Dear Mr. Marti:

We thank you and the Office of Management and Budget for the invitation to comment on the coordination and strategic planning of the federal effort against intellectual property infringement.

The views expressed in these comments are those of the American Bar Association Section of Intellectual Property Law (the “Section”). They have not been submitted to or approved by the ABA House of Delegates or Board of Governors, and should not be construed as views of the Association as a whole.

The Section is the largest intellectual property organization in the world and the oldest substantive Section of the ABA. Since 1894, we have advanced the development and improvement of intellectual property laws and their fair and just administration. As the forum for rich perspectives and balanced insight on the full spectrum of intellectual property law, the Section serves as the ABA voice of intellectual property law—within the profession, before policy makers, and with the public.

The September 1, 2015, Federal Register Notice (“the Notice”) invites public input and participation in shaping the federal government’s intellectual property enforcement strategy for 2016–2019. In particular, IPEC requested information pertaining to, and to the extent practicable, recommendations for combating emerging or potential future threats posed by violations of intellectual property rights, including threats to both public health and safety (in the United States and internationally) and American innovation and economic competitiveness. Our comments are directed to those issues raised in the Notice that relate to activities of our Section member practitioners.

October 15, 2015

Daniel Marti, Esq.
Office of the U.S. Intellectual Property Enforcement Coordinator
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503
via electronic submission to: http://www.regulations.gov

Re: Development of 2016 Joint Strategic Plan on Intellectual Property Enforcement
I. OBJECTIVES OF THE JOINT STRATEGIC PLAN

The Notice includes nine objectives, originally set forth by the PRO IP Act, 15 U.S.C. § 8113, including (1) reducing the supply of infringing goods, domestically and internationally; (2) identifying weaknesses, duplication of efforts, waste, and other unjustified impediments to effective enforcement actions; (3) promoting information sharing between participating agencies to the extent permissible by law; (4) disrupting and eliminating infringement networks in the U.S. and in other countries; (5) strengthening the capacity of other countries to protect and enforce intellectual property rights; (6) reducing the number of countries that fail to enforce intellectual property rights effectively; (7) assisting other countries to more effectively enforce intellectual property rights; (8) protecting intellectual property rights in other countries by certain specific actions; and (9) establishing effective and efficient training programs and other forms of technical assistance to enhance the enforcement efforts of foreign governments.

II. EMERGING OR POTENTIAL FUTURE THREATS POSED BY VIOLATIONS OF INTELLECTUAL PROPERTY RIGHTS

A. Threats to Public Health & Safety (in the United States and Internationally)

In the field of human medicine, intellectual property violations present a severe threat to public health and a high cost to the economy. Medicines sold under counterfeit imitations of trademarks are a growing problem with an estimated 1% of the total market, 50% of medicines sold on-line, and 10–30% of medicines sold in emerging markets, such as Latin America, South East Asia, and Africa. The problem is not limited to foreign jurisdictions with increasing reports of counterfeit medicines in the United States. The FDA has noted, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm, that:

Counterfeit drugs may
- be contaminated
- not help the condition or disease the medicine is intended to treat
- lead to dangerous side effects
- contain the wrong active ingredient
- be made with the wrong amounts of ingredients
- contain no active ingredients at all or contain too much of an active ingredient
- be packaged in phony packaging that looks legitimate.

The following statement from the National Association of Boards of Pharmacy, http://www.nabp.net/programs/consumer-protection/buying-medicine-online, is to similar effect and also captures the threats to both public safety and the economy posed by the trafficking of pharmaceutical products under counterfeit trademarks:
The majority of websites selling medications are not what they appear to be. NABP has reviewed over 11,000 online drug outlets and found that 96% percent appear to be operating in conflict with pharmacy laws and practice standards. What does this mean? If you buy from one of these sites, you might:

- Receive pills that contain such fillers as drywall and rat poison
- Have your financial and other personal information stolen
- Have your email inbox flooded with spam that could infect your home computer with viruses

In the worst cases, people have died from receiving counterfeit medications that didn’t treat their serious medical conditions.

