NATIONAL ASSOCIATION OF Manufacturers

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January 28, 2026

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 20503

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

Dear Mr. Lee:

The National Association of Manufacturers is the largest manufacturing association in the United States, representing manufacturers of all sizes, in every industrial sector and in all 50 states. Manufacturing drives American prosperity and innovation—the industry employs nearly 13 million people, contributes $2.9 trillion annually to the U.S. economy and accounts for nearly 52% of all private-sector research in the nation.[1]

The NAM appreciates the opportunity to comment as the Office of the U.S. Trade Representative conducts its annual review of foreign country laws, policies, and practices that fail to provide adequate and effective protection and enforcement of intellectual property rights held by manufacturers in the U.S.

Manufacturers have long relied on IP protections to incentivize and protect the return on their substantial investments in research and development, to drive innovation in advanced manufacturing processes, and to undergird exports of their world-leading manufacturing products. The rapid integration of automation and artificial intelligence into all facets of manufacturing operations is accelerating the rate of learning and innovation in manufacturing, making it more important than ever to ensure IP is protected from the R&D and design stage, to the data collected on the factory floor for optimizing operations, to the patents, trademarks, and copyrights associated with U.S.-manufactured products.

The NAM encourages the administration to leverage ongoing negotiations to achieve bilateral agreements with stronger IP protections that resolve longstanding regulatory and enforcement gaps. It is also vital for the administration to remain fully engaged in multilateral forums – particularly the World Trade Organization and the World Intellectual Property Organization – to ensure the highest

[1]National Association of Manufacturers, "Facts About Manufacturing," 2026.

standards are promoted and existing rights preserved, thereby ensuring that innovation generated by manufacturers in the U.S. serves to support economic productivity and American jobs while remaining a source of global competitiveness.

IP Rights are a Cornerstone of American Manufacturing Competitiveness

According to the U.S. Patent and Trademark Office, IP-intensive industries provide 63 million jobs, or 44% of national employment, with the manufacturing sector providing nearly 13 million of those jobs as an IP-intensive industry.[2] The manufacturing sector accounts for 90% of American jobs supported by utility patents and design patents.[3] As a result, American manufacturing innovation and IP remain major targets for theft by foreign competitors, enabled by relatively weaker IP protections and enforcement in overseas markets, threatening manufacturing growth and jobs in the U.S., posing risks to the health and safety of consumers, and creating vulnerabilities to U.S. national security.

Vigorous protection of U.S. IP rights abroad has long been a core component of U.S. trade policy. Manufacturers appreciate that IP protection is a priority for this administration. As American manufacturers seek to obtain, use, and enforce their IP rights in the markets in which they compete, they encounter a range of barriers, such as compulsory licensing, technical and regulatory roadblocks to obtaining and enforcing patents, inadequate protection of trade secrets, counterfeiting of branded manufactured goods, and piracy of industrial software. In addition to gaps in IP protections in individual markets, coalitions of governments and activists have engaged in sustained efforts in recent years to weaken global IP frameworks and core protections provided by international disciplines.

Cross-Cutting Trends and Concerns

Expanded Misuse of Compulsory Licensing

Compulsory licensing – government-led circumvention of patents or copyrights that allows local companies to produce a product without an owner's permission – has in recent years seen both an uptick and an expansion of application to an increasing number of products.

WTO members have recognized that compulsory licensing should operate under specific guidelines and strict limitations, as laid out in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the Doha Declaration on the TRIPS Agreement and Public Health. Compulsory licenses should only be granted and used when they meet the specific criteria in those agreements so as to not undermine IP benefits; such licenses also must result from transparent processes that involve consultation with all stakeholders.

