February 25, 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 – Post-Hearing Submission

Dear Ambassador Greer:

The Council for Innovation Promotion (C4IP) is pleased to submit this supplemental briefing in response to the Office of the U.S. Trade Representative's February 18 hearing on the 2026 Special 301 Review.

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. We appreciated the opportunity for our Chief Policy Officer and Counsel, Jamie Simpson, to testify before the Special 301 Subcommittee on February 18 about our suggestions for countries that should be named to the Watch List or Priority Watch List because their IP policies impose unfair burdens on American innovators.

Following her testimony, Subcommittee members posed several questions that C4IP would like to address more fully in writing. We would also like to take this opportunity to respond to a statement made by another witness that we believe warrants clarification. Our supplemental responses are below. Please note that, since the transcript of the Public Hearing Testimonies is not yet available, we have rewritten the questions as we best recall them, though they may not be precise replications.

1. **Question from Treasury representative: Which of C4IP's concerns about the European Union reflect enacted law, and which are pending proposals?**

A significant number of our concerns relate to the European Union's revised General Pharmaceutical Legislation (GPL), finalized at the end of 2025 following a provisional agreement between the European Council and European Parliament. The agreement is expected to be formally approved in early 2026 following a multi-step process. It will first undergo a legal-linguistic review, be formally voted on and adopted by both the Parliament and the Council, and be published in the EU's Official Journal. Once published, the legislation will enter into force and member states will receive a transitional period to adapt their national laws, which is expected to run through 2028. Finally, when the transitional period ends, the revised legislation will take full effect. This means that although there is limited room for reversal in the current legislative process, there remains a window for engagement on the issues of most concern before the revisions become fully operative in all EU member states.

We propose several avenues through which USTR can use this opportunity to protect American inventors: Before the revisions become fully operative, USTR should engage in bilateral dialogues with the EU to press for reconsideration of the provisions of greatest concern to U.S. innovators, such as curtailment of regulatory data protection. USTR should also strongly consider including the EU on the Priority Watch List of the 2026 Special 301 Report to formally signal concern with the EU's current course. A Priority Watch List designation would grant USTR leverage in future constructive negotiations. Then, over time, U.S. policymakers could use this leverage to press the EU toward stronger IP and RDP standards, potentially even driving a new set of revisions to European IP law.

The GPL revisions are concerning in large part because they would weaken regulatory data protection (RDP) — the exclusive legal rights a company holds over the clinical data required for the approval of a medicine, which itself requires enormous investment to generate. The new framework shortens the baseline period of RDP afforded to new medicines. It conditions the restoration of the full RDP period on meeting burdensome launch requirements that involve launching the drug in all 27 EU member states within a set period of time, effectively imposing new barriers to entry for smaller innovators that have difficulty scaling and navigating disparate regulatory regimes. Separate from RDP, the GPL revisions also broaden patent infringement exemptions, allowing generic and biosimilar drug developers to conduct certain regulatory and commercial actions during the brand drug's patent term. Taken together, these changes diminish the value of patent rights, disincentivize investment in the European market, and risk shifting a greater share of global drug development costs onto U.S. companies and consumers.

These policies warrant a Priority Watch List designation not only because of their direct harm to U.S. companies, but also because of the precedent they set for other countries that look to the EU as a policy leader and norm-setter. Placing the EU on the Priority Watch List, while unlikely to result in immediate legislative reversal, would send a clear diplomatic signal that this course of action is unacceptable from a close ally and trading partner. It would also give USTR leverage to press for stronger IP and RDP standards in future trade dialogues and negotiations.

Several other concerns for which we urge EU placement on the Priority Watch List address prospective policy changes, such as the proposed regulatory framework for standard-essential patents and the ongoing review of the EU Intellectual Property Rights Enforcement Directive (IPRED), which concerns, in particular, the availability of injunctive relief for patent infringement. Both of these prospective changes are discussed further below. Although neither is yet concrete, the mere fact that European policymakers are considering these policies is cause for alarm and scrutiny, as they would undermine the foundations of the patent system if allowed to take effect. C4IP believes these prospective policies warrant the EU's immediate inclusion on the Priority Watch List and hopes that near-term USTR engagement on these policies could play an important role in preventing additional EU policy changes from harming U.S. innovators.

In 2023, the European Commission proposed heavy-handed regulation of standard-essential patents (SEPs), including the creation of a centralized administrative body to set SEP licensing terms. This proposal would have displaced market-based licensing negotiations with no demonstrable justification. Although the Commission ultimately rescinded this proposal, it is currently subject to ongoing litigation between the Commission and the European Parliament, meaning its future status remains uncertain. The EU has also taken other recent actions — such as proposing guidance that would permit licensing negotiation groups (LNGs) — that reflect the intent of the SEP proposal and are cause for concern in their own right, as they — unless carefully calibrated — could increase the ability of licensees (technology implementors) to avoid taking patent licenses, to the detriment of the innovators who own the patents.

