



WRITTEN SUBMISSION OF THE NATIONAL FOREIGN TRADE COUNCIL

Request for Comments and Notice of a Public Hearing Regarding the 2026 Special 301 Review Docket Number USTR-2025-0243

January 28, 2025

The National Foreign Trade Council (NFTC) appreciates the opportunity to provide input in response to the Office of the U.S. Trade Representative's (USTR) Federal Register notice, Request for Comments and Notice of a Public Hearing Regarding the 2026 Special 301 Review (the FR Notice) (90 FR 57519, December 11, 2025).

The NFTC is pleased to provide comments as part of USTR's Special 301 process noting the outsized importance of intellectual property (IP) rights to the domestic success and global competitiveness of U.S. business, including many NFTC member companies.

Robust protection of IP is critical to the development of new and innovative treatments and cures. American companies invest approximately \$100 billion per year in the United States towards the research, development, testing, and manufacture of breakthrough medicines. The strength of the U.S. patent system and global IP norms fostered by the United States are critical to enabling these up-front investments.

About NFTC

The NFTC, organized in 1914, is an association of U.S. business enterprises engaged in all aspects of international trade and investment. Our membership covers the full spectrum of industrial, commercial, financial, and service activities, accounting for over \$6 trillion in revenue and employing nearly six million people in the United States.

I. IMPORTANCE OF IP IN U.S. TRADE AGREEMENTS

Over the years, U.S. trade agreements have included high-standard IP provisions that demonstrate continue U.S. leadership in innovation. These set high standards to ensure that U.S. trading partners strengthen their IP regimes consistent with a reciprocal approach to trade that ensures American innovations are protected and also creates a positive ecosystem globally. We were pleased to see IP protection included in the Malaysia and Cambodia reciprocal trade agreements, along with associated commitments in the digital trade section that prohibit mandates to transfer or provide access to IP such as source code, production process, or other proprietary knowledge, as a condition for doing business in these markets.

However, negotiating strong IP protections in trade agreements is only one side of the equation. Achieving effective enforcement of these commitments remains a challenge. Key trading partners still have not implemented certain IP obligations either fully or at all.

The NFTC urges the U.S. government to continue to include robust IP provisions in its trade agreements and ensure that those IP commitments are meaningfully enforced. This is essential to American leadership in critical industry sectors.

A. China

The IP chapter of the China “Phase One” Agreement included important commitments to address longstanding IP concerns, including provisions addressing trade secrets, pharmaceutical-related intellectual property, and enforcement against pirated and counterfeit goods. The NFTC provided detailed comments on China’s failure to implement these commitments in our [response](#) to USTR’s Federal Register notice, “Initiation of Section 301 Investigation: China’s Implementation of Commitments under the Phase One Agreement” (90 FR 48733, October 28, 2025).¹

1. Pharmaceutical IP

To date, China has not fully implemented provisions for acceptance of supplementary data to support patentability and requirements concerning patent term extension. This is in addition to the fact that China yet to implement meaningful regulatory data protection for pharmaceutical products launched first outside of China despite promising such protection in its World Trade Organization (WTO) accession commitments. Specifically, China agreed to:

- Consider supplemental data to meet relevant patentability criteria for pharmaceutical patent applications (Art. 1.10).
- Create an effective mechanism for the early resolution of pharmaceutical patent disputes, including enabling a patent holder to seek expeditious remedies before an infringing product is marketed in China (Art. 1.11) and
- Provide patent term extensions to compensate for unreasonable delays that cut into the effective patent term (Art. 1.12).

The successful implementation of these commitments would have helped to lay a solid foundation for investment and cooperation in the biopharmaceutical field between the two countries.

Unfortunately, China has completely failed to fulfill its obligations under Article 1.10 and Article 1.12, especially paragraph 2(b), and has only partially fulfilled its obligations under the remaining pharmaceutical-related IP provisions. China’s failure to comply with these Phase One commitments has helped it to maintain an unlevel playing field to the detriment of American pharmaceutical companies and enable China to continue to unfairly exploit American innovation.

¹ See, submission by the National Foreign Trade Council available at <https://comments.ustr.gov/s/commentdetails?rid=Y7DQGHJRXG>.

Although not strictly part of the U.S.-China Phase One Agreement, China also committed in its WTO accession in 2001 to provide regulatory data protection in accordance with Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 39.3 related to pharmaceutical products. However, China has never implemented this commitment, and pharmaceutical products approved first outside of China still do not receive regulatory data protection. In addition to full compliance with the Phase One obligations, China also should immediately implement regulatory data protection, consistent with best international practices, for all pharmaceutical products, including both small molecules and biologics, whether approved first in China or elsewhere in the world.

