update: Copyright Exceptions for AI Model Training, Viet An Law (Jan. 20, 2026), <https://vietanlaw.com/vietnam-ip-law-2025-update-copyright-exceptions-for-ai-model-training/>; C4IP, *supra* note 2, Part IV.

¹³⁶USTR, *supra* note 1, at 47.

VI. Conclusion

C4IP's principal concerns regarding Vietnam are the sharp decline in counterfeiting enforcement after the 2025 government reorganization, the absence of deterrent-level criminal penalties for commercial-scale online piracy, gaps in the biopharmaceutical IP framework, including patent-grant delays, limited patent enforcement, the absence of patent term restoration, and uncertain implementation of regulatory data protection and patent linkage, and provisions of the 2025 IP reforms that merit continued monitoring despite genuine progress elsewhere in that legislation. C4IP supports a vigorous Section 301 process aimed at durable improvements in IP protection and enforcement, outcomes that serve American innovators and Vietnam's own innovators and consumers alike.

C4IP respectfully requests that USTR include these issues in the 2027 NTE Report and continue its engagement with Vietnam, including through the Section 301 process, to secure measurable, verifiable improvements.