



The Honorable Andrei Iancu, 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
Frank Cullen, Executive Director

January 28, 2026

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

**Re: Docket No. USTR-2025-0243, Request for Comments and Notice
of a Public Hearing Regarding the 2026 Special 301 Review**

Dear Ambassador Greer:

The Council for Innovation Promotion (C4IP) is pleased to submit this response to the December 11, 2025, Request for Comments and Notice of Public Hearing Regarding the 2026 Special 301 Review [\[Docket Number USTR-2025-0243\]](#).

The Council for Innovation Promotion ([C4IP](#)) is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere.

C4IP is chaired by two former directors of the U.S. Patent and Trademark Office, Andrei Iancu and David Kappos, who served under Presidents Trump and Obama, respectively. Our board further includes two retired judges from the Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. It also features two distinguished public servants: Lamar Smith, former U.S. Representative for Texas's 21st congressional district and Chairman of the House Judiciary Committee, and Gary Locke, former Governor of Washington, U.S. Secretary of Commerce, and U.S. Ambassador to China under President Obama.

Strong IP protections allow American innovators to invest in high-risk research, bring new products to market, and compete fairly abroad. IP-intensive industries contribute [more than 40%](#) of U.S. economic output and support [over 62 million jobs](#). This success depends on predictable, enforceable protections not only at home, but in foreign markets.

The importance of IP to the progress, economy, and well-being of the United States is why Congress mandated annual Special 301 reports to ensure that U.S. trade policy identifies foreign countries that deny adequate and effective IP protection or fair and equitable market access to U.S. rights holders. It is vital to ensure that U.S. innovators and entrepreneurs operate on a level playing field.

C4IP commends USTR for treating the Special 301 report as a serious enforcement and accountability tool rather than a symbolic exercise. The credibility of this process depends on candid assessments and clear accountability. Recent actions, including USTR's [investigation into Brazil](#) amid longstanding concerns regarding IP enforcement, demonstrate the importance of scrutiny when progress stalls despite sustained engagement.

This submission highlights several such trends that undermine IP protection across multiple industries and recommends proportionate Special 301 designations for countries and jurisdictions where these concerns persist, threatening the ability of U.S. innovators to obtain and enforce their rights across the globe. We conclude with a summary of the major problem areas for each country or jurisdiction, along with a recommendation for placement on the Watch List or Priority Watch List.

Erosion of IP Incentives Harms Biopharmaceutical Innovation

Recent legislative and regulatory developments in several jurisdictions raise serious concerns regarding the future of biopharmaceutical innovation. Weakening patent protections and related exclusivities undermines the incentives necessary to support the costly, lengthy, and uncertain process of developing new medicines.

Last year, the European Council and European Parliament reached a provisional agreement regarding the [Patent Package](#), which would expand the EU's power to issue compulsory licenses and use patented inventions without the consent of the rights holder. Elements of this framework raise concerns regarding consistency with longstanding international norms, including those reflected in the [WTO TRIPS Agreement](#).

Likewise, **India's** restrictive patentability standard under [section 3\(d\)](#) — which bars patents on new forms of known substances absent a demonstrated significant enhancement in therapeutic efficacy — undermines protection for incremental pharmaceutical innovations. This statute effectively reduces the level of protection [required](#) under TRIPS and creates discriminatory barriers to patent protection that target the pharmaceutical industry.

Concerns regarding patent enforcement are also increasing in **India**. Of particular note is a recent [decision by the Delhi High Court](#), which reversed an injunction and permitted a biosimilar manufacturer to enter the market despite the existence of a valid innovator patent in India. Decisions of this nature weaken confidence in patent protection and risk signaling to follow-on manufacturers that market entry may proceed notwithstanding unresolved patent disputes.

In **China**, the [definition of a new drug](#) has been severely limited so that it applies only to drugs that have not yet been approved elsewhere upon filing in China. This definition leads to disparate regulatory treatment for drugs submitted for approval first in China, upending the normal process that a drug company might use to assess the merits of where to begin approval and marketing, in favor of needing to file first in China or forgo significant protections.

In addition, China's [patent linkage system](#) (a regulatory system that links approval of a generic or biosimilar drug to the patent status of the originator drug) does not provide a sufficient stay period to allow for the meaningful resolution of patent disputes before generic or follow-on products enter the market. As a result, biopharmaceutical patent holders can face commercial harm before infringement claims are fully adjudicated.

