



October 2, 2024

Mr. Daniel Lee
Assistant U.S. Trade Representative for Innovation and Intellectual Property
Office of the U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: 2024 Review of Notorious Markets for Counterfeiting and Piracy 89 Fed. Reg. 66754 Docket Number: USTR-2024-0013 (October 2, 2024)

Dear Mr. Lee:

The U.S. Chamber of Commerce (“Chamber”) Global Innovation Policy Center (“GIPC”) appreciates the opportunity to submit the following response to the Office of the U.S. Trade Representative’s (“USTR”) request for comments regarding the annual review of notorious markets for counterfeiting and piracy. The GIPC leads efforts worldwide to promote innovation and creativity through robust and enforceable intellectual property (“IP”) standards, with much advocacy focused on safeguarding and securing American IP through enforcement action.

Intellectual property is critical to U.S. economic development and competitiveness. In 2022, the U.S. Department of Commerce found that IP-intensive companies account for \$7.8 trillion in U.S. gross domestic product (GDP), or 41% of total GDP, and support 63 million American jobs—44 percent of the U.S. workforce—directly and indirectly. U.S. Chamber of Commerce research shows strong statistical correlations between the strength of a country’s IP environment and its performance against key socio-economic indicators, including private sector R&D funding, job creation in knowledge-intensive industries, innovative output, and access to innovation¹. The strength of its IP system is a core competitive advantage of the United States.

The Counterfeiting and Piracy Challenge

Effective and consistent IP enforcement creates a rule of law environment that provides the legal certainty needed for investment in IP value creation across all industries. Unfortunately, in many global economies, effective enforcement options

¹ *International IP Index 9th Edition*; https://www.theglobalipcenter.com/wp-content/uploads/2021/03/GIPC_IPIndex2021_FullReport_v3.pdf

are not practically available or fully utilized². Judicial and administrative routes of enforcement are often overloaded and under-resourced. With respect to effective border measures, not all economies grant their customs authorities, border guards and/or other designated officials *ex officio* authority to seize suspected counterfeit and pirated goods, including goods in transit, without a formal complaint from a given rightsholder.

Volatility of the global enforcement environment greatly affects U.S. Chamber members' ability to create, use, and protect their IP both at home and abroad, and correspondingly, their capacity to create and sustain American jobs. The lack of effective enforcement efforts is an increasingly significant problem given the rise in overall levels of global trade. In 1990, the value of world trade in goods was an estimated USD 3.5 trillion. Recent data from 2022 shows, the value of global trade in goods is over seven times that amount at an estimated USD 25.05 trillion³; and this is not counting trade in services.

International efforts to measure the scale of counterfeit and pirated goods have increased in tandem, with the work primarily being driven by the Organization for Economic Cooperation and Development (“OECD”) and EU Intellectual Property Office (“EUIPO”), which have been instrumental in developing new metrics and regular assessments of levels of trade-related counterfeiting. The global scope of physical counterfeiting is the largest it has ever been—measured at \$509 billion dollars by the OECD⁴. Unfortunately, criminals are infiltrating and exploiting both online and physical marketplaces to traffic in counterfeit products and pirated movies, television, music, and other copyrighted works.

Illicit trade also undermines the economic and consumer benefits of our digital economy and threatens the health and safety of our citizens and businesses. The challenges around counterfeiting and piracy cannot be solved simply with additional resources, additional seizures, or advanced targeting, though each are integral elements to disrupting counterfeits downstream. It is evident that public-private partnerships between governments and businesses that focus attention on systemic, upstream challenges create the opportunity for lasting impacts and foundational change.