The European Commission is also starting the process of considering revisions to the EU IPRED, which could limit injunctive remedies available to patent holders, similar to the U.S. Supreme Court's 2006 decision in *eBay v. MercExchange*. In *eBay*, the U.S. Supreme Court held that courts must apply a four-factor test before issuing a patent injunction, rather than treating injunctive relief as the presumptive remedy for infringement. U.S. courts have read this holding excessively broadly, resulting in the substantial curtailment of injunctions and limiting small innovators' recourse against calculated infringement by larger competitors. The Trump

administration has recognized the mistakes of the court system in reading *eBay* out of proportion: the Department of Justice and USPTO filed joint Statements of Interest in *Radian Memory Systems v. Samsung* (June 2025) and at the ITC in *Certain DRAM Devices* (November 2025) arguing that strong injunctive remedies are critical to a well-functioning patent system that rewards innovation and that exceptions to the presumption in favor of enforcement should be reserved for extraordinary circumstances.

If the EU proceeds to weaken injunctions, it would be repeating America's mistake at the same moment U.S. policymakers are working to correct course — and doing so in a way that would set a damaging global precedent. Additionally, as in the SEP proposal, European policymakers have failed to deliver evidence that overturning the status quo is necessary.

No legislative changes have been finalized on either the SEP proposal or IPRED, but USTR would be wise to monitor both developments and engage proactively to prevent outcomes that would undermine the global IP framework on which U.S. innovation leadership depends.

2. **Question from USTR representative: Is the forced technology transfer of biomedical know-how in Brazil, as referenced in C4IP's submission, actually voluntary?**

This question concerns Productive Development Partnerships (PDPs) between Brazil's government and private biopharmaceutical companies. In Brazil, the government is the primary purchaser of medicines. PDPs are agreements under which private biopharmaceutical companies share inherently proprietary information and manufacturing processes with the Ministry of Health, enabling state-backed manufacturers to produce copies of the medicines the companies invent and distribute them across the public health system.

Companies are not legally required to enter into PDPs, making them technically voluntary. In principle, foreign companies can bid for government contracts via a licensed local representative. In practice, however, the direct bidding route is not a realistic substitute for PDP participation. Under Brazilian law, the government may pay up to 15% more than the best competing imported price to secure a contract with a domestic manufacturer, putting foreign companies at a structural pricing disadvantage. Further, direct bids are often limited in ways that PDP agreements are not; they are often tied to defined quantities, pricing, or durations. For companies seeking a long-term, sustainable commercial relationship with the Brazilian public health system, PDPs are effectively the only viable pathway.

The terms of PDP participation are onerous. Under governing ordinances, the full transfer of all manufacturing technology and know-how necessary to enable the Brazilian partner to produce the product independently must be completed within the 10-year term of the government supply contract, including transfer of the drug master file or master cell bank — the genetically engineered cell line that is used to grow and produce the active ingredient. PDPs have been publicly documented for biosimilars of numerous common medications, including adalimumab, bevacizumab, etanercept, infliximab, rituximab, and trastuzumab. The PDP system has faced recent domestic scrutiny over several concerns, including patent infringement.

Brazil's PDP system stands in sharp contrast to how biosimilar competition develops in the United States. Biosimilar products regularly enter the U.S. market after regulatory and patent exclusivity periods have run their course, through a well-defined regulatory pathway that does not require the originator to transfer manufacturing know-how to any third party. Requiring U.S. companies to surrender this information as a condition of accessing the Brazilian market is an unfair and unnecessary barrier. Particularly given that numerous biologics have now been through the PDP process and their manufacturing know-how transferred to Brazilian entities, Brazil has less reason — not more — to impose the same conditions on future products.

Put simply, while it may not be accurate to characterize the PDP system as straightforward IP theft, it exerts non-negligible pressure on firms wishing to participate in the Brazilian public health market. A truly voluntary arrangement would involve both parties negotiating on a level playing field, with the innovating company ultimately receiving appropriate compensation in exchange for a license to its IP and proprietary data.

3. **Question from HHS representative: What are the problems with patent term extension and adjustment in Canada?**

Canada's patent term adjustment (PTA) and patent term extension (PTE) frameworks fall short of Canada's obligations under the United States-Mexico-Canada Agreement (USMCA). In practice, the deficiencies in these two frameworks erode the efficacy of patent protection in Canada, harming innovative companies that operate in the Canadian market.

Patent term adjustment is intended to compensate patent holders for time lost due to unreasonable delays between the filing and issuance of a patent. The U.S. patent system is calibrated to compensate patent holders in proportion to administrative delay, and the USMCA requires Canada to do the same. However, while Canada has

established a PTA system in an attempt to comply with the USMCA, the specific regulations it has implemented still limit inventors' access to and use of PTA.

First, merely acquiring PTA in Canada is far more difficult than in the United States. Unlike in the United States, where the USPTO calculates PTA automatically and includes it in the patent's issue notification, Canadian inventors must calculate PTA availability themselves and then pay an application fee of up to CAD $2,570 to have the office evaluate their claim. Canadian PTA only starts to accrue 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 in the United States, PTA begins accruing days of adjustment once prosecution exceeds three years from filing. Further, Canada's PTA calculation subtracts any delay "not directly attributable to the patent office," whereas time is not as easily subtracted in the United States, particularly for overlap, disclaimed terms, or if the applicant fails to engage in "reasonable efforts" to respond to USPTO notices. This means that in Canada, the effective duration of PTA can be far shorter than the actual delay applicants experience.