Canada's existing patent term extension and patent term adjustment frameworks are inadequate and therefore do not fully comply with its obligations under the United States-Mexico-Canada Agreement (USMCA). In particular, Canada caps patent term extensions at [two years](#) and restricts eligibility for term extensions by requiring that new drug submissions be filed within [12 months](#) of filing in certain other jurisdictions, including the United States. In addition, Canada's [Patented Medicine Prices Review Board](#), which reviews "patent abuse related to excessive prices," has the unintended effect of punishing companies that introduce new medicines into the Canadian market. By subjecting the price of patented medicines to [a highly subjective review process](#) that lacks input from patients or clinicians, the PMPRB weakens the effective value of patent protection for innovative medicines.

Mexico fails to meet current [USMCA IP commitments](#) to provide an [effective patent linkage system](#) or to [provide proper notice](#) to patent holders prior to marketing of a generic or biosimilar patent.

Brazil's [Product Development Partnerships](#) between the Ministry of Health and private biopharmaceutical companies continue to raise concerns about the protection of proprietary data and confidential business information. While these partnerships are intended to lower costs by expanding domestic drug production through technology transfer to public or state-backed labs and manufacturers, they

effectively condition access to Brazil's public health market on the disclosure of sensitive data and manufacturing know-how, reducing incentives for companies to invest in and develop new medicines.

Reductions in Regulatory Data Protection Threaten New Medical Innovation

Regulatory data protection (RDP) refers to the exclusive legal rights a company obtains over the clinical data required for the approval of a medicine, reflecting the substantial costs borne by the company to conduct the associated clinical trials. Once the RDP period expires, a generic company may rely on the existing clinical trial data on safety and efficacy to secure approval of a generic version of that drug, instead of conducting (and paying for) its own clinical trials. The length of the RDP exclusivity and the terms of applicable patents are the critical factors governing when a generic can enter the market.

Changes that jurisdictions make to RDP, accordingly, shift the burden of global drug development disproportionately onto innovators and weaken incentives for investment. Because the United States [leads](#) in biopharmaceutical innovation and has strong RDP protection, these changes effectively mean that more of the burden of paying for R&D costs falls on U.S. companies and U.S. consumers. Requiring other countries to have similar RDP regimes to the United States and to pay their fair share should accordingly be a top U.S. priority.

At the end of 2025, the **European Union (EU)** [reached an agreement](#) on sweeping reforms to its general pharmaceutical legislation. These changes reduce RDP for new medicines and condition some RDP on meeting burdensome, EU-wide launch requirements. Such measures diminish the value of underlying patent rights and risk discouraging U.S. drugmakers from investing or launching products in Europe.

Although **India** has acknowledged the need for a more ["level playing field"](#) and has [taken steps](#) to strengthen its data protection framework, the [continued absence](#) of RDP and effective trade secret protection undermines incentives to invest in costly research and development and discourages innovators from conducting clinical trials or launching new medicines in India.

In **Brazil**, lawmakers have [considered](#) legislation to establish an RDP framework for pharmaceutical products, but [no such framework](#) is currently in force, leaving drugmakers without protection against unfair commercial use of their regulatory data.

Likewise, [Mexico](#) does not provide clear RDP for all new pharmaceutical products; drugmakers' requests for data exclusivity are often rejected.

Other jurisdictions, including [Malaysia](#), also fail to provide effective regulatory data protection.

Market-driven Standard-Essential Patent Negotiation Is Being Abandoned in Favor of Heavily Regulated Approaches that Depress the Value of Innovation

Strong and balanced protection for standard-essential patents (SEPs) is critical to standards-based industries, including telecommunications, connected devices, automotive technologies, and emerging applications in artificial intelligence.

Legal uncertainty surrounding SEP licensing undermines incentives to contribute patented technologies to global standards, ultimately harming technological progress and interoperability. Recently, challenges to this market-driven system have emerged across the globe, reflecting widespread foreign interest in asserting global leadership over the governance of SEP licensing, effectively leading to the depression of patent value and harm to American innovators and industry in critical areas like wireless communications.

SEPs Concerns: Patent pools

Patent pools have arisen as market-based entities that serve as intermediaries between the owners of standard-essential patents and implementers whose products use standards and therefore need to license the relevant patents. Pools help aggregate patent owners and allow implementers to take a single license that can cover a large percentage of the outstanding relevant patents. They reduce transaction costs, mitigate alleged royalty stacking, and promote access to standardized technologies. Typically, pools offer non-exclusive licenses, meaning that an implementer could still negotiate with each patent owner directly. But the pool offers the convenience of a single license. Importantly, however, the firm organizing a pool is not always the owner of the patents themselves.

