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March 24, 2010

Ms. Victoria A. Espinel
United States Intellectual Property
Enforcement Coordinator

(Via email to: intellectualproperty@omb.eop.gov)

Dear Ms. Espinel:

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 the attached commentary are those of the Section of Intellectual Property Law of the American Bar Association. 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 ABA Section of Intellectual Property Law 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.

Many of the questions in the Federal Register Notice of February 23, 2010 are addressed to United States Government budgetary resources and the efforts of foreign governments to combat infringement. Our responses do not address these questions. Rather, our comments are directed to those questions raised in the Federal Register Notice that relate to activities of our Section member practitioners.

Sincerely,



Don W. Martens
Chair
Section of Intellectual Property Law
American Bar Association

Response of the ABA Section of Intellectual Property Law to the Request for Comments from United States Intellectual Property Enforcement Coordinator (“IPEC”), and the Office of Management and Budget, For the Coordination and Strategic Planning of the Federal Effort against Intellectual Property Infringement (Federal Register Notice of February 23, 2010)

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I. PART I (Infringement: Impact on the U.S. Economy)

Section 337 of the Tariff Act of 1930,¹ provides significant protection to domestic industries to combat unfair competition from imported goods that infringe U.S. intellectual property (IP) rights. Any company that owns U.S. IP rights and has invested in the commercialization of those rights in the United States can obtain speedy relief against infringing imports through U.S. International Trade Commission (“ITC”) administrative procedures. Although the Request for Comments is not limited to Section 337 relief, such relief is a major focus of our comments because it is a vital tool in the enforcement arsenal of U.S. IP rights owners, and is in addition to relief available in district courts for infringement of IP rights.

The 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. 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.

¹ 19 U.S.C. § 1337.

Typically, 90 percent or more of the annual ITC docket of Section 337 investigations involves adjudication of patent infringement claims relating to imported goods; the remainder involve trademark infringement (including gray market claims), trade dress, trade secret, copyright infringement, and other unfair competition claims. These cases span a broad spectrum of technologies and industries, including telecommunications and computer-related products, semiconductor chips, medical, biotechnology, chemicals, pharmaceuticals, pesticides, industrial/commercial products, and consumer products. By far, the largest portion of cases, however, relate to technologies in the computer and telecommunications areas.

Importantly, Section 337 empowers the ITC to weigh the impact of its remedial orders on certain statutorily enumerated public interest factors in every case. Specifically, the statute directs the ITC to consider 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.² Thus, emerging and future threats to the U.S. economy, public health and safety are appropriately balanced within the confines of the statutory framework of Section 337. Indeed, on a few occasions, the Commission has found that public interest factors foreclose relief despite a finding of a violation of the underlying intellectual property right.

As Section 337 has increasingly become an integral vehicle in U.S. IP rights-holders’ enforcement strategy for the protection of valuable intellectual property rights, especially in the high-technology sphere, the positive financial impact on the U.S. economy resulting from the elimination of infringing imports by reason of Section 337 orders has also risen significantly. Section 337 investigations have resulted in a reduced supply of infringing imported merchandise by virtue of the entry of 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. However, publicly available import data by Harmonized Tariff Schedule subheadings may be used as a proxy to quantify the volume of affected imports and to extrapolate the positive effect of Section 337 orders on the U.S. economy. Equally important is the positive effect on the U.S. economy that Section 337 actions have had by spurring innovation through the protection of valid U.S. IP rights and through design-around efforts undertaken by respondents in order to lawfully manufacture, import, and sell non-infringing merchandise to the benefit of U.S. consumers.

The Federal Government’s IP 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

² 19 U.S.C. §§ 1337(d)(1), (e)(1), (f)(1).

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. IP rights.

II. PART II (Specific Recommendations for Enforcement Efforts)

Against the above background, the following considerations and recommendations should be a major focus of the IPEC in order to enhance the effectiveness of the Section 337 remedial framework in the protection of U.S. intellectual property rights.