Beyond these considerations, intellectual property violations in the public health sector trigger economic costs – lost productivity of patients who take substandard counterfeit medicines, lost revenue of U.S. manufacturers and corresponding loss of jobs and R&D investment. The following additional references are representative resources on the issue:


Specific strategies for reducing the threats to public health and safety associated with the use of counterfeit trademarks include the following:

- Increased transparency in product labeling as to the manufacture of the drug product, particularly active pharmaceutical ingredient (“API”) manufacture, fill/formulation manufacture, and location(s) of manufacture: Current regulations lack sufficient transparency inside and outside of the United States, which enables and threatens a secure manufacture through-market supply chain. Increased transparency would also facilitate enforcement action against unapproved and/or infringing manufacturers.
- Improved export/import regulations and enforcement: Drugs, medical devices, and biologics associated with infringing and counterfeit marks frequently pass through customs in one or more countries. Improved regulations (in countries lacking strong regulation) or enforcement based on customs laws, patent or trademark infringement would help disrupt the flow of counterfeit and infringing goods into the public health systems of destination countries.
• Tightened regulation of API, particularly in China and India: Finished medicinal products are generally regulated under health laws. Bulk API is far less regulated in some countries. Regulating API as a drug product (requiring health authority approval if such API is ultimately intended for medicinal use in any country) will help limit rogue manufactures who export API to avoid health regulations.

• Leveraging health regulations and approval of a drug as a point to stop infringing drugs, medical devices, and biologics. Drugs, medical devices, and biologics associated with infringing and counterfeit marks should not be approved by foreign health regulators and released into commerce. Approval by foreign health regulators permits infringing product to be manufactured and sold in the local market in violation of intellectual property rights, and also to be exported and sold as substandard or counterfeit medicines in other markets. Regulatory approval pathways should be transparent and permit intellectual property enforcement prior to approval. The U.S. government should advocate for early mechanisms for resolution of patent/infringement disputes in advance of health authority approval of infringing product in countries presently lacking any such mechanism.

• Continued efforts by the United States to encourage countries to improve their enforcement environment, particularly in the developing countries with a high level of counterfeiting (China, India, Pakistan, and Mexico).

B. Online Piracy and Counterfeiting

Over the past several years, the United States Congress has attempted to implement legislation to address, reduce and (potentially) eliminate the phenomenon of online piracy and counterfeiting undertaken by “Predatory Foreign Websites.” As described more fully below, the Section has supported these attempts and has advanced specific recommendations on this front. Because the Section appreciates that the regulation of online content through the use of copyright law is a controversial topic, these comments do not make recommendations on it.

These comments also do not attempt to choose any particular definition of the illegal conduct as proposed by the various legislative initiatives. Instead, they address the limited category of foreign-originated websites engaged in large-scale counterfeiting of U.S. trademarks (in this case, intentional use of a spurious trademark that is identical to, or substantially indistinguishable from, an authentic trademark, in connection with products that are not authorized by the trademark owner or its agent). These comments use the phrase “Predatory Foreign Websites,” or “PFWs” to refer to websites engaged in the type of conduct sought to be remedied, but recognizes that sponsors of prior versions of

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1 By way of further clarification, these comments do not attempt to pull within the definition of “Predatory Foreign Websites” any sites that are already subject to U.S. jurisdiction under existing U.S. law or other treaty obligations, and specifically excludes those sites from their analysis.
legislation introduced in Congress have used different phrases to describe this conduct, without establishing a universal definition.

In particular, while the conduct itself may be identical to that prohibited under existing law, these specific actions are not readily subject to adjudication in the United States because the website is either beyond the jurisdiction of U.S. enforcement authorities entirely or, even if technically subject to such jurisdiction, is beyond the reach of such authorities to effectively enforce a judgment against it.

The Section supports bipartisan efforts by IPEC and both chambers of Congress to find solutions to the problem of PFWs, in that obtaining jurisdiction over these defendants in civil actions filed in federal courts may be impossible and as the costs to the U.S. economy and rights holders caused by PFWs continue to climb. From a practical perspective, a PFW’s ability to close down its operations in connection with one domain name and almost immediately re-establish them under another domain name makes enforcement tied to a specific domain name impractical and ineffective. Indeed, the speed with which these PFWs can change domain names allows them to evade enforcement as the law is currently established.

Therefore, although legislation often requires refinement, compromise and a balancing of the various interests involved, the IPL Section continues to believe in and support the general proposition that the enactment of legislation targeting PFWs can be accomplished without compromising legitimate constitutional and public policy concerns.

More specifically, the IPL Section recommends that IPEC:

- continue to pursue the development and enactment of more effective laws to deter online piracy and counterfeiting, particularly by PFWs;
- consult with a broad spectrum of interests within the intellectual property and technology communities to ensure a viable legislative solution is proposed that:
  - appropriately balances the interests of, and the respective burdens that would be placed upon, intellectual property rights-holders, Internet businesses, and Internet users;
  - avoids unduly impeding freedom of speech and expression, retarding the future growth of the Internet, or stifling legitimate innovations in the structure or functionality of the Internet;
  - includes new remedies only after taking full account of the impact on the structure or functionality of the Internet and the potential for harm thereto;
  - absent clear justification, neither expands nor contracts existing third party liability, or exceptions and limitations on liability under existing trademark law;
ensures that any new legislative proposals comply with existing treaty obligations, particularly those governing the international treatment of intellectual property rights;

vests jurisdiction of actions seeking civil or criminal remedies in the United States District Courts;

permits the imposition of civil remedies following a judicial determination that online piracy and/or counterfeiting has been undertaken by specifically identifiable PFWs as well as facilitators of such activities;

supplements the following civil remedies (which already are available under U.S. law to redress piracy and/or counterfeiting that occurs within U.S. borders) to redress online piracy and counterfeiting undertaken by PFWs, in cases in which the intermediary in question does not take action voluntarily:

- injunctions directing financial payment processors to freeze the assets of PFWs and to cease doing business with such websites;
- injunctions preventing online advertisers from paying PFWs or from displaying additional ads on those websites;
- injunctions requiring search engines to remove PFWs from paid, sponsored links;
- injunctions requiring website hosts to cease hosting PFWs;
- injunctions permitting the seizure and destruction of goods associated with counterfeit or pirated trademarks, or their delivery to rights holders who are willing to bear the shipping and handling costs;
- injunctions requiring the immediate removal of pirated works and/or content, counterfeit marks, logos, insignia, or trade dress that have been made available, displayed, or otherwise promoted by PFWs; and
- monetary relief in the form of disgorgement of profits of the PFWs achieved as a result of the illegal activity, which shall be paid to the rights holder from the assets frozen or advertising/sponsored links revenue that had been withheld by the intermediaries, as described above;

- develop comprehensive public outreach programs to educate the public about recognizing and avoiding pirated works and/or content and counterfeit goods, and about the negative impacts that online piracy and counterfeiting have on the U.S. economy, in an effort to decrease public traffic to PFWs;
- permit trademark rights holders to pursue civil remedies on their own behalf (thus creating a private right of action);
enable the U.S. government to prosecute criminally and/or undertake civil enforcement of trademark counterfeiting initiated or induced by PFWs and directed to U.S. end-users/customers;

include within any proposed legislation the adequate provision of government resources to ensure effective enforcement of intellectual property rights;

encourage and expand adoption of voluntary efforts by Internet businesses based in the U.S. to combat online counterfeiting undertaken by PFWs, including through the following mechanisms:

- streamlining and expediting submission and processing of non-judicial infringement complaints;
- implementing online non-judicial complaint forms and automatic takedown tools; and
- developing programs designed to educate Internet users about intellectual property rights and to deter infringing activities;

encourage and expand robust and proactive voluntary industry programs to identify and deny access to counterfeited products and/or disassociate from infringing activity, such as voluntary content filtering by hosting sites and partner website vetting by ad networks and payment processors;

encourage wider adoption of voluntary industry initiatives both in the United States and around the world, as part of a multi-pronged approach to reduce the harm caused by illegal activities of PFWs; and

establish and maintain effective border controls to prevent exportation of goods associated with counterfeit trademarks from manufacturing countries such as China and to prevent importation into destination countries.

C. Threats to American Innovation & Economic Competitiveness

Emerging and future threats to the U.S. economy are appropriately balanced within the confines of the statutory framework of Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, which provides significant protection to domestic industries to combat unfair competition from imported goods that infringe U.S. intellectual property rights. Section 337 relief is a major focus of the Section’s comments because it is a vital tool in the enforcement arsenal of U.S. intellectual property rights owners, and is in addition to relief available in district courts for infringement of intellectual property rights. Importantly, Section 337 empowers the ITC to weigh the impact of its remedial orders on certain statutorily enumerated public interest factors in every case, including the effect of such orders “upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers” in each investigation. Id. §§ 1337(d)(1), (e)(1), (f)(1).

The U.S. International Trade Commission (“ITC”), located in Washington, D.C., adjudicates claims of Section 337 violations, issues relief in the form of exclusion orders
against infringing imports and cease and desist orders against further sale of domestic inventory, and enforces its own remedial orders when a violation is alleged. These Section 337 investigations include adjudication of patent infringement claims relating to imported goods as well as trademark infringement (including gray market claims), trade dress, trade secret, copyright infringement, and other unfair competition claims. U.S. Customs and Border Protection (“CBP”) is charged with enforcement of ITC exclusion orders at the borders. These agencies are responsible for investigating and stopping infringing goods from entering the commerce of the United States.

Violations of U.S. intellectual property rights subject to ITC exclusion orders and cease and desist orders (enforceable against entities found in violation that maintain U.S. inventory) are dealt with through seizures and forfeitures of infringing goods by CBP upon the direction of the ITC, and/or by way of severe monetary penalties adjudicated at the ITC.