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[2] U.S. Patent and Trademark Office, "Intellectual property and the U.S. economy: Third edition," Andrew A. Toole, Ph.D., Chief Economist Richard D. Miller, Ph.D., Economist Nicholas Rada, Ph.D., Deputy Chief Economist, 2019.
[3] *Ibid.*

Innovative manufacturers continue to be concerned that governments are issuing compulsory licenses that do not adhere to WTO disciplines. For example, **Colombia's** issuance of a pharmaceutical compulsory license in 2023 is believed to overreach the WTO's strict criteria and guidelines for compulsory licensing.[4] Manufacturers are also closely watching if licenses will be granted in **Australia, Brazil, Canada, Germany, Hungary,** and **Indonesia,** where legislation has directed how compulsory licenses may be issued beyond WTO guidelines. Companies are concerned that broad circumvention of compulsory licensing disciplines will discourage investment into R&D for new medicines and other technologies as licenses are applied to more products.

Several countries have also expanded the scope of circumstances and products subject to compulsory licensing actions. For example, **Mexico's** Federal Law for Protection of Industrial Property, which went into effect in 2020, authorizes compulsory licenses for any patented products that have not been manufactured, sold, or imported in-country within three years.[5] **Saudi Arabia** in 2022 expanded compulsory licensing to sectors beyond pharmaceuticals, where the practice is most common, to defense, energy, and food and beverage.[6] Many governments have also pushed to enshrine in the United Nations Framework Convention on Climate Change compulsory licensing of environmental technologies, which would undermine U.S. intellectual property in a potentially large swath of manufacturing process and technology innovation.

Growth of Global Counterfeiting

Counterfeiting and illicit trade remain some of the most prominent risks to manufacturers' IP and global market access. A 2025 report by the Organisation for Economic Co-operation and Development estimates that global trade in counterfeit goods was valued at approximately $467 billion in 2021 based on seizures of counterfeit goods.[7] This staggering figure fails to capture the vast majority of traded counterfeit goods that evade detection by customs authorities.

The growth of online channels, from e-commerce marketplaces to social media platforms, has created valuable opportunities for manufacturers to sell their products, most particularly for small- and medium-sized manufacturers. But these platforms have also made it easier for counterfeiters to undertake tactics including:

- Misrepresenting products online by posting authentic pictures while shipping fake products directly to consumers or posting fake reviews to promote the impression that their products are legitimate.
- Deflecting suspicion by maintaining a small stock of legitimate products to fulfill orders placed by law enforcement officials or brand representatives.

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[4] Republic of Colombia, "Ministerio de Salud y Protección Social Resolutión Numero 1579 de 2023 [Ministry of Health and Social Protection Resolution Number 1579 of 2023]," 1 December 2023.
[5] World Intellectual Property Organization, "Federal Law on the Protection of Industrial Property, Mexico..," 1 July 2020.
[6] Saudi Authority for Intellectual Property, Compulsory licensing of patents issued by the Saudi Authority for Intellectual Property, June 2022.
[7] Organisation for Economic Co-operation and Development, "Mapping Global Trade in Fakes 2025," 7 May 2025.

- Hiding their identity or other business details in ways that make it more difficult to enforce penalties when counterfeit products are discovered.

A concerning regional trend, companies see a serious uptick in counterfeit products on online marketplaces such as Shopee and Lazada that serve the ASEAN markets. Infringers use generative artificial intelligence to create false, misleading, or otherwise unfair listings that associate themselves with copyright-holding brands. **Indonesia, Vietnam, and Thailand** do not require adequate notice and takedown measures to address counterfeiting on these platforms. Shopping on social media platforms is also exploding in popularity; sellers on these platforms increasingly sell infringing products, but platforms are generally unwilling to address IP infringement on their sites.

Third-party markets that lack effective mitigation, enforcement, and prosecution against counterfeiters amplify the growth of illicit trade. Counterfeit and pirated goods arrive in the U.S. from numerous countries, but **China and Hong Kong** accounted for nearly 93% of total seizures by CBP in 2024. [8]

Small cross-border shipments have become an outsized vector for trade in counterfeit goods in the age of e-commerce.[9] Customs declarations among national postal services are outdated and beset with data quality issues, resulting in inadequate screening for counterfeit products. In addition, artificially low rates for postal packages persist due to rate setting done at the Universal Postal Union (UPU). These two issues were discussed at a recent meeting of the UPU Congress in September 2025. On customs reform, UPU acknowledged that it was countries' "sovereign right to adopt customs and security policies as they see fit."[10] As such, CBP and other U.S. border agencies should consider strengthening the rules so that imported postal shipments comply with the same requirements as non-postal shipments.