Congress and the U.S. Government Accountability Office (“GAO”) have previously noted concerns regarding the CBP’s enforcement of Section 337 exclusion orders owing to limitations on CBP resources for the enforcement of such orders, particularly since the enforcement of IP rights may no longer garner the high priority by CBP that it once had.³

Given that CBP has a significant role in the enforcement of Section 337 orders, we recommend an examination of whether and to what extent resources may be allocated so as to ensure that adequate resources are devoted, and that high priority is accorded by CBP to the targeted enforcement of Section 337 exclusion orders.

Second, it has been noted that CBP may be able to improve its enforcement of Section 337 orders by creating and implementing procedures to enable adversarial proceedings to inform its determination as to whether particular foreign merchandise falls within, or outside, the scope of an ITC exclusion order. At the present time, CBP renders its determination as to the admissibility of potentially excludable merchandise in an *ex parte* process, largely without any assistance from the ITC. In contrast, the parties to the ITC investigation that culminated in the issuance of the ITC exclusion order, and the relevant ITC staff, are best equipped to provide invaluable information and argument concerning the scope of the IP rights adjudicated in the ITC and the particular features and functions of the products adjudicated to violate these rights in the ITC proceeding.

Third, CBP’s decision-making process would be enhanced by the establishment of statutory and/or regulatory authority to enable parties (*i.e.*, the IP rights-holder and the importer/manufacturer) to exchange confidential information within the confines of a CBP proceeding to make a scope determination. Whereas the administrative protective order entered in the ITC proceeding enables such exchange of confidential information,

³ See, e.g., U.S. Government Accountability Office, *Intellectual Property: Federal Enforcement Has Generally Increased, but Assessing Performance Could Strengthen Law Enforcement Efforts*, GAO-08-157 (March 2008); Congressional Research Service, *Intellectual Property Rights Protection and Enforcement: Section 337 of the Tariff Act of 1930*, 7-5700, RS22880 (Oct. 26, 2009).

the ITC protective order does not extend to any proceeding before CBP to determine the breadth or scope of the ITC exclusion order as applied to particular imported products.

Fourth, in the course of its investigation, the ITC accumulates a large body of information within its administrative record underlying the issuance of an exclusion order with respect to the IP rights adjudicated in that proceeding and the imported merchandise at issue there. At the present time, there do not appear to be open channels of communication between the ITC and CBP in the course of CBP's enforcement of ITC exclusion orders. It is recommended that consideration be given to whether procedures should be implemented to facilitate and encourage communications between CBP and the ITC with respect to the scope of the adjudicated IP rights and the merchandise subject to the ITC's investigation.

Notably, in October 2008, the U.S. Court of Appeals for the Federal Circuit ruled in *Kyocera v. ITC*⁴ that the statute, as written, does not authorize the ITC to extend limited exclusion orders to reach the downstream products of third parties. Proposed legislation to provide explicit statutory authority to the ITC to issue exclusion orders that reach downstream products of third parties is under consideration. However, significant due process and notice concerns have been raised with respect to the proposed legislation. In addition, *Kyocera* raised an issue as to the enforceability of ITC limited exclusion orders with respect to goods manufactured by the named respondent but imported by non-respondents. Proposed legislation to amend Section 337 to address this issue is also under consideration.

The ABA IPL Section is prepared to provide any and all information and advice to the IPEC in order to ensure that Section 337 remains a strong and vital mechanism for the enforcement of U.S. IP rights.

Reducing the supply of infringing goods, domestically and internationally:

(First Bullet Point, Federal Register Notice, page 8137)

The ABA IPL Section commends the efforts of the administration and IPEC to combat the supply of infringing goods but believes that additional steps should be taken to make these efforts more effective. These steps include, but are not limited to:

- Better communication, coordination and sharing of information between and among CBP, U.S. Immigration and Customs Enforcement ("ICE"), ITC, the U.S. Patent and Trademark Office ("USPTO"), U.S. Department of Justice ("DOJ"), U.S. Food and Drug Administration ("FDA"), U.S. Department of Justice Computer Crime and Intellectual Property Section ("CCIPS"), the U.S. Postal Service and rights holders.
- Expansion of the CPB e-Allegations online reporting system, including better promotion of the system to increase use.

