



INTERNATIONAL INTELLECTUAL PROPERTY UPDATE

Our Intellectual Property (IP) and International Trade (Trade) groups work hand-in-hand to aid clients both in improving domestic and international IP enforcement and advancing their interests under the current systems. We work together to help clients ensure fair trade at the U.S. border, or devising strategies for modifying domestic law and international treaty regimes to improve the effectiveness and predictability of IP enforcement.

IP Practice

We have experience over the full spectrum of intellectual property rights including patents, trademarks, copyrights, trade secrets, and unfair competition. The group successfully litigates IP cases for companies in a variety of industries including biotechnology, chemical, consumer product, electronics, computer hardware and software, entertainment, medical device, pharmaceutical, telecommunications and the internet.

Trade Practice

Our lawyers have handled more cases before the WTO in the field of intellectual property than any other firm in the world. The group draws on extensive government and industry experience to assist companies and trade associations in navigating the international, domestic and foreign systems for intellectual property protection and engaging in processes, including Section 301 and trade policy initiatives, to ensure that these systems meet their needs.

Section 337 Practice

Our lawyers have been involved in over 60 Section 337 investigations before the U.S. International Trade Commission. Drawing upon the strengths of the IP, Trade, and Appellate practices, the group has the depth and flexibility to present a global perspective, prepare a global response, and provide experienced, trial-tested legal representation to clients worldwide.

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United States Announces New Strategies for Intellectual Property Enforcement

On June 22, 2010, the Obama Administration released its [2010 Joint Strategic Plan on Intellectual Property Enforcement](#) to enhance the enforcement of intellectual property (IP) rights at home and abroad, to protect innovation and creativity and to combat IP infringement. Reflecting input from eight federal agencies, the plan provides valuable insight into U.S. IP enforcement priorities for the near and mid-term. Companies active in industries targeted by infringers and counterfeiters, including pharmaceuticals, medical devices, textiles and consumer electronics, may reap significant benefits from the new programs identified in the strategic plan.

Broad Strategic Goals

The strategic plan identifies six broad goals intended to guide the U.S. government's efforts to enhance the protection of IP rights against counterfeiting and infringement. These goals are:

- Ensure that the U.S. government does not purchase or use infringing products;
- Increase transparency in the development of enforcement policy, information sharing and reporting of law enforcement activities in the United States and abroad;
- Improve the coordination of IP law enforcement and training efforts at the Federal, state and local levels, including resources located abroad;
- Work with U.S. trading partners to better enforce IP rights in the global economy;
- Secure supply chains to stem the flow of infringing products into the United States; and
- Enhance data and information collection from IP-related activities and share this information with IP rightholders.

The plan calls for the implementation of 33 programs to achieve these strategic goals. In some cases, the programs identified in the strategic plan require only changes in the

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use of existing agency resources and thus their implementation can be expected in the near term. Other identified programs require the enactment of new laws or the promulgation of new regulations and, as a result, their implementation may be delayed.

Key programs identified by the strategic plan are described below.

Enhancing IP Enforcement at the U.S. Border

The strategic plan identifies a number of programs aimed at protecting IP rights from counterfeit and infringing imports into the United States. Companies facing unfair competition from such imports should benefit from these initiatives.

Section 337 Programs

The strategic plan identifies enhancements to the way in which the administration of exclusion orders issued by the U.S. International Trade Commission (ITC) under Section 337 of the Tariff Act of 1930 could be enhanced.

Section 337 exclusion orders are most frequently issued after a finding of violation based on the importation of products that themselves infringe upon some IP right or were manufactured using an infringing process. Thereafter, U.S. Customs and Border Protection (CBP) is charged with administering the orders, deciding whether specific products sought to be imported fall within the scope of specific exclusion orders. In some cases, this requires a determination of whether an article has been successfully redesigned so that it is no longer infringing and in other cases, a determination of whether an entirely new article is or is not infringing is required. These decisions are most often made *ex parte* upon the request of a manufacturer or potential importer without significant input from the ITC or all of the parties involved in the ITC's Section 337 investigation, including the IP rightholders.

The strategic plan calls for greater communication between the ITC and CBP with respect to the scope of exclusion orders. Likewise, the strategic plan calls for greater communication

between CBP and IP rightholders regarding the administration of Section 337 exclusion orders, including statistics on denials of entry, seizures and other actions. Further, CBP is encouraged to consider the establishment of *inter partes* proceedings to permit all interested parties, including the IP rightholder and where appropriate, the ITC to provide useful information and analysis of the products at issue to CBP when making determinations regarding the proper scope of Section 337 exclusion orders. It is proposed that such a proceeding would enhance the efficiency and transparency of CBP decision-making and lead to better administration of Section 337 exclusion orders. As a related measure, the strategic plan also calls for CBP to share information with IP rightholders regarding the administration of Section 337 exclusion orders, including statistics on denials of entry, seizures, and other actions.

Customs Initiatives

In addition to targeting CBP's role in administering Section 337 exclusion orders, the strategic plan also identifies a number of other programs aimed at improving CBP's ability to identify and halt imports and exports of counterfeit or infringing products at the border.

Currently, CBP and related agencies lack authority to share seized pirated or counterfeit goods or circumvention devices¹ with rightholders or even to share information about such devices before they are seized. The inability to utilize the expertise of the IP rightholders is a weakness since rightholders are particularly well-equipped to assist the U.S. government in determining whether certain goods are legitimate or whether the import of a circumvention device violates current law. Rightholders could also use such information in their own efforts to investigate and protect against infringements. The strategic plan calls for CBP and related agencies to be given the authority to share samples and information about suspect

¹ Circumvention devices are devices that may be used to defeat mechanisms put in place to prevent the playing of pirated copies of copyrighted works.

imports, so long as safeguards are implemented to protect personally identifiable information. If this authority is granted, the strategic plan also calls for streamlined bonding requirements, which would permit IP rightholders to post a single bond to cover the receipt from CBP of goods for analysis and investigation.