2. Piracy and Counterfeit Goods

According to the Organization for Economic Cooperation and Development (OECD), China and Hong Kong continue to be the top source for pirated and counterfeit goods in international trade.² Chinese online marketplaces Temu, AliExpress, and SHEIN have become central actors in the global counterfeit economy. Pirated and counterfeit goods such as semiconductors, automobile parts, apparel, footwear, toys, cosmetics, and medicines endanger the public and pose significant health and safety risks.

The Phase One Agreement IP chapter included specific obligations to ensure China addressed these concerns. In particular, China committed to:

- Provide effective and expeditious action, including takedowns, against infringement in the online environment (Art. 1.13).
- Take effective action against e-commerce platforms that fail to take necessary measures against infringement (Art. 1.14).
- Take effective enforcement action against counterfeit pharmaceuticals and related products, including active pharmaceutical ingredients (Art. 1.18)
- Significantly increase actions to stop the manufacture and distribution of counterfeits with significant health or safety risks (Art. 1.19).

As recently as this past September, submissions and testimony for USTR's 2025 Review of Notorious Markets for Counterfeiting and Piracy (Notorious Markets List, or NML) demonstrate that the outcomes sought through the above commitments still have not materialized due to China's failure to take effective action to address these issues as required. The 2024 NML reported on the growth of illicit online pharmacies and the risks of counterfeit medicines, including from sources in China.³

B. USMCA

USMCA IP chapter included a number of new provisions to strengthen IP protection, particularly in the pharmaceutical sector. Of notable importance were new commitments

² OECD/EUIPO (2025), Mapping Global Trade in Fakes 2025: Global Trends and Enforcement Challenges, Illicit Trade, OECD Publishing, Paris, <https://doi.org/10.1787/94d3b29f-en>, p. 7.

³ United States Trade Representative, [2024 Review of Notorious Markets for Counterfeiting and Piracy](#), p. 3-10.

strengthening the protection of trade secrets. Unfortunately, both Canada and Mexico are both deficient in fully implementing certain pharmaceutical-related IP obligations.

1. Canada

a) Inadequate patent term restoration

Canada does not provide restoration mechanisms that are consistent with the USMCA Article 20.44 requirement to provide patent term adjustment for unreasonable delays during the prosecution and issuance of any patent. Canada's patent term adjustment framework includes inequitable barriers that constructively undermine the treaty provision and prevent American patent holders from obtaining compensation for unreasonable delays. The Canadian government should provide up to five years of patent term restoration that runs consecutively with patent term adjustment instead of concurrently.

b) Weak patent enforcement

The Canadian Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations") include several key deficiencies that weaken Canada's enforcement of patents, including excessive and windfall damage awards to generic litigants, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. Jurisprudence under the PM(NOC) Regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages. Finally, Canada has used implementation of the Canada-EU Comprehensive Economic and Trade Agreement (CETA) to implement reforms not required by that Agreement, which expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations.

c) Confidential Business Information - Standard for Disclosure

Provisions in Canada's Food and Drugs Act, codified in Bill C-17 of 2014, grant the Health Minister discretion to disclose a company's confidential business information (CBI) without notice to the owner of the CBI. This is inconsistent with Canada's obligations under Article 20.71 and Article 20.66 of the USMCA, which requires that CBI be protected against disclosure except where necessary to protect the public. Under Canadian law, there is not a threshold of serious risk of injury to justify the disclosure; rather the provisions merely require that the Minister believes the disclosure to be necessary. The Act allows the Minister to disclose CBI to individuals involved in "the protection or promotion of human health or safety of the public," though there is no necessity requirement for this disclosure to occur. USMCA does not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public. The Canadian government should ensure that the regulations and guideline documents to implement the Food and Drugs Act are consistent with Canada's USMCA obligations on confidential business information.

2. Mexico

a) Lack of implementing regulations and patent linkage

The Mexican Institute of Industrial Property (IMPI) has not yet issued the necessary regulations to implement key provisions of the Federal Law for the Protection of Industrial

Property (LFPPI), such as patent linkage. Additionally, recent court precedents have undermined patent usage by preventing their publication in the linkage gazette. All of these issues are in direct violation of Mexico's IP commitments under the USMCA. As a result, COFEPRIS has issued numerous marketing authorizations for generic versions of patented protected products, occurring at least 10 times in 2023 and 2024 alone ([PhRMA, 2025](#)). This harms innovation and allows generics in China to take market share away from U.S. companies operating in Mexico.

