November 13, 2018

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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: intellectualproperty@omb.eop.gov

Re: Development of 2019 Joint Strategic Plan on Intellectual Property Enforcement

Dear Mr. Amin:

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 13, 2018, Federal Register Notice (“the Notice”) invites public input and participation in shaping the federal government’s intellectual property enforcement strategy for 2019–2022. In particular, IPEC requested comments organized along the lines of the Administration’s four-part strategic approach to promote and protect intellectual property:
1. Engagement with our trading partners;
2. Effective use of all our legal authorities, including our trade tools;
3. Expanded law enforcement action and cooperation and
4. Engagement and partnership with the private sector and other stakeholders.

Our comments address separately the various fields of intellectual property, specifically: 1) trademark counterfeiting (including public health and safety concerns and online counterfeiting); 2) copyright piracy; 3) trade secrets; and 4) patents.

I. TRADEMARK COUNTERFEITING

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 National Association of Boards of Pharmacy (NABP) has previously commented on the threats to both public safety and the economy posed by the trafficking of pharmaceutical products under counterfeit trademarks. The NABP explained that “the majority of websites selling medications are not what they appear to be” after having reviewed approximately 11,000 online drug outlets and having found that 96% percent “appear to be operating in conflict with pharmacy laws and practice standards”2. They explained that this may lead to patients who “receive pills that contain such fillers as

1 http://www.nabp.net/programs/consumer-protection/buying-medicine-online
2 Id.
drywall and rat poison” and warned that “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.  

1. Engagement with our trading partners

The Section recommends that the U.S. Government engage with trading partners to tighten regulation of active pharmaceutical ingredients (“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 manufacturers who export API to avoid health regulations.

The U.S. Government should also leverage 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 an 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 an infringing product in countries presently lacking any such mechanism.

In addition, the U.S. Government should continue efforts to encourage countries to improve their enforcement environment, particularly in the developing countries with a high level of counterfeiting (China, India, Pakistan, Canada and Mexico).

3 Id.

Lastly, the Section commends the conclusion of the negotiations of the new United States-Mexico-Canada trade agreement (USMCA), which replaces NAFTA, on September 30, 2018. USMCA Chapter 20 on IP matters upgrades enforcement of IP rights, including border measures that were not mandatory in the NAFTA text. These measures include inspection, detention and destruction of counterfeit trademark goods that are imported or in transit without a court order once customs officials determine that the goods are infringing. The United States should closely monitor the implementation of these enhanced border measures by Canada and Mexico.

2. **Effective use of all legal authority, including trade tools**

Current regulations lack sufficient transparency inside and outside of the United States, which enables and threatens a secure manufacture through-market supply chain. The Section recommends increased transparency requirements in product labeling as to the manufacture of the drug product, particularly API manufacture, fill/formulation manufacture, and location(s) of manufacture. This would also facilitate enforcement action against unapproved and/or infringing manufacturers.

The Section recommends that the U.S. Government should improve export/import regulations and enforcement in this area. 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, patent or trademark infringement laws would help disrupt the flow of counterfeit and infringing goods into the public health systems of destination countries.

In addition, the U.S. Government should enhance the Customs Recordation Systems to include U.S. Design Patents. As counterfeiters become more sophisticated, they are finding ways to avoid the currently available tools for stopping importation at the border, such as by removing infringing trademarks and logos from lookalike products. By enhancing the Customs Recordation Systems to also include U.S. Design Patents, design rights holders would have another tool available to them to ensure that in many cases inferior and possibly dangerous knock-off products are not allowed into the U.S.

**B. Online 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 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.

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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).6 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 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 especially given 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 under currently-established law.

Therefore, although legislation often requires refinement, compromise and a balancing of the various interests involved, the 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.

In this area, the focus of our recommendations pertains to the expanded use of enforcement action and cooperation as well as engagement and partnership with the private sector and other stakeholders.