Despite this market-driven solution to make SEPs licensing more efficient, several jurisdictions have taken recent actions that could ultimately undermine this arrangement, harming patent owners and implementers, and possibly providing a pretext for government regulation to set rates for the market even though these non-governmental intermediaries have proven to be an effective means of licensing for certain standards. The implications for patent pools are particularly severe. If

courts effectively usurp the role of pools and retroactively impose revised global rates, patent owners will have little incentive to continue participating in pools, let alone continuing to invest in R&D, knowing that returns are uncertain and subject to political whim.

In 2024, the Supreme People's Court of **China**, in *TCL v Access Advance*, [claimed jurisdiction](#) to set, at the request of a standards implementer, global fair, reasonable, and non-discriminatory (FRAND) rates for all SEPs licensed through a foreign patent pool.

This raises two significant concerns. First, that it permits a court to determine licensing terms for a patent pool that does not itself own the underlying patents, potentially imposing licensing conditions to which individual patent holders never agreed. Second, that it is the implementers — not the patent owners, who were not even the ones being sued — asking the court to set a worldwide rate even though patents are territorial. The Chinese court should have, at most, jurisdiction to establish rates relative to China, absent agreement from the patent owners to consider the patents of other jurisdictions.

These practices reflect a broader pattern in which China has operationalized its judicial system to systematically devalue foreign — particularly U.S. — intellectual property. By asserting extraterritorial jurisdiction [to set global licensing rates](#) without patent-holder consent and without any affirmative assertion of patents in China, Chinese courts functionally compel access to patented technologies at court-imposed discounts. This approach subsidizes China's domestic manufacturing base while undermining the ability of U.S. companies to compete for leadership in standards-based industries.

Unfortunately, this aggressiveness of court actions is not limited to China. In April 2026, the Supreme Court of the **United Kingdom** is expected to rule in *Tesla v InterDigital* on grounds of appeal that raise similar questions regarding judicial authority to impose global SEP licensing terms in suits against patent pools.

Against both pools and patent owners, U.K. courts have increasingly relied on "interim licenses" that effectively force global disputes into the United Kingdom and restrict patent holders' ability to enforce their rights elsewhere. For example, in *Acer v Nokia* at the end of last year, the U.K. court [granted an interim license](#) to include non-standard essential patents, moving beyond the contractual scope of standard-setting obligations. Like China, U.K. courts permit implementers to initiate global SEP rate determinations without patent holder consent and without the patent holder asserting its patents domestically.

SEPs Concerns: Proposed Regulations and Regulatory Actions

In 2025, the European Union [raised concerns](#) at the WTO about a harmful practice to innovators being adopted by courts in **China**, which were determining worldwide licensing conditions without patent-holder consent. According to the [European Commission](#), this practice pressured companies to accept below-market global rates, unfairly advantaging Chinese implementers by granting them cheaper access to European technologies. While the United States [did not support](#) the EU before the WTO at that time, it is now clear that the same risks apply to U.S. companies and research institutions that develop technologies incorporated into global standards and that are counting on fair returns on their R&D investments.

Earlier, in 2024, the **European Union** itself [proposed regulations](#) to create a new administrative body to determine SEP licensing terms instead of allowing them to be set by market-driven negotiations or patent pools, despite [no evidence](#) of systemic market failure. Although the EU [rescinded](#) the proposal, it represented a significant departure from the market-based licensing framework that has supported decades of transatlantic collaboration. The rescinded proposal is now the subject of [ongoing litigation](#) between the European Commission and the European Parliament. Any resulting further developments that might bring this proposal back into active status warrant continued scrutiny in the Special 301 process, given its likely harm to standards innovation as well as the detrimental impact it will have as a precedent for other jurisdictions.

While the Commission's SEP Regulation proposal has stalled, the underlying policy intent remains active: to shift leverage from innovators to implementers. For example, the European Commission has [explicitly allowed automotive licensing groups to collectively negotiate](#) for SEPs. Subsequently, it announced more general plans to provide for antitrust safe harbors for [Licensing Negotiation Groups](#) (LNGs) in the EU's revised Technology Transfer Guidelines. This would formalize a mechanism for collective bargaining among downstream competitors, effectively [endorsing buyer-side cartels](#) in the market for standard-essential patent licensing.

