

The Special 301 Process: An Opportunity to Impact on Global IP Policy

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Where can you go to get an overview of significant IP policy issues across different countries and regions all in one place? Either the U.S. Trade Representative's (USTR) annual [Special 301 Report](#), or [IPO's annual comments](#) to USTR for the Report can provide you with this needed resource. IPO's Special 301 comment letter provides a roadmap for IPO's international advocacy efforts throughout the year and offers the chance to impact global IP policy.

The USTR's Special 301 Report

The USTR Special 301 Report is the Congressionally mandated annual review of the global state of intellectual property rights (IPR) protection and enforcement. The Report has been published each year since 1989 and identifies U.S. trading partners that do not "adequately and effectively" protect or enforce IP rights or otherwise deny market access to U.S. innovators and creators. Many countries and regions are featured in the Special 301 Report, in which the USTR may designate a country as a "Priority Foreign Country"—a rarely used designation that identifies those countries that have the most egregious IP policies. Such countries may face trade sanctions. More commonly, however, countries are placed on the "Priority Watch List"¹ or "Watch List,"² indicating that a particular IP-related problem exists. USTR also may conduct an Out-of-Cycle Review, which is a tool that encourages progress on IP issues through heightened engagement with the trading partner, or a country may be subject to Section 306 monitoring.³

¹ The 2020 Priority Watch List countries were Algeria, Argentina, Chile, China, India, Indonesia, Russia, Saudi Arabia, Ukraine and Venezuela.

² The 2020 Watch List countries were Barbados, Bolivia, Brazil, Canada, Colombia, Dominican Republic, Ecuador, Egypt, Guatemala, Kuwait, Lebanon, Mexico, Pakistan, Paraguay, Peru, Romania, Thailand, Trinidad & Tobago, Turkey, Turkmenistan, the United Arab Emirates, Uzbekistan and Vietnam.

³ In 2020, USTR conducted an Out-of-Cycle Review of Saudi Arabi and extended Malaysia's 2019 Out-of-Cycle Review; China remained subject to Section 306 monitoring. (See, e.g., <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/april/ustr-releases-annual-special-301-report-intellectual-property-protection-and-review-notorious>).

The Special 301 Report is used to develop and support U.S. positions in discussions and negotiations with other countries, including the negotiation of trade agreements, such as the U.S.-China Phase 1 Trade Agreement and USMCA (US-Mexico-Canada Agreement). U.S. government officials have indicated that they refer to the Special 301 Report and IPO's comment letters in their day-to-day interactions with their counterparts and to carry out their mission to improve IP systems internationally.

IPO's Special 301 Comments

Each year, USTR invites public participation in the review process and solicits comments to help in its assessment of trading partners' IP protection and enforcement. For the last few years, IPO's International Patent Law and Trade Committee (IPLTC) has lead IPO's engagement in this process. It has consolidated input from IPO committees and IPO member companies and firms in order to assist in the preparation of IPO's comment letter. IPO's comments, among other things, highlight many of the issues and concerns raised by international-focused IPO committees throughout the year. Several themes have been developed in IPO's Special 301 comment letters, including trade secret protection, counterfeiting, compulsory licenses, and weak (or delayed) patent enforcement regimes.

Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires WTO members to ensure effective protection of trade secrets. In the years since TRIPS Article 39 has been agreed (December 15, 1993), there has been an insufficient effort in many WTO member countries to bring the laws, regulations and enforcement environment up to compliance with the required standard. Improving the global environment for protection of trade secrets is one of the top priorities for the U.S. Trade Representative. As part of marketing authorization submissions of medicines, regulatory authorities require pre-clinical and clinical trial information demonstrating the safety and efficacy of a medicine, which includes trade secrets. Regulatory data protection (RDP) provides a minimum level of protection to innovators, during which time no unauthorized third party can rely on the data submitted by the innovator

for regulatory approval. Unfortunately, several U.S. trading partners do not provide RDP or have inadequate RDP regimes. Examples include Argentina, Brazil, China, Egypt, India, and Turkey.

At the very intersection of consumer protection and IP are measures to stop counterfeiting. The sale and manufacture of counterfeit goods harms the public, consumers, patients, hospitals, governments, industry, and more. [Counterfeiting has well known links to organized crime](#) and money laundering, and is a threat to public safety. IPO members have reported counterfeiting issues in countries such as, for example, Canada, China, Russia, Thailand, Turkey, the United Arab Emirates, Vietnam, and the United Kingdom.

Compulsory licenses threaten intellectual property rights and the ability to maintain an innovation ecosystem. Active compulsory licensing policies are not helpful in promoting partnerships—and undermine investment in innovative solutions that benefit society. Several countries, such as Argentina, Chile, Colombia, Egypt, Philippines, Russia, Thailand, Turkey, and Ukraine, have adopted or considered laws or regulations that promote or provide broad discretion to issue a compulsory license, and in recent years India, Indonesia, Malaysia, and Russia have issued compulsory licenses. The IPO IPLTC also has an active Compulsory Licensing Subcommittee.

Effective, efficient, and fair means for enforcing patents are foundational principles for a legal system to deliver the intended benefits of patent rights. Unreasonable barriers to patent enforcement include excessive evidentiary burdens for the initial complaint, statutory caps or limited damage awards, slow resolution of legal disputes, failure of courts to understand technical issues or IP-specific legal concepts.

Conclusion

The Special 301 Process is one of the most effective ways to make a difference in global IP policy. The IPO IPLTC is eager to hear from any IP member or committee that can provide input for IPO's next Special 301 comment letter. This is a great opportunity for IPO to have an impact on the U.S. government's international efforts to improve IP systems abroad. You don't need to be a trade specialist, trade expert, economist, lobbyist, or government affairs expert to provide input or participate in this effort. And given how sensitive trade-related IP issues can be, feedback is considered anonymous. IPO's 2022 Special 301 comment process will kick off later this year and we look forward to hearing from you.