USTR should continue to encourage the Mexican government to implement USMCA requirements to create and enforce patent linkage, using FDA's Orange Book system as a model. This should include nullifying marketing authorizations for generic/biosimilar versions of patent protected products.

b) Lifting injunctions without sufficient legal justification:

The Mexican government, including IMPI, has adopted the practice of lifting injunctions against products that infringe industrial property rights under the justification of access to medicines and the right to health. Although the protection of public health is a constitutional principle, this principle must be balanced against constitutionally protected industrial property rights, as required under USMCA articles 20.78.1, 20.78.2, 20.81.2, 20.82.1 and 20.82.2.

USTR should urge the Mexican government to ensure preliminary injunctions remain valid and are not lifted unless compelling evidence of lack of access and/or non-infringing evidence is filed by the defendant.

c) Compulsory disclosure of IP in tax audits

In addition to the growing list of tax issues in Mexico that are well documented in NFTC's comments for the [2026 National Trade Estimate Report](#) and [USMCA post-hearing submission](#), NFTC members also report being required to disclose proprietary IP as during the tax audit process.

II. COMPULSORY LICENSING THREATS

Compulsory licensing by foreign nations threatens these investments by nullifying the patent rights held by American innovators and weakens the global norms that allow U.S. firms to deliver innovation to the world.

These powerful national and multilateral drives to normalize the use of compulsory licenses merit particular U.S. government attention at this time due to the increased threat of retaliatory behavior from trading partners. Recent U.S. efforts to ensure that the cost of researching, developing, and testing breakthrough pharmaceutical innovations is not wholly borne by the United States, as it has been for many years, should not be met by compulsory licensing measures from trading partners who do not wish to pay their fair share. If U.S. innovators are to be in a position to command a fair price in those markets, in line with prices paid in the United States, the threat of compulsory licenses – often accompanied by demands for technology transfer – must be contained.

A. Multilateral Compulsory Licensing Initiatives

From its inception, the WTO TRIPS Agreement has been plagued by activism that consistently undermines implementation of its commitments by WTO members. In particular, activists have exploited the WTO to advance an agenda of normalizing the use of compulsory licenses in the name of special and differentiated treatment and “flexibilities” that contradict the express intent of the minimum standards created by the TRIPS Agreement.

This agenda found fertile ground in deliberations at both the WTO and the World Health Organization (WHO) in response to the Covid-19 pandemic. The WTO’s June 2022 approval of a “TRIPS Waiver” of intellectual property commitments, affecting vaccines that were pioneered on an unprecedented timeline by the United States during Operation Warp Speed, is a case in point. Ongoing WHO negotiations for a “Pathogen Access/Benefit Sharing” agreement aim at similar ends: the dismantling of global IP norms in order to routinize the use of compulsory licenses accompanied by mandatory technology transfer.

B. National Compulsory Licensing Actions

Certain countries, among them Colombia and Russia, have been at the forefront of promoting the compulsory licensing of biopharmaceutical patents. For example, in 2023, Colombia’s Ministry of Health and Social Protection (MSPS) issued a Declaration of Public Interest allowing compulsory licensing of an HIV treatment. Throughout 2025, the U.S. government, including USTR, responded to continuing threats of a second compulsory license aimed at a patented medicine researched and developed in the United States. These actions originate from a longer list of patented pharmaceutical products that the MSPS has declared its intention to compulsorily license. If this plan advances without consequence, the attendant normalization of compulsory licenses will be seen as an invitation for many other countries to do the same.

Russia’s case is less ideological and more purely retaliatory and mercantile: As noted in the 2025 Special 301 Report, “Russia continues to implement measures that allow uncompensated use of IP held by right holders based in countries that have sanctioned Russia.” In the pharmaceutical space, local generic manufacturers jockey to exploit this geopolitical directive in order to occupy the market for manufacturing breakthrough medicines without bearing any of the costs of research and development borne by U.S. patent holders.

Members of Brazil’s National Congress continue to pursue efforts to expand inappropriately compulsory licensing provisions in Brazil’s Industrial Property Law. Recent efforts, such as PL No. 12/2021, included several unprecedented, vague, and broad provisions that go beyond what was envisioned under the WTO TRIPS Agreement. These efforts fundamentally undermine the predictability and certainty necessary for U.S. innovators from all sectors to successfully invest in and accelerate the launch of new products in Brazil.