The approval of an automobile LNG sets a troubling precedent, allowing influential segments of European industry to determine licensing terms for technology innovators in America. If European manufacturers are permitted to coordinate licensing demands as a united front rather than in bilateral negotiations as individual licensees, U.S. firms will not be able to adequately enforce their patent rights, thereby artificially lowering the market rate for U.S. technology.

By issuing guidance letters that validate these LNGs — as seen in [Germany](#) and at the [European Commission level](#) — the EU is sanctioning anticompetitive behavior

that targets U.S. IP holders. This is inconsistent with U.S. law. Under the Sherman Act, competitors banding together to fix the price of an input, such as a technology, is often a *per se* violation of antitrust law. Dina Kallay, the Deputy Assistant Attorney General at the Antitrust Division of the U.S. Department of Justice, recently [emphasized](#) that under U.S. law and antitrust policy, "antitrust immunity should be narrowly construed and carefully considered."

A similar erosion of core antitrust principles is now emerging in the **United Kingdom**, where policymakers are considering regulatory interventions that would replace market-based SEP licensing with government-directed rate setting, limiting the ability of standards innovators to realize the fair value of their inventions.

One such measure they are exploring is a "[Rate Determination Track](#)" that would allow "specialists" instead of judges to set the royalty rate for an SEP holder's entire global portfolio at the request of the implementer. If the U.K. advances this proposal, it would set a dangerous global precedent. Under this logic, any national court could claim the power to license a foreign company's entire commercial portfolio without consent, undercutting the sovereign right of nations like the United States to adjudicate the patents that they issue under laws reflecting their own domestic priorities.

Another proposal being considered by the U.K. is setting up [a U.K.-specific SEP database](#) to help U.K. businesses navigate the complex SEP ecosystem. While framed as non-regulatory guidance, if the government issues materials on FRAND licensing, pricing transparency, and dispute resolution, it risks exerting de facto normative pressure on private licensing negotiations. This would effectively shift FRAND from a negotiated, contract-based framework toward an administratively-guided model. In addition, efforts to address perceived "information asymmetry" would disproportionately burden SEP holders with expanded transparency expectations, without corresponding disclosure obligations for implementers, thereby weakening patent holders' bargaining positions and increasing the risk of below-market royalty outcomes.

Antitrust authorities are also engaged in efforts to investigate innovators in a manner that could distort global negotiations and undermine incentives for high-value R&D. In **Brazil**, the Administrative Council for Economic Defense (CADE) [is investigating](#) Ericsson for alleged anticompetitive conduct related to SEP licensing. CADE raised concerns that Ericsson's refusal to license on a territorial basis may harm competitive conditions in Brazil. Similar concerns have arisen in **China**, where the State Administration for Market Regulation has [expanded](#) antitrust enforcement to intervene in standard-essential patent licensing to favor domestic implementers.

Expansion of Compulsory Licensing Devalues Patents and Defunds Future Innovation

While the WTO TRIPS Agreement permits compulsory licensing [in limited situations](#) — such as national emergencies — recent actions in some countries, including the **European Union** as described above, suggest an effort to normalize compulsory licensing as a routine policy or cost-containment tool.

The European Commission's [continued push for "proportionality" assessments in patent cases](#), in lieu of the more routine award of injunctive relief to prevailing patent holders, risks creating a de facto compulsory licensing regime where infringement is cheaper than negotiation. The United States has, unfortunately, [moved](#) in this direction itself. Although, as recent filings from the [Department of Justice](#) and [USPTO](#) demonstrate, strong injunctive remedies are critical for a well-functioning patent system that rewards innovators and risk-takers.

The EU's actions have emboldened other countries, like [Malaysia](#) and [Colombia](#), to pursue compulsory licensing strategies out of line with the parameters established under TRIPS.

When countries issue compulsory licenses without meeting TRIPS safeguards, they discourage long-term investment — particularly in industries such as biopharmaceuticals, standards development, and advanced manufacturing, where innovation depends on sustained capital over many years.

Patent Prosecution Delays Discourage Innovators and Innovation

In several key markets, excessive bureaucratic delays continue to undermine the effective enjoyment of patent rights.

Brazil faces severe challenges. [Long prosecution delays](#) at the Brazilian Patent and Trademark Office have been a longstanding concern, particularly given the absence of a meaningful [patent term adjustment mechanism](#) to compensate for unreasonable administrative delay. As a result, innovators often lose substantial portions of the effective patent life through no fault of their own, placing Brazil out of step with best practices among major innovation economies and discouraging investment in R&D-intensive sectors.