Counterfeit Enforcement in an Online Environment

² *International IP Index 12th Edition*; <https://www.uschamber.com/intellectual-property/2024-ip-index>

³ https://www.wto.org/english/res_e/booksp_e/trade_outlook23_e.pdf

⁴ *Trends in Trade in Counterfeit and Pirated Goods*, <http://www.oecd.org/gov/risk/trends-in-trade-in-counterfeit-and-pirated-goods-g2g9f533-en.htm>

The technological revolution of the past three decades has helped foster international trade growth, most keenly evidenced by a booming e-commerce environment. While this development has enabled businesses of all sizes the ability to reach consumers in markets that a generation ago would have been inaccessible, the resulting increase in volume and value of global trade has made it increasingly difficult to enforce against counterfeit and pirated goods. Lax overseas enforcement means U.S. consumers are vulnerable to fake, sub-standard, and counterfeit goods from sources all over the world where considerably lower standards of transparency, accountability, and seller vetting are in evidence.

As the e-commerce ecosystem continues to expand and evolve, combating IP theft becomes more and more challenging, particularly in a global trade environment in which many global trade powerhouses have vastly different enforcement capabilities. Criminals and transnational criminal organizations have adopted sophisticated strategies to peddle illicit, IP violative products directly to consumers shopping online, mirroring strategies used in physical marketplaces for counterfeit and pirated goods. Despite considerable investments by legitimate businesses to secure product integrity, chemical safety standards, and customer trust, the pervasiveness of counterfeiters infiltrating the global supply chain is unyielding and rapidly evolving. To protect the health and safety of consumers and the continued viability of trusted brands that employ millions of people worldwide, it is imperative that law enforcement authorities both in the United States and abroad have the resources and tools to combat counterfeiters operating in the online environment.

IP infringement is increasingly complex and globalized, requiring sophisticated investigatory tools. No IP enforcement program can be effective without the ability to trace, on a cross-border basis, counterfeiting and other illicit activities with insights and information derived from foreign source countries, distribution hubs and networks, and end-user markets. Data localization measures and unnecessary data transfer restrictions directly interfere with the ability to investigate and counteract transnational IP infringing activities. Cross-border data transfers are critical to many aspects of IP enforcement, from monitoring marketplaces, to gathering evidence of infringement in multiple locations, to researching details of illicit networks, and using administrative or judicial tools in multiple jurisdictions to preserve evidence and secure recourse.

The Chamber supports collaborative global initiatives dedicated to combating transnational criminal networks that produce and sell counterfeits, pirated works, and other illicit goods, including in the online ecosystem. For example, the OECD illicit trade taskforce continues its valuable work to study illicit trade activity, creating a foundational understanding of the significant threats illicit trade poses to our global economy and examining, through quantitative metrics, novel solutions to combat the production and sale of counterfeit goods.

The Chamber believes the U.S. government plays a critical role in combatting the sale of IP-infringing goods online, and for this reason, we support the USTR's annual effort to identify marketplaces that consistently allow counterfeit and pirated products to be listed and sold on their platforms at the expense of American IP rightsholders and consumers. While this year's notorious markets report includes a specific focus on online pharmacies, we believe the marketplaces listed below have historically sold a wide range of counterfeit goods, pirated works, and other illicit items, all of which endanger consumer safety and undermine the legal certainty necessary for adequate global trademark protection. The Chamber recommends that USTR pay special attention to the following online marketplaces:

- IndiaMART
- PDD Holdings (Pinduoduo and Temu)
- Shopee
- TaoBao
- TradeIndia
- WeChat/Weixin

Counterfeit Medicines and Online Pharmacies: Challenges and Recommendations

The Chamber remains greatly concerned about the health and safety of American consumers who purchase potentially counterfeit medications through online pharmacies and marketplaces that do not adhere to a rule of law intended to safeguard and secure consumer health. Online transactions for prescription drugs are made through standalone websites, online marketplaces, and social media platforms and these transactions can be unregulated and dangerous for patients⁵. Oftentimes, patients purchase medications from these online sources believing they are getting low-cost versions of FDA-approved medicines, but instead are being deceived by criminals purely for financial gain⁶. At best, patients receive illegally diverted drugs that arrive at their doorstep with zero regulatory oversight on how the drugs were stored, packaged, or shipped. At worst, they receive counterfeit medicine that can put the consumer in lethal danger. Given the internet's lack of central governance, enforcement typically lies solely with internet service providers and the platforms' willingness to enforce their own terms of use. Many do nothing after being put on notice that their services are used to illegally sell prescription drugs, creating a refuge for this type of illegal activity online.