1. Expanded use of enforcement action and cooperation

In order to effectively combat online trademark counterfeiting, the Section recommends specifically that the U.S. Government 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. China (and

6 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.
Hong Kong) continue to be the source of the largest percentage of counterfeit products seized by ICE and Customs and Border Protection; 87% of all seizures emanated from these countries in 2017 continuing a decades long problem that has not improved. Greater efforts need to be placed on stopping exports of counterfeit products from China and Hong Kong.\(^7\)

The Section also recommends enforcement improvements that would permit trademark rights holders to pursue civil remedies on their own behalf (thus creating a private right of action), and also 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.

2. **Engagement and partnership with the private sector and other stakeholders**

The Section recommends that the U.S. Government continue to pursue the development and enactment of more effective laws to deter online piracy and counterfeiting, particularly by PFWs. This legislation should include the adequate provision of government resources to agencies such as Immigration and Customs Enforcement (ICE) to ensure effective enforcement of intellectual property rights. In order to develop this legislation, the U.S. Government should 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. The legislations should avoid 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. Any new legislations should include new remedies only after taking full account of the impact on the structure or functionality of the Internet and the potential for harm thereto; and absent clear justification, neither expands nor contracts existing third party liability, or exceptions and limitations on liability under existing trademark law. The U.S. Government should ensure that any new legislative proposals comply with existing treaty obligations, particularly those governing the international treatment of intellectual property rights and should vest jurisdiction of actions seeking civil or criminal remedies in the United States District Courts. With respect to remedies the legislation should permit 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. In addition, any new proposed legislation should supplement 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:

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• 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 resulting from 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.

The Section also recommends that the U.S. Government 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. These efforts should include the development of programs designed to educate Internet users about intellectual property rights and to deter infringing activities.

In addition, the U.S. Government should 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.

The U.S. Government should also encourage and expand robust and proactive voluntary industry programs both in the United States and around the world 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;

II. COPYRIGHT PIRACY

The “core” copyright industries--those industries whose primary purpose is to create, produce, distribute or exhibit copyright materials--play a large, and growing, role in the U.S. economy. Even 3 years ago, in 2015, these industries were estimated to
contribute about $1.2 trillion (almost 7%) to the U.S. GDP, to employ over 5.5 million men and women paid, to pay such workers, on average, almost 40% more than the average U.S. worker, to have an annual growth rate over the preceding 4 years that was more than twice that of the economy as a whole, and to generate $177 billion in export revenues.\(^8\) With three years of additional growth since then, these numbers can only have grown larger.

But whatever their exact amount, they are clearly of sufficient size to establish that a strong copyright system that rewards creativity and discourages piracy—domestically and abroad—is essential to a healthy and vibrant U.S. economy. They are also clearly of sufficient size to merit the utmost in effective domestic and international enforcement efforts. To qualify as effective, such efforts must address not only the challenges posed by traditional forms of piracy, but also by emerging forms, especially Internet-based streaming.

**Emerging Piracy Challenges: The Rise of Streaming**

Since the previous Joint Strategic Plan, Internet-based streaming of copyrighted works (as compared with other delivery methods such as electronic downloading, over-the-air broadcasting, and embodiment on physical media like CDs, DVDs and Blu-ray Discs) has become an even more vital business model for the U.S. copyright industry than it was previously. For example, it has become the dominant model for recorded music, with streaming services now providing 75% of the U.S. music industry’s revenues in the first half of 2018.\(^9\) Similarly, U.S. streaming video subscription services (e.g., Netflix, Hulu, Amazon Prime Video, etc.) continue to grow rapidly compared to alternative delivery methods.\(^10\) Consumers appreciate the wide selection of content, portability and ease-of-use these services offer, and their increased spending reflects that appreciation.

As with these legitimate services, however, streaming-based pirate services are also becoming more popular with users, and for the same reasons. While long-established channels of piracy, such as peer-to-peer and cyberlocker downloading, remain popular,\(^11\) emerging threats such as illicit streaming to set-top boxes and apps, and stream-ripping

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services, have gained considerable ground. One 2017 study estimated that six percent of North American homes had a Kodi-type set-top device configured to stream pirated content, and a consumer survey from the same year found that over one-third of all internet users (and over half of those 16-24) accessed infringing music via stream-ripping in the previous three months.