⁴ 545 F.3d 1340 (Fed. Cir. 2008).

- Further publication to rights holders of the availability of the continuous bond option.
- Faster release of samples to the rights holder.
- Expansion of the Cyber Crimes Center under ICE.
- Expansion of the U.S. International IP Attaché program to additional countries including Hong Kong, Taiwan, Pakistan and Korea.
- Increase in amount and use of civil and criminal penalties and fines.
- Additional funding of CBP and allocation of resources to IP enforcement and protection.

Finally, the ABA IPL Section also recommends that IPEC encourage and facilitate greater enforcement against the unauthorized importation into and sale in the U.S. of materially different gray market goods (also known as parallel imports), bearing a trademark that is the same as the mark used with domestic products. The ABA IPL is not asking IPEC to address gray market goods with minor or immaterial differences from their domestic counterparts, but only those that violate federal trademark law or U.S. governmental regulations. Federal courts and the ITC have found that the importation and sale of materially different gray market goods may constitute trademark infringement and unfair competition under the Lanham Act.

Such material differences create likelihood of confusion and disappointment among consumers and potential physical harm depending upon their nature. Material differences may include different composition, ingredients or functionality from their U.S. counterparts, as well as different directions, warranty, safety or allergen, information. The gray market goods also may not comply with U.S. laws and regulations, e.g., FDA, Environmental Protection Agency (EPA), etc.

Encouraging and facilitating enforcement and cooperation among CBP, the FDA (e.g., gray market pharmaceuticals and other products subject to its regulatory control), the U.S. Postal Service (e.g., gray market goods mailed into the U.S. after Internet sales), EPA (e.g., gray market pesticides), and other relevant agencies, against the unauthorized importation and sale of infringing gray market goods would help to counter a problem that impacts consumers and trademark owners alike.

Identifying Weaknesses, Duplication of Efforts, Waste, and Other Unjustified Impediments to Effective Enforcement Actions:

(Second Bullet Point, Federal Register Notice, page 8137)

The ABA IPL Section has a strong commitment to legal education and training. We support efforts by the U.S. government agencies to educate foreign officials on legal and policy issues related to effective intellectual property protection, law enforcement (civil, administrative, criminal and border) and judicial reform.

Several U.S. government agencies have dedicated resources, both financial and human, to provide training on intellectual property rights' law and enforcement to officials from foreign countries. This kind of training, cooperation and capacity building is a worthy and needed effort, and this work is welcomed. The U.S. State Department hosts a public website that invites both U.S. government agencies as well as rights holders to populate the database with training information conducted (see www.training.ipr.gov). This Intellectual Property Rights Training Database ("IPR") serves as a repository for descriptions of IPR-related trainings by U.S. government agencies and participating private sector groups, but it is, understandably, not used as a planning or coordination tool (and the ABA IPL Section is not suggesting that it should be used in such a manner).

However, given the multitude of government agencies involved and the understandably differing objectives for IPR-related trainings given by different agencies, there have been incidents where the trainings (either here in the U.S. or abroad) have fallen short in several ways. In some cases, there were duplicate trainings over a short period of time given to the same set of foreign officials. In other cases, trainings were provided by private contractors not familiar with U.S. IP policy and/or who were not fully expert in the field for which they were teaching. In other cases, agencies are not aware of IPR-related trainings that have been offered by their counterpart agencies, and that results in duplicative efforts. At other times, agencies may not have been transparent with their counterpart agencies on what trainings they have conducted or plan to conduct. These problems can be improved with better communication and disclosure among the agencies.