Any company that owns U.S. intellectual property rights and has invested in the commercialization of those rights in the United States can obtain speedy relief against infringing imports through ITC administrative procedures.

Section 337 investigations have reduced the supply of infringing imported merchandise through ITC orders, as well as by the settlement and licensing of accused imports. Precise quantification of the financial impact of Section 337 orders on the reduced volume of infringing imported merchandise on the U.S. economy is not readily available because sales and importation data are maintained under protective order in the confidential administrative record of ITC investigations pursuant to statute.

The federal government’s intellectual property enforcement strategy should ensure that the ITC, including the Office of Unfair Import Investigations (an internal office of the ITC that participates as a party representing the public interest) and the Office of the Administrative Law Judges, and CBP continue to be adequately funded and structured to fulfill their mission of protecting U.S. intellectual property rights within the framework of Section 337 and the statutory public interest considerations. Further, the Federal Government should ensure that the statutory and regulatory authority for administration of Section 337 investigations by the ITC and the enforcement of Section 337 orders by CBP are strengthened to enhance the continued efficacy of Section 337 as a critical tool for companies to enforce their U.S. intellectual property rights.

Importations of goods that infringe U.S. patent rights have been and continue to be an ongoing threat to American innovation and economic competitiveness. Potential infringement liability for acts occurring or products made overseas has expanded in the past few years. For example, the ITC has interpreted Section 337 of the Tariff Action of 1930 to authorize issuance of exclusion orders blocking importation of goods that directly infringe U.S. patent rights only after importation into the U.S. and modification or use by the importer.

This creates new enforcement challenges for the CBP, which is charged with enforcing such ITC exclusion orders. At the time of importation, it is difficult for CBP to
determine that a particular good will be, or could be, combined with another and together infringe U.S. patent rights. The ITC is well within its authority to prevent importation of goods that infringe the legitimate rights of patent owners. Nevertheless, broadened liability for importation of non-infringing goods that are used, after importation, to directly infringe patent rights may subject importers to vague or amorphous patent infringement assertions. The resulting cloud of suspicion can be difficult to address quickly and cost effectively regardless of innocence, as victims of patent assertion entities have learned.

*Suprema, Inc. v. U.S. Int’l Trade Commission*, 796 F.3d 1338 (Fed. Cir. 2015) (en banc), presents a perfect example. Suprema made fingerprint scanners in Korea and imported them into the United States. Although these scanners did not infringe the asserted patented method at the time of importation, a U.S. distributor combined the scanners with software that completed the patent infringement. The ITC found that Suprema induced direct infringement and issued an exclusion order preventing importation of the accused scanners into the United States. The Federal Circuit agreed that the ITC has authority to issue exclusion orders to bar importation of articles of commerce that may later be used by third parties to infringe a U.S. patent. *See also In re Certain Digital Models*, No. 14-1527 (Fed. Cir.) (pending appeal regarding whether ITC has authority to block importation of digital files that may later be used in the United States to make infringing plastic braces).

U.S. intellectual property enforcement strategy should balance the needs of patent owners to police cross-border infringement of U.S. patents with the needs of technology companies to participate fully in the global economy. In particular, IPEC should do what it can to ensure that the ITC has adequate authority to address creative infringement schemes involving cross-border activity, without impeding lawful commercial activity.

IPEC also can reduce threats to American innovation and economic competitiveness by:

- advocating a study:
  - to determine the volume and source of goods being imported into and subsequently used in the United States by the importer to infringe U.S. patent rights;
  - to estimate the economic impact of such activities on the U.S. economy; and
  - to assess whether amendment of Section 337 is desirable;
- pursuing legislative or judicial clarification of the ITC’s authority to provide trade relief for induced infringement as well as infringement of patented methods;
- if a particular country or countries are identified as the source of goods knowingly imported for use in the United States to infringe U.S. patent rights, encouraging the United States Trade Representative to include that information as part of its Special 301 report and work with officials from those countries to disincentivize such importation to the United States;
• encouraging the amendment of import regulations to require the identification of those importers who have established businesses for the purpose of importing articles that, after importation, will be used by the importer to directly infringe U.S. patent rights, rather than merely requiring the identification of infringing goods as they pass through customs; and

• advocating for early mechanisms to resolve patent infringement disputes involving importation of goods to distinguish between lawful commercial activity and unlawful infringement schemes that involve cross-border activity.

Once again, the ABA Section of Intellectual Property Law appreciates the opportunity to provide these comments to you and the OMB. If you have any questions on the above comments please feel free to contact us.

Very truly yours,

Theodore H. Davis Jr.
Section Chair
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Section of Intellectual Property Law