Left unchecked, there is every reason to expect these consumer-friendly forms of piracy will continue to grow. The results for the American economy are predictable—less creation of new content, less investment in new content-delivery services, less innovation and growth, and less job creation. As such, the active involvement of IPEC is critical to addressing these threats. The Section therefore urges IPEC to make combatting the fastest-growing forms of piracy (especially illicit streaming services and related devices and apps) a major priority in its next 3-year Joint Strategic Plan. Responding to this growing problem will require all of the strategic tools IPEC has identified: engagement with our trading partners; effective use of all legal authorities, including trade tools; expanded law enforcement action and cooperation; and engagement and partnership with the private sector and other stakeholders.

1. Engagement with our Trading Partners

The Section applauds the steps the Administration has already taken to engage with our trading partners on the protection of American intellectual property rights. For example, the U.S. Trade Representative (USTR)’s Special 301 Report recently named a total of 36 countries to either the Priority Watch List or Watch List for failing to provide adequate protection for intellectual property rights. For the 12 countries on the Priority Watch List, the USTR promised that “the IP issues in these countries will be the subject of intense bilateral engagement during the coming year.” The USTR has also secured important concessions regarding the protection of copyrighted works as part of the proposed USMCA Agreement, e.g., its requirements to prohibit camcording in cinemas and to effectively impose liability for aiding and abetting infringement. Looking forward, the Section encourages the USTR to build on these successes, e.g., by discouraging our trading partners from adopting or maintaining conditional safe harbors for internet intermediaries that do not sufficiently incentivize cooperation with rights holders in

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addressing infringement through their services.

The Section encourages such efforts to make foreign markets more hospitable to intellectual property rights and more open to competition from American businesses. Internet piracy thrives where intellectual property protections are weak. For that reason, engaging with our trading partners and persuading them to adopt and enforce copyright protections that are equal to the task of combating modern internet piracy will be a key strategic tool for addressing this problem. We also urge the U.S. Government to prioritize cooperation with our trade partners to identify and shut down sources of piracy located within their borders.

2. Effective Use of All Legal Authorities, Including Trade Tools

With respect to the effective use of legal authorities, including trade tools, the Section advocates that the next Joint Strategic Plan promote effective and deterrent remedies, effective investigation methods, less burdensome evidentiary standards, and improved border measures.

With respect to remedies, it is important to seek the availability from our trading partners of: (1) civil damages that both fully compensate rightsholders and deter infringement, and allow them full recovery of costs and attorneys’ fees; (2) effective, enforceable injunctive relief, including on an ex parte basis when necessary; and (3) preliminary seizure of pirated goods and associated implements, assets and documentary evidence of infringing activity, as well as (4) final forfeiture of such goods and implements and confiscation of the proceeds.

With respect to investigation methods, it is important to seek from our trading partners: (1) removal of impediments to information sharing and cooperation between law enforcement authorities and rightsholders; (2) the availability of search warrants and similar processes on an ex parte basis in appropriate cases; (3) authorization of seizures of pirated items within described categories, rather than being limited to specific named titles; (4) expansion of investigations and information demands by courts to include upstream suppliers and manufacturers rather than just downstream distributors and retailers; and (5) establishing presumptions regarding the subsistence and ownership of copyright, and “sampling” presumptions, to forestall frivolous challenges.

With respect to border measures (both our own and our trading partners’), key enhancements that the Plan should promote include: (1) ex officio authority to customs officials to detain or seize imports that are suspected of being infringing copies, illicit circumvention devices or illicit streaming devices; (2) information sharing with rightsholders regarding border seizures (including information on points of origin and destination), as well as access by rightsholders to samples of pirate product for inspection and analysis under appropriate safeguards; (3) availability of searches and seizures of exports and goods in transit, including those passing through free-trade zones; and (4) a destruction remedy for goods seized by customs officials to prevent such seized pirated goods or devices from being returned to the country of origin or being re-shipped into the
target country through another port.