III. EUROPEAN UNION’S GENERAL PHARMACEUTICAL LEGISLATION

In December 2025, the Parliament and the Council of the EU reached a political agreement on the European Union’s General Pharmaceutical Legislation (GPL). Unfortunately, this final

political agreement includes provisions that weaken the IP framework in the EU, impacting both regulatory protections and the ability to enforce patents in Europe. In particular, the following items are extremely concerning:

- **Bolar Exemption:** The final legislative agreement expands the scope of the Bolar exemption to potentially include pre-commercial and commercial activities—such as offering for sale or marketing that may occur during health technology assessments, pricing and reimbursement procedures, and tender applications. Including commercial activities in the exemption is unprecedented and contradicts original intent of the Bolar exemption. This change is inconsistent with the fundamental purpose of the Bolar exemption, which is to permit use of an invention solely to develop information for national regulatory authorities. It is contrary to practices in the rest of the world and appears to violate the EU’s commitments under the WTO TRIPS Agreement, particularly if activities constituting sales or offers for sale, such as tenders, are included within its scope. Moreover, the expanded Bolar scope would appear to render effective patent enforcement generally more difficult and, at least in some cases, essentially impossible, as innovators currently can demonstrate the “imminent infringement” required by European courts to initiate patent enforcement proceedings through evidence of acts that, once implemented, may no longer be considered infringing.
- **RDP/Market Protection:** Existing European law provides regulatory data protection along an 8+2+1 structure, that permits generic or biosimilar companies to rely on the innovator data to support marketing approval only after the 8 year mark, and further does not permit placing of products on the market until the expiry of 2 further years (known as “market protection” in the EU). The new political deal reduces market protection to one year, effectively reducing protection in Europe by 10% compared to current standards. In its place, the new agreement permits restoration of this lost term only if new adding burdensome, potentially unworkable, localization criteria are met, e.g., concerning conducting clinical trials in multiple EU Member States or seeking marketing authorization in the EU within 90 days of first global submission.

These changes unfairly impact American innovators in Europe and continue a negative trend of reduced protection for American innovation in Europe, which began several years ago when exceptions were introduced to European Supplementary Protection Certificates. Moreover, these changes exacerbate ongoing concerns about European “freeloading” on American pharmaceutical innovation.

We still await official publication of the final negotiated text for the GPL. However, NFTC members are concerned by these changes. We urge the U.S. government to engage European colleagues through the bilateral trade dialog and other channels to change the legislation to ensure consistency with Europe’s TRIPS obligations and global best practice, restore confidence in ability to enforce patents in Europe, e.g., through adoption of guardrails such as notification requirements to innovators as a matter of fairness, and to ensure a more equitable competitiveness landscape for American innovators.

IV. ACCESS TO INJUNCTIONS

Injunctions are a cornerstone of a well-functioning patent system, one that has fueled American innovation and sustained U.S. technological leadership for decades. U.S. agencies have recently reiterated that injunctions and other exclusionary remedies are essential to promoting innovation, supporting competition, and maintaining U.S. leadership in key sectors.⁴ They also said that “[w]ithout the possibility of injunctive relief, ‘the right to exclude granted by the patent would be diminished, and the express purpose of the Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined.’”⁵ Yet, we continue to see growing threats to effective patent-infringement remedies, including injunctions, across multiple jurisdictions.

The European Union is currently revising its Intellectual Property Rights Enforcement Directive (IPRED), which includes access to injunctions. Some stakeholders are actively lobbying for new requirements that would substantially restrict the ability of American innovators to secure meaningful remedies in Europe. Similar efforts to narrow the availability of injunctions in patent-infringement cases are underway in China, where the China IP Research Association has already made suggestions to that effect. In the United Kingdom, the Intellectual Property Office launched a 2025 consultation on standard-essential patents (SEPs) that raises questions about the appropriateness of injunctions in SEP disputes, even though the UK Supreme has previously affirmed that injunctions should remain available. It is essential to stop these activities and ensure that foreign jurisdictions maintain a balanced patent-enforcement framework, one that provides effective access to injunctions.