The UPU Congress also discussed postal renumeration systems. The NAM has long supported initiatives by the UPU to move a portion of the postal volume to a system of self-declared rates. However, at the September 2025 UPU Congress, members largely agreed to delay this transition.

Manufacturers encourage the administration to remain committed to ensuring that countries implement UPU reforms, including domestic rate-referencing and self-declared rates to mitigate artificially low rates for postal packages. Targeting these market distortions and strengthening domestic customs rules are critical to ensuring that imported postal shipments comply with the same requirements as non-postal shipments and mitigate counterfeit through small parcels.

The significant volume of counterfeit goods sold on e-commerce platforms necessitates stronger mechanisms to address this unlawful activity and more work to hold these platforms liable for their role in the rise of counterfeits. This must include efforts to ensure that e-commerce providers prevent counterfeiters from abusing their platforms by exercising stronger oversight, including, for example,

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[8] U.S. Customs and Border Protection, Intellectual Property Rights (IPR) Seizures, 2024.
[9] Organisation for Economic Co-operation and Development, "Misuse of Small Parcels for Trade in Counterfeit Goods: Facts and Trends," 2018.
[10] Statement for the Record, United States of America, UPU Congress Report 5, Annex 3, rev. 1 (Dec. 11, 2025); UPU Press Release (Aug. 26, 2025) available at https://www.upu.int/en/press-release/2025/press-release-upu-working-to-ready-global-postal-network-for-imminent-suspension-of-the-dutyfree-d.

standards that some U.S.-based e-commerce marketplaces are using. Manufacturers also urge stronger transparency requirements for providers to require users to provide verifiable contact and other information to platforms and consumers. This approach would help to limit the ability of counterfeiters to remain anonymous and circumvent applicable IP laws.

Manufacturers urge the administration to continue to work bilaterally with trading partners to strengthen penalties against counterfeiters and engage closely with foreign trading partners and their law enforcement to tackle counterfeit shipments.

Spread of Geographical Indications

The **EU** continues to aggressively promote widespread adoption of its approach to geographical indications (GIs), undermining trademarks held by American manufacturers and creating significant market access barriers for U.S.-made goods that rely on common names. The EU has entered bi-lateral agreements with **Japan, Vietnam, Chile, China, MERCOSUR** states, and **New Zealand**, guaranteeing protections for EU producers and restricting access for American manufacturers. Additional negotiations with **Australia** and **India** are underway, including proposals to extend GI protections to non-agricultural sectors such as industrial, textile, and craft products.[11]

In addition to requiring GIs in its bilateral agreements with trading partners, the EU is pushing for stronger global GI protections at WIPO and seeks to secure funding for that initiative, contrary to the interests of the U.S. and other WIPO member states. This effort to legitimize EU GIs under the mantle of WIPO would undermine the ability of the U.S. and other countries to protect existing trademarks and ensure fair treatment for products marketed using generic terms.

GI protections have created monopolies on specific products in certain markets and have created undue burdens for American manufacturers, who must adapt existing trademarks and marketing to maintain market access. Manufacturers urge the U.S. to remain vigilant and engaged at WIPO and other international forums to ensure that these expanded GI measures do not become international standards. Such efforts would also send a strong signal to EU trading partners to avoid making commitments to the EU that undermine U.S. IP rights.