3. Expanded Law Enforcement Action and Cooperation

The Section commends the Department of Justice (DOJ), through the Computer Crime and Intellectual Property Section and other components, for taking an active role in responding to complaints about online video piracy and investigating complaints regarding illicit streaming devices.16 The Section also strongly recommends that DOJ continue to act aggressively to hold internet pirates accountable for their willful violations of copyright law, and to consider pursuing manufacturers and distributors of illicit streaming devices as well. Strong law enforcement action will be needed well into the future to make the world more hospitable to American intellectual property and enterprise. Law enforcement is also a highly effective tool for disrupting criminal networks that are determined to profit off of pirated video content. For example, and as other commenters have pointed out in prior IPEC proceedings, legitimate digital sales of copyrighted works in foreign markets have increased when DOJ has taken action to shut down sources of pirated content.17

Because many manufacturers and marketers of illicit streaming devices and services operate from abroad, the Section supports DOJ’s efforts to work closely with their law enforcement partners in countries and regions of concern, both to support specific investigations and prosecutions and to enhance our partners’ capacities to improve and enforce their own laws. To this end, DOJ’s Intellectual Property Law Enforcement Coordinator (IPLEC) program has currently deployed prosecutors in several locations overseas. Programs like the IPLEC initiative should be an element of the next Joint Strategic Plan.

4. Engagement and Partnership with the Private Sector and Other Stakeholders

Finally, the Section supports continuing efforts by IPEC and the Administration to work with the private sector and other stakeholders to tackle internet piracy. IPEC has previously recognized that combatting large-scale internet piracy requires a “follow-the-money” approach that “must target and dry up the illicit revenue flow of the actors engaged in commercial piracy online.”18 Doing this requires the buy-in of many different actors, including copyright owners, content providers, online and brick-and-mortar retailers, advertisers, banks, and payment processors. IPEC can serve a valuable role in convening all relevant stakeholders and impressing upon them the need for greater


18 IPEC, 2016 Joint Strategic Plan, at 62.
vigilance and action. Given the importance that small and medium enterprises and individual creators play within the copyright industries, we encourage IPEC to ensure that these entities and individuals are included in its outreach and enforcement efforts.

III. TRADE SECRETS

Several research studies have shown that trade secret protection (i.e. proprietary interests in commercially valuable private information) is the form of intellectual property that is most widely and strongly relied upon by businesses to protect their assets. As this Administration has recognized, trade secrets are also increasingly vulnerable to state-sponsored economic espionage as well as misappropriation by unscrupulous competitors and departing employees. In particular, as the Section has previously described to the Administration, trade secret protection in China, or lack thereof, has long been a source of concern for U.S. companies. During the past few years, the list of U.S. companies that have brought trade secret-related cases in Chinese courts include, among others, American Superconductor, Corning, E.I. du Pont, Eli Lilly, and General Motors. In addition, in recent years, several other U.S. companies, including SI Group, Fellowes, Manitowoc Company, and U.S. Steel, have brought trade secret-related actions at the U.S. International Trade Commission (“ITC”) relating to allegations of trade secret misappropriation that occurred in China and resulted in the importation of unfairly traded merchandise into the United States, and in all of these cases except for the one involving U.S. Steel, the ITC issued orders excluding the importation of the subject merchandise into the United States for periods ranging from five years to ten years.

1. Engagement with our trading partners

Engagement with our trading partners is crucial to the enforcement of trade secrets. Particularly where there are multiple parties involved in international supply chains, it may be difficult to get information as to what information is taken and the extent of its misuse or dissemination without cooperation of other parties in the supply chain or local authorities. Because the discovery process available in U.S. litigation is virtually unique to the U.S., but limited inspection of facilities may be allowed in foreign jurisdictions by local authorities, it is crucial to engage with those authorities.

Although the subject matter of the alleged thefts appear to include specific protectable information – as distinguished from more general “know how” or the “general skills, experience, and knowledge” recognized by U.S. law to be usable post-employment without restriction – and the conduct appears clearly culpable, these actions are still subject under U.S. law to defenses including a failure of the information to enjoy trade secret status because of publication, lack of specificity, or failure of the “owner” to exercise reasonable measures to maintain secrecy.