⁵ OECD/EUIPO (2020), *Trade in Counterfeit Pharmaceutical Products*, Illicit Trade, OECD Publishing, Paris, <https://doi.org/10.1787/a7c7e054-en>.

⁶ <https://www.nytimes.com/2023/05/16/well/live/ozempic-alternatives-semaglutide.html>

The rise of counterfeit medicine sales globally is a public health issue with dangerous consequences. Sales of counterfeit and illicit drugs, including those peddled through illegal diversion on the grey market, are growing around the world. Most alarmingly, the North American region consistently ranks highest in annual incidents of illegal pharmaceutical seizure, transit, and destination⁷. The Chamber is increasingly concerned about counterfeit GLP-1 medications infiltrating the U.S. market⁸. Bad actors around the world are taking advantage of American consumers seeking popular diabetes and weight-loss drugs by selling substandard, counterfeit, and sometimes lethally dangerous active pharmaceutical ingredients (“API”) to online pharmacies for sale within our borders. This poses a significant public health threat and directly undermines the IP of the drug makers who own the rights to such medications.

The Role of Public-Private Partnership to Combat Counterfeiting

In 2021, U.S. Customs and Border Protection (“CBP”) and the Chamber signed an historic Memorandum of Understanding (“MOU”) to implement a dedicated public-private partnership with a multi-faceted program of anti-counterfeiting work. Since its inception, the MOU has facilitated, developed, and spearheaded models for public-private information-sharing related to illicit trade.

A particularly fruitful component of the MOU is a program of work in which Chamber member companies, representative of highly counterfeited industries, are sharing foreign counterfeit seizure data with CBP and the National IPR Center through a designated Chamber secondee. The secondee is physically embedded at the National IPR Center and can regularly interface with data analysts and investigative agents at the Center to help comb foreign seizure data for themes or commonalities that indicate illicit activity, develop investigatory leads, fact-check sources, and use limited resources and bandwidth in the most effective fashion possible.

Furthermore, the Secondee and Chamber member participants have been able to assist in strengthening current criminal investigations by identifying additional infringing importers and exporters that were unknown to Homeland Security Investigations (“HSI”). The Secondee works with CBP to identify transshipment routes of counterfeit goods that enter the United States before its ultimate destination to another country. CBP and the Secondee analyze data provided by the U.S. Chamber’s members in real time to identify transshipment routes and related information that is

⁷ <https://www.psi-inc.org/geographic-distribution>

⁸ <https://www.vanityfair.com/news/story/counterfeit-ozempic-global-growth-industry>

then utilized by CBP to conduct targeting of the counterfeit goods before they reach their ultimate destination.

The information sharing program has resulted in the seizure of millions of dollars' worth of IP violative goods in the United States, and in this and many other ways, may provide a useful template for public-private partnerships in the global enforcement arena. In particular, the work has been shown to make a significant impact on the efficiency with which CBP can detect and seize counterfeit pharmaceutical products and medical devices at our borders. This is, in part, due to international training sessions the Secondee has planned and executed for biopharmaceutical member participants. In 2024, the Secondee led successful trainings in Mauritius and Türkiye where U.S. customs officers and foreign customs officers were trained on how to spot counterfeit medicines. These efforts are making a real impact on American consumer safety.

Conclusion

We appreciate the focus of the Office of the U.S. Trade Representative in protecting the IP rights of creators and innovators, and especially appreciate the attention being paid to the public health threat of counterfeit medicines. Illicit markets offer a refuge to sellers of infringing goods and those who lure consumers to—and exploit them through—digitally pirated content. The persistently high levels of global counterfeiting and digital piracy demonstrate that government and industry must be equally relentless in meeting the challenge.

Sincerely,

A handwritten signature in black ink, appearing to read 'TK' followed by a long, sweeping horizontal stroke.

Tom Quaadman
Senior Vice President
Economic Policy
U.S. Chamber of Commerce