Country-Specific IP Challenges

As the administration is actively engaged in bilateral negotiations, the NAM supports this opportunity to prioritize securing IP commitments that address regulatory gaps and improve enforcement of IP rights. USTR's Special 301 Report with its Priority Watch List and Watch List highlights laws, policies, and practices that fall short of obligations and undermine American manufacturing innovation. Below are practices and markets that NAM members have assigned priority to addressing in this year's Special 301 Report.

Canada: Manufacturers remain concerned about Section 51.1 of Quebec's Charter of the French Language (referred to as Bill 96), which mandates significant labeling and packaging changes for

[11] Association of European Regions for Products of Origin, "EU Trade Policy."

manufacturers to include French translations of non-French trademarked items, potentially upending decades of IP law, creating burdens for manufacturers and limiting access to the Quebec market.[12]

Canada also does not provide patent restoration mechanisms that are consistent with USMCA commitments. The USMCA requires Canada to provide a patent term adjustment (PTA) for unreasonable delays during the prosecution and issuance of any patent. The process of applying for a PTA is burdensome and costly and creates significant market uncertainty. The Canadian government should provide up to five years of patent term restoration that runs consecutively with PTA instead of concurrently.

China: In 2025, China took additional steps to upgrade IP laws and regulations in an attempt to build a stronger business environment for innovative sectors. In October, China released new amendments to its Anti-Unfair Competition Law that introduced penalties for the illegal acquisition of company data and fraudulent practices on e-commerce platforms. In November, the China National Intellectual Property Administration finalized Patent Examination Guidelines to include standards of punitive damage for infringement, increase criminal enforcement capabilities, and provide procedural efficiency for new patent applications. As the new guidelines went into effect on January 1, 2026, it is critical for USTR to closely monitor the implementation and effectiveness of these new initiatives and ensure they adequately protect and enforce IP rights.

American manufacturers, large and small, nonetheless continue to face a range of challenges to protect their data, trademarks, and technology in China. Challenges include inadequate and unclear filing procedures, lack of efficiency of the Chinese IP court system, and discriminatory treatment by many local enforcement officials. Additional concerns include:

- Broad industrial policies designed to promote the development of Chinese IP-intensive industries and pressure American manufacturers to localize R&D and technology in China.
- Structural barriers to strong IP enforcement, such as value thresholds that effectively preclude criminal enforcement, and inadequate or politicized judicial procedures that effectively discriminate against foreign companies.
- Inconsistent or lack of enforcement at the local level.
- Inadequate enforcement of trademark violations, particularly in online sales.
- Persistently elevated levels of counterfeiting, piracy, and trade secret theft, both physically and online, as well as weaknesses in judicial enforcement of trade secrets.
- Cybertheft and hacking that targets U.S. companies and their technology.
- New laws, regulations, and policies in areas such as competition, standards, and product price controls that undercut U.S.-generated innovation and IP.
- Overall information transparency remains insufficient, as platforms provide inadequate disclosure regarding the source of goods and sellers' qualifications.

[12] Quebec Law, "Charter of the French Language," 24 October 2025.

- Enlisting by the Chinese government of private companies and individuals throughout its industrial base to use economic espionage to acquire U.S. trade secrets and proprietary information.[13]

Colombia: In recent years, Colombia has improved IP protections and strengthened enforcement, for example by increasing civil liability for copyright violations. However, Colombia has yet to implement key aspects of CONPES 4062, the national IP policy released in 2021, and recent policy proposals are not sufficient to address concerns over piracy and counterfeit, particularly through e-commerce platforms.

European Union: The European Council and Parliament have finalized a series of regulatory proposals in the General Pharmaceutical Legislation that would reduce protection of regulatory data for new medicines and expand exceptions for patent infringement and IP protection.[14] If approved, the proposal could weaken data protection, condition IP protection incentives on undefined criteria, and create an EU-wide compulsory licensing system.

India: Over the past several years, India has taken steps to strengthen its recognition of the value of innovation and IP in the Indian economy. Patent rules have been introduced that aim to address delays in pre-grant opposition and expedite the grant of patents. Additionally, Patent Amendment Rules introduced by the Ministry of Commerce in November provide an adjudicatory framework for penalties and appeals under the Patents Act, 1970.[15] Nonetheless, manufacturers continue to face considerable barriers at every step of the patent application process.