Another program identified by the strategic plan would require CBP to provide relief from civil enforcement actions to importers and other parties that voluntarily disclose the import of counterfeit or infringing products. This relief would be available only where the disclosing party had no knowledge that the products were counterfeit or infringing prior to their acquisition. Currently, such parties face civil penalties for the unknowing import of counterfeit or infringing products, which discourages their voluntary disclosure and thus inhibits CBP's enforcement efforts. Under the strategic plan, upon receipt of a valid voluntary disclosure, CBP would require the disclosing party to destroy the counterfeit or infringing products (at that party's expense) but would not impose any additional monetary penalties or fines.

In addition, the strategic plan calls for the enhancement of CBP's authority over infringing exports. Although CBP may seize such exports at the border, the agency lacks express authority to issue administrative penalties on infringing exports. The strategic plan indicates that the U.S. government will seek legislation to fill this gap in CBP's enforcement powers.

Programs Targeting Counterfeit Pharmaceuticals and Medical Devices

Finally, the strategic plan outlines a number of programs that specifically target the problem of counterfeit pharmaceuticals and medical devices. For example, the plan calls for the Food and Drug Administration (FDA) to establish a notification program for counterfeit products, whereby manufacturers and importers must notify the FDA of known counterfeits and any potential adverse health consequences associated with them. Under this program, which would require a statutory

amendment, drug manufacturers would also be required to provide the FDA with a list of legitimate drug products distributed in U.S. commerce on a semi-annual basis.

In addition, the strategic plan calls for a statutory change requiring manufacturers, wholesalers and dispensers of pharmaceuticals and medical devices to implement a track-and-trace system. According to the plan, such a system will permit the easier identification of counterfeit products by enforcement officials. The plan recognizes that privacy concerns will have to be considered in the implementation of such a system.

The strategic plan also calls for the creation of a Counterfeit Pharmaceutical Interagency Committee, which would be charged with analyzing the problems associated with online pharmacies and the health and safety risks associated with the sale of counterfeit pharmaceuticals. The plan also calls for increased enforcement cooperation in this important public health area.

Enhancing International IP Rights

The strategic plan contains a renewed commitment to securing the protection and enforcement of international rights globally. Innovative companies seeking to protect IP in emerging markets and other foreign countries should take note.

Section 301 Process Improvements

The strategic plan highlights the important role played by the Section 301 process in identifying non-U.S. sources of counterfeit and infringing products, including online store fronts operated from abroad. The Office of the U.S. Trade Representative (USTR) is charged with administering the Special 301 process, which is an annual review of the global state of intellectual property protection, and includes analysis of Internet and physical markets that are either the subject of IP enforcement actions or warrant scrutiny in this area. As part of this process, the USTR publishes a report identifying so-called Notorious Markets, or markets in which IP violations are rampant. The strategic plan calls for the continuation of this

process and the identification of additional ways to further publicize these Notorious Markets throughout the U.S. government and the general public.

In a similar vein, the strategic plan also calls for a more focused effort to combat non-U.S. web sites that sell counterfeit or infringing products, such as the web sites identified through the Special 301 process. As noted in a [previous Sidley update](#), sales of counterfeit and infringing products via the Internet is a growing challenge for many industries. According to the plan, U.S. law enforcement agencies will develop a better coordinated approach to address this challenge, including by leveraging U.S. government resources stationed abroad. The U.S. government will also draw more on private sector support, such as the voluntary protocols recently implemented by Internet search engines to prevent the sale of counterfeit pharmaceuticals.

The strategic plan also calls for improving the implementation of Special 301 “Action Plans” in respect of countries placed on the “priority watch list.” Companies seeking assistance with systemic failure to procure and enforce intellectual property rights in key markets should consider engaging in this process.

Promotion of Enforcement of U.S. Intellectual Property Rights through Trade Policy Tools and International Organizations

Beyond the Special 301 process, the strategic plan specifically notes the intent of the U.S. Government to engage more readily with trading partners through trade policy mechanisms, such as the conclusion of the Anti-Counterfeiting Trade Agreement and the expansion of the Trans-Pacific Partnership. These pending trade agreements are intended, in relevant part,

to secure global norms to facilitate the procurement and enforcement of intellectual property rights across borders. In addition, the strategic plan cites the willingness, when appropriate, to protect rights through use of the World Trade Organization (WTO) dispute settlement process. Through this process, innovative companies or trade associations may petition governments where they encounter violations of WTO Agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights. While not suitable for every type of infringement problem, such action can be a critical tool in resolving matters relating to inadequate frameworks for protection of intellectual property rights, including patents, trademarks, copyright, trade secrets and test data.

In addition, the strategic plan includes a renewed commitment to work with international organizations, such as WTO, the World Intellectual Property Organization, the World Customs Organization and the World Health Organization, to strengthen intellectual property protection and enforcement. Private sector stakeholders can engage not only with governments, but also directly advocate in many of these processes in relation to issues of key concern. This is particularly effective to address recurring problems in emerging markets that are not susceptible of resolution by a domestic court – if indeed such a process is practically available. Innovative companies that rely on intellectual property rights in global markets should consider more actively engaging with the U.S. Government to ensure that this renewed commitment reflects key concerns of U.S. industry.

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