The U.S. defenses may be even more potent in foreign jurisdictions. Although most jurisdictions have acceded to TRIPS Article 37 which guarantees some protection of
undisclosed information, generally, unlike the U.S. since the 2016 enactment of the
Defend Trade Secrets Act (DTSA) amendments to the 1996 Economic Espionage Act,
other nations do not consider trade secrets “intellectual property.” Moreover, other
nations have different views of the employment relationship, of what constitutes
enforceable contracts or consent, and of what is protected by local competition law.
(Until DTSA, and still under state law, trade secret misappropriation was one type of
unfair competition). Engagement with local players to agree on application of the
disparate considerations should aid compliance over rejection.

2. Effective use of all our legal authorities, including our trade tools

As noted in the previous IPEC 2017-19 strategic plan, the ITC has been used
effectively to remediate trade secret misappropriation perpetrated abroad, for example in
One possible enhancement of ITC effectiveness is to extend Section 337, 19 U.S.C. §
1337 (unfair practices including intellectual property infringement) protection against
importation of “articles” to digital products such as denied in _ClearCorrect Operating

3. Expanded law enforcement action and cooperation

In addition to the engagement suggested in Section 1 and the use of the ITC and
its enhancement suggested in Section 2, trade secret enforcement would benefit from
expanded cooperation with the DOJ and additional Federal Bureau of Investigation
cooperation and provision of investigative and enforcement resources.

IV. PATENTS

The Section recommends that the U.S. Government work with our trading partners to
establish and strengthen their patent rights. A key to patent protection is having
predictability regarding both securing and enforcing effective patent protection. Such
predictability is necessary to protect U.S. investment in technology around the world. The
next Joint Strategic Plan should prioritize coordinated action by the government as a
whole to formulate a coherent plan for IP education and policy development with our
trading partners to be sure that IP rights globally are strengthened and predictable. The
recently negotiated U.S.-Mexico-Canada Agreement is an example of such efforts.

Also key in the enforcement of against infringing imports is the role of the U.S.
International Trade Commission (“ITC”), which 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. 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.

1. **Engagement with our trading partners**

An effort to educate our partners globally on the importance of patent rights should focus on patentability criteria that promotes innovation and the economy. Such criteria should ensure that patents are obtainable on all inventions that are new, involve an inventive step and have industrial application. These efforts should call attention to the disincentive for innovation and business development of having laws or regulations that prohibit patents on, for example, certain types of pharmaceutical inventions such as medical use patents. Such laws and regulations can work to disincentivize inventions that would benefit patients in those countries.

The U.S. Government should also encourage our global partners to work to eliminate patent backlogs. With a patent term that begins running upon the filing date, delays in patent examination can greatly reduce the value of patents and disincentive a company from bring an invention to that country. Delay in patent issuance is of particular concern for small businesses with small budgets for patents and lack of resources.

The Section further advocates that the U.S. Government should promote mechanisms for early and efficient resolution of patent disputes. Certain countries, for example, do not provide for preliminary injunctions to prevent the sale of infringing products during enforcement actions. In other countries, innovators may be routinely denied such orders, and court proceedings can stretch beyond the patent term.

2. **Effective use of all our legal authorities, including our trade tools**

The Section reiterates support for effective use of our legal authorities and trade tools for effective protection of innovation. The next Intellectual Property Enforcement Strategy should ensure that the International Trade Commission (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 U.S. 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.

The Section recommends that the 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, the U.S. Government should ensure that the ITC has adequate authority to address creative infringement schemes involving cross-border activity, without impeding lawful commercial activity.

3. Expanded law enforcement action and cooperation

The Section encourages a study to assess the need for further capacity building and opportunities to improve enforcement through enhanced trading partner cooperation. For example, the Section suggests a study to: assess 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; and to assess whether amendment of Section 337 is desirable, in order to clarify 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, the Section encourages 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. The Section also encourages 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.

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,

Mark K. Dickson
Section Chair
ABA Section of Intellectual Property Law