Patent term extension is designed to compensate innovators for the time spent awaiting regulatory approval when a medicine has received patent protection but cannot yet be marketed. Canada caps PTEs, or Certificates of Supplementary Protection (CSPs), at two years, an arbitrary limitation that may not adequately compensate innovators for longer regulatory review periods. In FY 2024-2025, 15 of the 16 medicines that received CSPs were issued the full two-year terms, indicating that longer extensions may be needed to compensate for the typical regulatory delay. The inadequacy of Canada's PTE limit is also supported by the fact that the United States and European Union both allow five-year PTEs despite granting regulatory approval faster than Canada, on average.

Additionally, Canada 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 constraint eliminates a company's ability to make regulatory filings based on commercial considerations, such as resource availability, market prioritization, and clinical strategy, and forces companies to either file in Canada on a timeline dictated by their filings elsewhere or forfeit PTE eligibility entirely. Most importantly, PTE in Canada runs concurrently with PTA rather than adding to it. This means that patent holders who face both administrative and regulatory delays are not compensated for the total time lost.

Taken together, these deficiencies mean that Canadian patent rights for innovative medicines routinely provide exclusivity that is meaningfully less effective than the USMCA requires. That limits incentives for innovation and shortchanges inventors

who have taken on the risks of developing medicines for the Canadian market. With the upcoming renewal of the USMCA, C4IP urges USTR to press Canada to reform both frameworks to provide genuinely compensatory protection in compliance with its treaty obligations.

4. **Statement by ACT (The App Association) representative: Germany and EU courts are "forcing" implementors into global SEP licenses.**

This remark was not directed to C4IP's testimony, but rather stated in response to one of the panelists' questions. But it merits clarification, as it concerns a distinction central to the SEP licensing debate.

Courts in Germany and the Unified Patent Court (UPC) issue injunctions when they find that an SEP is valid and infringed. Injunctions require the infringer to cease its infringing activity, often prompting it to negotiate a license to continue selling its products in the relevant jurisdiction. However, these courts do not issue injunctions automatically or without regard for the patent holder's FRAND obligations. Under the framework established by the Court of Justice of the European Union in *Huawei v. ZTE* (2015), injunctions are issued only when the implementor has failed to negotiate in good faith — for example, by ignoring licensing offers or declining FRAND terms without a reasonable counter-proposal.

Critically, a territorial injunction is not an order to enter a global license. Infringing implementors have multiple options to resolve injunctions, including bilateral negotiations that may produce a global license or exiting the relevant market. After the Munich Regional Court ruled that Oppo infringed on two of Nokia's SEPs in *Nokia v. Oppo* (2022), Oppo pre-empted the injunction and withdrew from the German market rather than abide by terms it found unfavorable. This illustrates how the system is supposed to work: an injunction addresses the adjudicated infringement within the territory controlled by the court. It creates pressure to negotiate, but does not force either party to surrender its rights.

The approach of German and UPC courts with respect to SEP injunctions is appropriately limited to their jurisdictions and is consistent with principles of territorial patent enforcement. Likewise, U.S. courts have generally confined their FRAND rate-setting to patents issued within their own jurisdiction, declining to assert authority over patents issued by other sovereignties. This stands in sharp contrast to the problematic conduct of courts in other places, such as China and the United Kingdom, where courts have asserted authority to unilaterally set SEP licensing rates.

In China, courts have asserted jurisdiction to set global FRAND rates for all SEPs licensed through a foreign patent pool, effectively imposing licensing conditions on patent holders worldwide without their consent in order to give Chinese implementors a discounted rate. UK courts have engaged in similar overreach, ruling on global licensing rates without patent holders' consent and in some cases mandating "interim licenses" that effectively foreclose patent holders' ability to seek fair licensing rates in other jurisdictions. The UK Supreme Court's anticipated ruling in *Tesla v. InterDigital* in April could further expand the UK courts' claimed authority over global SEP licensing terms.

When courts enforce valid patents within their jurisdictions through appropriate injunctive relief — as German and UPC courts do — there is no threat to innovators or U.S. sovereignty; it is the patent system working as intended. But when foreign courts impose worldwide licensing conditions on U.S. patent holders without their consent, they undermine the right of the United States to grant patents under its own laws, deprive American and foreign rights holders of the remedies they are entitled to seek in U.S. courts, and impair the ability of the United States to set its own innovation policy.

Conclusion

C4IP appreciates the USTR panel's engagement at the February 18 hearing and welcomes the opportunity to provide these supplemental responses. We remain committed to working with USTR to ensure that American innovators receive fair and effective intellectual property protection abroad. We would be happy to provide further information or clarification if requested.

Respectfully submitted,

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