There are also indirect attacks on the availability of injunctions. One such example is the interim license construct developed by UK courts in global patent disputes that effectively limits access to injunctions not only in the UK, but also in the United States and other jurisdictions. Under an interim license, an infringer may continue using an entire global patent portfolio, including U.S. patents, simply by paying royalties while a UK court sets global licensing terms. UK courts have ruled that such licenses shall be available even when the patent holder has not consented to UK jurisdiction. Because an infringer granted an interim license is treated as a licensee globally, this construct effectively deprives the patent holder of injunctions (and potentially other infringement remedies) not only in the UK but worldwide.

The approach adopted by UK courts mirrors the trajectory taken by Chinese courts, which have issued anti-suit injunctions to prevent the enforcement of U.S. patents in U.S. courts while Chinese courts determined the terms of a global license, including the terms for the use of U.S. patents. Foreign courts and governments have pushed back against this kind of extraterritorial overreach, and the United States should do the same. It is critical to ensure that foreign courts do not force U.S. innovators to relinquish or weaken their U.S. patent rights or limit their ability to seek remedies in U.S. courts.

⁴ Statement of Interest of the United States: Disney Enterprises, Inc. v. Interdigital, Inc., et al., Case No. 25-cv-996-MN (D. Del.) (Oct. 6, 2025); Joint Comment on the Public Interest of the United States Patent and Trademark Office and the United States Department of Justice, In the Matter of Certain Dynamic Random Access Memory (DRAM) Devices, Products Containing the Same, and Components Thereof, Dock. N. 3854; Statement of Interest of the United States of Am. in Radian Memory Sys. v Samsung Elecs. Co. Civ. Action No. 2:24-cv-1073 (Ed. Tex. June 24, 2025) (quoting *Smith Int’l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-78 (Fed. Cir. 1983)) (hereinafter *SOI Radian v Samsung*).

⁵ *SOI Radian v Samsung* at 3.

V. WEAKNESSES OF IP PROTECTION IN BRAZIL

Brazil continues to have challenges with intellectual property protection, which is reflected in the fact that it remained on the Watch List in the [2025 Special 301 Report](#). Problems with intellectual property protection in the pharmaceutical sector persist, including:

Patent backlogs: Historically, patent applicants in Brazil have experienced some of the longest patent pendency times in the world. A recent analysis finds that the issue persists today, with the average patent examination timelines for biopharmaceutical patents exceeding nine years, hindering innovation and significantly raising investment risk. We are encouraged by the National Institute of Industrial Property's (INPI) efforts to tackle the examination backlog and improve the efficiency of patent prosecution in Brazil, including expansion of the Patent Prosecution Highway pilot program to all sectors. Nevertheless, it is critical for Brazil to establish a Patent Term Adjustment mechanism to offset these undue delays in Brazil's patent examination process. The need is more acute than ever following the Brazilian Supreme Court's 2021 decision to eliminate the minimum patent term, which was applied retroactively to the health innovation sector eliminating thousands of patents overnight.

Lack of regulatory data protection (RDP): Brazil does not provide RDP for biopharmaceutical products (despite applying RDP for veterinary, fertilizer, and agrochemical products).

VI. OTHER ISSUES

Chile: Chile has had longstanding and persistent issues with IP protection and enforcement, reflecting on its continued status on the Priority Watch List. Pharmaceutical companies continue to voice concerns regarding the inconsistent enforcement of IP rights within the government tender process, particularly where procurement practices may permit the award or purchase of products that infringe valid and existing patents.

VII. CONCLUSION

The NFTC remains committed to American leadership in innovation globally and the role that trade policy plays in this regard. We seek to collaborate further to ensure that existing agreements, such as China "Phase One" and the USMCA, achieve full implementations of IP obligations in these key markets.

For the reasons discussed above, the NFTC believes USTR should maintain Brazil, Canada, China, Chile, Colombia, Mexico, and Russia at their respective, current designations in the 2026 Special 301 Report. It is critical that the United States must continue to be vigilant to compulsory license measures around the world.

Moreover, we urge the United States to engage with colleagues in the European Union to address, and reverse, the recent negative changes made with respect to the Bolar exemption and RDP in Europe. Europe is ostensibly a leader in global IP matters and acceptance of such

measures in a leading jurisdiction and critical market for U.S. life science innovators are likely to lead to similar practices adopted by others if not appropriately addressed.

The NFTC appreciates the opportunity to share our input for the 2026 Special 301 Review. We look forward to working with you to make progress on these issues.

If you have questions, need additional information, or would like to discuss our input further, please reach out to Tiffany Smith at NFTC at tsmith@nftc.org.