India created new criteria for innovative products that do not align with internationally accepted criteria. Inventions related to chemical compositions or pharmaceutical substances must pass standard global requirements of novelty, inventive step, and industrial application, as well as "non-patentability" tests described under Section 3(d) of the Patents Act.[16] This practice is unusual, and the Indian Patent Office does not provide manufacturers clear guidance as to how patent examiners should interpret this criterion, leading examiners and courts to interpret it subjectively and inconsistently in patent proceedings. As a result, India has rejected, invalidated, or otherwise revoked dozens of patents over the last decade for innovative products, including pharmaceuticals and therapies widely patented in other countries.

Manufacturers also continue to have concerns about burdensome requirements contained in the Biological Diversity Rules, 2024 that only apply to foreign entities. These requirements require any foreign entity seeking IP protection for inventions derived from R&D, including digital sequence information, based on Indian biological resources, to obtain prior approval from the National Biodiversity Authority. These requirements impose undue burdens on researchers and innovators and do not align with international standards.

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[13] National Counterintelligence and Security Center, "Foreign Economic Espionage in Cyberspace," 2018.
[14] European Council, "'Pharma package:' Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector," 11 December 2025.
[15] K&S Partners, "An Overview of the 2025 Patent (Amendment) Rules Related to Penalty Adjudication," 9 January 2026.
[16] World Intellectual Property Organization, "The Patents Act, 1970, India."

Broad challenges persist, including:

- Lack of enforcement of Ministry of Corporate Affairs orders and weak border enforcement measures.
- Inconsistent cooperation from e-commerce sites (e.g., Flipkart, Myntra) on implementation of IP standards as well as non-compliance with labelling requirements.
- Delayed Customs recordation of trademarks and burdensome requirements for copyright registrants to show proof of ownership, which some manufacturers find impractical and onerous given the large range of copyright assets of brand owners and the nature of copyright infringements.
- Investment restrictions or regulatory hurdles for IP-intensive industries, including high tariffs, high regulated pricing regime, and procurement frameworks that disincentivize the importation of patented drugs by public entities.
- Lack of training opportunities with Customs authorities, including brand identification trainings.

Indonesia: Since the 2025 Special 301 Review, the Indonesian government passed IP legislation and is expected to adopt implementing regulations that further strengthen protections for American manufacturers. The revised 2024 Patent Law has improved coordination among government agencies and provided transparency as to how patent applications are approved and monitored. A presidential decree established a task force on IP enforcement across twenty ministries, agencies, and law enforcement agencies. The NAM encourages continued monitoring of implementation of these developments.

Indonesia still maintains localization requirements that impact innovative manufacturers and enforcement of copyright laws. For example, trademark owners are required to have a local office to register and protect their trademarks with the Directorate General of Customs and Excise. As a result, enforcement efforts are concentrated in major urban centers—and infringing content in online marketplaces is prominent. Additionally, while Indonesia has a specialized Commercial Court, IP cases are not always overseen by judges with expertise in IP law. Specialized IP courts could improve the effectiveness of Indonesia's IP protection environment.

Japan: Japan has continued to make significant progress in rewarding innovation and eliminating drug-lag for pharmaceutical innovators. Key reforms made in 2024, including the expansion of product eligibility criteria for the Price Maintenance Premium program and the introduction of schemes to incentivize early launch, have been welcomed by manufacturers. However, Japan's previous use of off-year drug pricing revision has resulted in price reduction during patent periods. Additionally, expanded repricing rules are outdated for innovative modalities (e.g., for regenerative medicines) and pose a market access issue for foreign companies.