In **India**, procedural mechanisms intended to promote patent quality have instead contributed to systemic delay and uncertainty. India's [pre-grant opposition system](#) permits third parties to challenge patent applications at early stages of examination, frequently resulting in protracted proceedings and repeated cycles of review.

Inefficient and Cumbersome Patent Litigation Hinders Innovators from Vindicating Their Rights

In **China**, [initiating a patent-infringement lawsuit](#) is burdensome due to the absence of a formal discovery process and elevated pleading and evidentiary requirements. Plaintiffs are required to present extensive evidence of infringement — and often of damages — at the outset of litigation, which can limit access to timely judicial relief and create procedural delays that systematically disadvantage innovators seeking to enforce their patent rights.

In addition, China [does not publish](#) all patent-related judicial decisions and has increasingly anonymized those it does release, reducing transparency and making it difficult to assess whether, and to what extent, foreign and U.S. rights holders face discriminatory treatment.

In **India**, despite [recent improvements](#), patent litigation timelines remain lengthy and unpredictable across much of the country. The average duration of a patent infringement trial in India is [approximately 18 months](#) in fast-track forums such as the Delhi High Court, but trial duration varies widely in other jurisdictions.

Counterfeiting and Digital Piracy Hurt U.S. Brands and Content Producers

In multiple markets, U.S. rights holders continue to face persistent challenges related to counterfeiting and digital piracy. Counterfeiting and digital piracy impose significant harm on U.S. trade by undermining trademarks and copyrights, distorting legitimate markets, and eroding incentives for innovation.

According to [OECD-EUIPO](#) findings, in 2021, counterfeit goods accounted for approximately 2.3% of global trade, valued at roughly \$467 billion. In 2020 and 2021, footwear and apparel [represented](#) nearly half of all seizures, but infringed goods spanned [almost 50](#) product categories, including electronics, advanced manufactured products, pharmaceuticals, and food and beverages.

[China](#) remains the world's leading source of counterfeit and pirated goods, with China and Hong Kong together accounting for [more than 90%](#) of the value of counterfeit goods seized by U.S. Customs and Border Protection in fiscal year 2024. Despite periodic enforcement efforts, counterfeiting remains widespread, facilitated by fragmented enforcement and the growing role of [e-commerce platforms](#) that lack sufficient deterrence and transparency.

The 2025 Special 301 Report underscored that [both Canada and Mexico](#) have failed to fully uphold their commitments under the USMCA, particularly with respect to imposing deterrent-level penalties for counterfeiting and piracy. As the [renewal of the USMCA](#) approaches, the United States should insist that Canada and Mexico recommit to robust prevention and prosecution of these crimes, which undermine legitimate trade, harm rights holders across all three countries, and erode confidence in the agreement itself.

Localization Requirements Harm a Robust Copyright Marketplace

Recent policy developments in several U.S. trading partners reflect a troubling shift away from market-driven copyright systems that prioritize the creation of content based on consumer demand towards using the IP systems as leverage to force content creators to support domestic content quotas. Such domestic priorities should not come at the expense of U.S.-based creators.

[Canada's Online Streaming Act](#) represents a significant expansion of government control over the audiovisual marketplace and raises serious concerns under [Articles 19.4 and 19.5](#) of the USMCA, which prohibit discrimination against digital products on the basis of country of origin. The Act subjects foreign streaming services to oversight by the Canadian Radio-television and Telecommunications Commission, empowering regulators to impose financial contribution requirements and other obligations historically applied to traditional broadcast television. Under the Act, U.S. streaming services must subsidize Canadian production companies in order to access the Canadian market.

[Australia](#) is pursuing a similar approach through the Content Requirement for Subscription Video on Demand (Streaming) Services Bill, which requires major global streaming platforms to meet domestic content quotas by making significant financial contributions to fund local Australian content and programs.

Over time, this regulatory intervention risks shifting copyright from a system that rewards creativity and voluntary licensing to one governed by administrative mandates and compliance obligations. This erodes the core function of copyright: enabling creators and investors to rely on exclusive rights, voluntary transactions, and consumer choice to determine value.

Recommended Special 301 Designations

Based on the concerns described above, C4IP recommends that China, India, and Mexico remain on the Priority Watch List and that Brazil be elevated to the Priority Watch List. We recommend that Canada remain on the Watch List and that the United Kingdom be elevated to the Watch List.