Korea: Korea has imposed discriminatory and nontransparent policies that undervalue American innovation and limit resources available to support U.S.-invested R&D. Manufacturers maintain concerns over Korea's patent term extension (PTE) system that was amended in 2024 to limit the number of patents eligible for PTE based on a single drug approval. Korea's PTE system has

previously been criticized for being more restrictive than other countries', and structural deficiencies and lack of due process continue to pose additional challenges.

Kazakhstan: Counterfeiting continues to increase in Kazakhstan, as border control measures have worsened in recent years. IP rights enforcement is not consistent, and, in several cases, enforcement actions are a result of manufacturers facilitating pre-litigation work and investigations. The Department of Justice is not investigating IP infringements, despite being the main authority responsible for IP enforcement. Growing digital markets have caused counterfeit and piracy to increase as limited regulations address online IP enforcement. The administration has made efforts to deepen the Enhanced Strategic Partnership Dialogue with Kazakhstan, with commercial deals in sectors including AI and information technology. As dialogue continues, manufacturers urge the administration to consider how fundamental IP commitments can be useful in addressing non-tariff market barriers, opening market access, and protecting innovation.

Mexico: Mexico has taken increased steps to improve IP protections and enforcement; however, effectiveness is limited due to budget and staffing restrictions in key government agencies and bureaucratic redundancies.

The Mexican Institute of Industrial Property (IMPI) has taken more aggressive administrative actions against counterfeiters, though the size of the agency and its limited staff have impacted the effectiveness of enforcement. Manufacturers are still seeking regulations to implement important IP protections, such as patent term adjustment and patent linkage. As a result, manufacturers continue to experience IP violations in Mexico, harming innovation and allowing generics from foreign countries to take market share away from American companies.

In some cases, the Mexican government has proceeded to international tenders of medicines with invalid patents. Despite the presentation of direct evidence to Mexican authorities, the infringing companies are still able to participate in government tenders, and IMPI is not enforcing its laws or issuing injunctive relief. Recent court precedents have compounded these challenges, undermining patent usage by preventing their publication in the linkage gazette and allowing injunctions against products that infringe industrial property rights to be lifted without sufficient legal justification.

Additionally, the National Custom Agency faces challenges in regular border enforcement due to its inability to make determinations or to seize or destroy counterfeit goods without an order from the Attorney General's Office (FGR) or IMPI. FGR's internal ban on seeking search warrants in IP cases has stalled criminal investigations and prosecution.

There remains a serious backlog at Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS) for the authorization of clinical trials and approval of new medicines. These delays in marketing approval from the Mexican government are a major hurdle for pharmaceutical manufacturers operating in-country.

Saudi Arabia: The Saudi Authority for Intellectual Property (SAIP), Saudi Arabia's new administrative IP authority, has undergone rapid development in recent years. However, enforcement actions lack transparency, and SAIP continues to provide contradictory opinions on enforcement measures. The current border enforcement and surveillance system, led by SAIP, has

not yielded any detentions while infringements and counterfeiting continue. The administration should urge the Saudi government to establish an official Customs recordation system.

Thailand: The U.S.-Thailand Framework for an Agreement on Reciprocal Trade included important commitments on GIs, enforcement of trademark counterfeiting violations, and other IP protections. These provisions are welcomed by manufacturers who have faced difficulties with local enforcement of counterfeit and delayed progress on civil complaints of infringements. Robust implementation and enforcement will be important to monitor through continued dialogue over the coming year to ensure these commitments are met. Focus should continue to be placed on border enforcement measures, infringing content in online marketplaces (e.g., Shopee TH), and streamlining infringement cases to ensure timely remedy for copyright holders.

Ukraine: Counterfeit and piracy have decreased in Ukraine in recent years. In July 2025, Ukraine signed a Memorandum of Understanding with WIPO to strengthen the strategic partnership between Ukraine and the international IP community. Recognizing that Ukraine was not included in the 2025 Report due to the ongoing war, there are areas of improvement that, with U.S. support and engagement, would support future investments and economic activity in post-war recovery. This includes support for standing up specialized IP courts and implementation of measures to combat the growing global trend of counterfeits in e-commerce.

United Arab Emirates: Each of the seven Emirates have their own autonomous IP enforcement institutions, including Customs, Ministry of Economy/Department of Economic Development, Police, and Public Prosecution Office. Decentralization poses a challenge, as enforcement can vary significantly from one Emirate to another. Since the UAE does not possess a central registration system, IP holders must record their rights with each Emirate separately, which increases costs of customs surveillance. A more coordinated approach between Emirates and their enforcement institutions is critical to control the transshipment of counterfeit and infringing goods. Civil litigation in the UAE can be lengthy and costly due to targets generally not complying with warning letters. Manufacturers rely more heavily on raids, which have been successful in the seizure of infringing products and fines imposed on perpetrators. However, fines and actions against first-time and repeated infringers vary and are solely up to the administrative authority’s discretion.

Vietnam: Vietnam maintains a copyright registration system that does not align with international standards and creates burdens for manufacturers. To register with the Copyright Office of Vietnam, registrants must include passport and national ID cards of the creator and employment contracts that may contain private information and trade secrets. A signed declaration by the creator is an additional requirement, which may be difficult to obtain if the creator has left the company or is deceased. There are no other alternatives to copyright registration.

Manufacturers face a complex IP enforcement system that is unresponsive and fails to target infringement effectively. For example, IP enforcement agencies typically request formal opinions from IP agencies like the Vietnam Intellectual Property Research Institute and the Expertise Center for Copyright and Related Rights before initiating enforcement actions. This requirement reduces the speed of enforcement significantly. When remedies are imposed on infringers, they are viewed as relatively lenient and do not deter future infringements. Additionally, while recordation and production identification have improved, seizures remain low and infringement in online marketplaces persists.

Promoting High Standards in Multilateral Forums

In many multilateral forums, detractors of IP rights promote a false dichotomy between public health, environmental, or developmental goals and the implementation and enforcement of robust IP protections, seeking to legitimize policies that undermine IP protections at the national level. These approaches not only seek to strip IP rights holders of their benefits, but they would also in effect disincentivize the R&D and innovation needed to solve societal concerns. These efforts are present at institutions that carry a mandate to promote IP standards, but gain the most traction in forums such as the WHO and UN initiatives that have no such mandate, but that seek to develop treaties or other forms of obligation that attempt to override or create conflicts with core agreements, most importantly, the WTO TRIPS Agreement.

At the WTO, manufacturers urge the administration to reinforce the minimum standards embedded in the TRIPS Agreement and prevent unnecessary expansion of flexibilities in interpretation or application the agreement. With the upcoming Ministerial Conference (MC14) in mind, the U.S. should not agree to further extend the moratorium on “non-violation” and “situation” complaints, sending a signal regarding compliance with the agreement while restoring U.S. rights to address TRIPS-violating behaviors. At the same time, the U.S. should continue to contribute thought leadership in the Working Group on Trade and Transfer of Technology to promote norms of technology transfer through voluntary and mutually agreed contracts.

At the OECD, countries that are approved candidates for accession are required to demonstrate that their trade-related laws, regulations, and enforcement systems are in line with the standards set by the Trade Committee, including in the critical areas of innovation and IP. The OECD is currently engaged in accession negotiations with Argentina, Brazil, Bulgaria, Croatia, Peru, Romania, Indonesia, and Thailand. Manufacturers strongly urge the administration to make full use of the accession process to garner commitments from each of these countries to raise their IP standards to the level of OECD countries as a firm criterion for accession.

Conclusion

Manufacturers in the U.S. are world leaders in R&D and innovation. USTR’s Special 301 Review is a vital opportunity to shine a light on critical shortcomings in foreign country IP laws, policies, and practices—and more importantly to vigorously pursue improvements so that the intellectual property rights held by manufacturers in the U.S. remain a core source of global competitiveness now and well into the future. Thank you for the opportunity to comment.

Sincerely,

Andrea Durkin
Vice President, International Policy