In each of these markets, U.S. rights holders continue to face persistent challenges that impede fair and equitable market access. While C4IP recognizes that some countries, including India, have taken steps to improve aspects of their IP frameworks, significant deficiencies remain that warrant continued Priority Watch List designation. C4IP commends USTR for its continued engagement with these countries and encourages further collaboration toward effective, predictable, and reliable IP protection.

Drawing from the narrative above, we summarize the reasons for the inclusion of each jurisdiction below.

First, for China, its inclusion on the Priority Watch List is warranted due to the devaluation of IP embedded in its definition of a "new drug" being limited to drugs only first introduced in China; its deficient patent linkage system; the continued proliferation of counterfeit goods from within its jurisdiction; court practices that unfairly treat innovators, such as onerous requirements for initial complaints, prior to case discovery, and lack of transparency of court decisions; and finally, recent court actions that asserted the right to set global rates without patent owner consent and in contravention of other nations' right to set their own patent policies.

India's inclusion on the Priority Watch List is warranted due to its restrictive patentability standard under section 3(d), which limits protection for incremental pharmaceutical innovations; its recent court decision permitting biosimilar market entry despite a valid patent; the sustained delays in patent litigation; and the lack of a meaningful RDP framework.

Mexico's inclusion on the Priority Watch List is warranted due to the persistent failures to implement IP commitments under the USMCA; its inadequate and ineffective patent linkage system; its lack of timely notice to patent holders prior to the approval or marketing of generic or biosimilar products; and its lack of a clear RDP framework.

Brazil's inclusion on the Priority Watch List is warranted due to Brazil's Product Development Partnerships that condition access to the public health market on extensive technology transfer and information sharing with public or state-backed entities; longstanding patent prosecution delays; and the absence of meaningful patent term adjustment.

Canada's inclusion on the Watch List is warranted due to the combination of inadequate patent term restoration mechanisms and regulatory price controls that erode the effective value of patent rights for innovative medicines; its insufficient patent term extension framework and unreasonable regulatory delays; the Patented Medicine Prices Review Board's price ceiling process that lacks meaningful input from patients or clinicians; and its Online Streaming Act that violates Chapter 19 of the USMCA and disadvantages U.S. streaming services. If Canada fails to uphold its commitments under the USMCA, we recommend that the USTR consider elevating its status to the Priority Watch List.

The U.K.'s inclusion on the Watch List is warranted because of its SEP proposals that, if implemented, weaken the rights of patent holders, and its judicial decisions that allow implementers to impose global SEP licensing terms in lawsuits against patent pools. At the same time, several of these actions are recent or prospective, and we understand that discussions between the United States and the United Kingdom are ongoing. Given the U.K.'s status as a close trading partner and its history of constructively engaging to de-escalate trade and IP concerns, we urge the U.K. to reconsider these approaches and align its SEP policies with market-based licensing principles, with the goal of resolving these issues and facilitating removal from the Watch List in the near term.

C4IP also considers that recent policy developments in the European Union merit heightened scrutiny in the 2026 Special 301 Report and recommends consideration for placement on the Priority Watch List.

The EU plays a critical role as a global standard-setter for IP policy. Legislation affecting biopharmaceutical patents, compulsory licensing, and standard-essential patents, therefore, carries implications far beyond Europe's borders. Recent actions raise concerns regarding IP protection in key sectors and risk diverging from longstanding international norms.

The EU's inclusion on the Priority Watch List is warranted due to the reforms in its general pharmaceutical legislation that reduced market exclusivity periods for new medicines; its proposed reforms to expand compulsory-licensing authority; its attempt to establish an administrative body to determine SEP licensing terms; and regulatory approaches that enable collective licensing negotiation groups that undermine the patent rights of U.S. innovators.

Given the EU's global influence and the potential spillover effects of these policies, C4IP urges USTR to formally address these concerns in the Special 301 Report and to consider an appropriate designation to encourage constructive engagement.

C4IP appreciates USTR's continued leadership in defending strong intellectual property protections through the Special 301 process. As global competition for leadership in advanced technologies intensifies, maintaining strong IP norms is increasingly important to U.S. economic security, supply-chain resilience, and technological leadership. C4IP looks forward to continuing to work with USTR to ensure that U.S. innovators receive fair treatment abroad.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Frank Cullen", is positioned below the "Respectfully submitted," text.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)