With respect to U.S. government efforts in training and capacity building for foreign IP officials, we offer several observations. First, we recommend that the IPEC work to support that the appropriate resources for IPR trainings be made available to all participating U.S. Government agencies. Second, the IPEC should work with the agencies to ensure that each agency has in place proper systems that ensure that training selection, development and production are consistent with U.S. IP and trade policy goals. We are not suggesting that the IPEC have micro-oversight over each and every individual program under consideration, but rather that the IPEC should be properly informed of all programs as part of oversight management. Regular agency reporting on prospective training plans would be useful. Third, we believe that each agency should have in place its own system to evaluate the effectiveness of the programs they produce, including follow-up efforts to evaluate whether actual improvements were made in the officials' respective countries, based on these trainings. The IPEC should ensure that such agency-specific review systems are in place. Given limited resources, it is imperative that available resources be properly employed to deliver effective trainings that will serve to improve the IP landscape in the countries receiving the trainings.

Promoting Information Sharing Among Participating Governmental Agencies:
(Third Bullet Point, Federal Register Notice, page 8138)

The PRO IP Act (P.L. 110-403) and its legislative history make clear that a core function of the IPEC is coordination of the activities of federal enforcement agencies with responsibilities relating to intellectual property.

Central and essential to this function is information sharing between participating agencies. Without robust and meaningful information sharing, the Intellectual Property Enforcement Coordinator cannot successfully carry out her statutorily assigned coordination function. The developmental history of the PRO IP Act gives cause for concern that the requisite level of information sharing will be difficult to achieve. Law enforcement agencies, for reasons that are sometimes legitimate but often ill-founded, have a long history of demonstrated reluctance and resistance to sharing information with other enforcement agencies. These agencies are often seen as competitors rather than as cooperating partners.

As revealed in the Report of the 9/11 Commission, shortcomings in law enforcement agency information sharing can have tragic consequences. Fortunately, Congress has acted to take down legal barriers to cooperation and information sharing between agencies. Nonetheless, institutional barriers may still exist. Particularly noteworthy is the strong opposition to the creation and authority of the IPEC as demonstrated by the U.S. Department of Justice. The Department opposed the creation of the IPEC as proposed in the PRO IP Act and in S. 522, predecessor legislation by Senators Bayh and Voinovich. In a joint U.S. Justice/Commerce Department September 23, 2008 letter to U.S. Senate Judiciary Committee Chairman Leahy, the modest and carefully circumscribed authority proposed for the IPEC was opposed “on constitutional separation of powers grounds” as “a legislative intrusion into the internal structure and composition of the President’s Administration.” Continued opposition such as this from two of the leading federal IP enforcement agencies is likely to diminish agency information sharing and cooperation, and the overall effectiveness of the Intellectual Property Enforcement Coordinator. We urge the present leadership of these agencies, as well as all IP enforcement agencies, to participate fully, cooperatively and effectively in carrying out the functions of the IPEC, including by information sharing to the extent permitted and called for by law.

Methods to Improve Federal Efforts in the Enforcement of Intellectual Property:

1. Suggest methods to improve the adequacy, effectiveness and/or coordination of the various Federal departments, agencies and programs that are charged with enforcement of intellectual property.

(Question 1, Federal Register Notice, page 8138)

The Section recognizes that a coordinated approach to intellectual property law enforcement will enhance the efficacy of such efforts and their deterrent effects. That

said, federal departments, agencies and programs that are or may be tasked with enforcement of intellectual property laws and rights are many and varied. Moreover, they by and large operate independently and allocate their resources in accordance with their own budgetary and policy priorities, within the limits of their own jurisdictional reach. The Section believes that a coordinated approach to such efforts will therefore be elusive without robust encouragement from the White House, through the formulation and promotion of clear policy initiatives.

Specific Enforcement Activities Employed by the U.S. Government that have been Effective at Curtailing or Preventing Infringement

2. Identify specific existing enforcement actions, methods, procedures or policies employed by the U.S. Government or governments of other countries that have been particularly effective at curtailing or preventing infringement (including, if possible, specific examples illustrating the effectiveness of those methods).

(Question 2, Federal Register Notice, page 8138)

The Section observes that the federal judicial system in the U.S. generally offers effective relief in both civil and criminal intellectual property actions here in the States. The ABA IPL Section has been active in addressing specific legal issues of concern to our membership. We hold conferences, produce books, engage in legislative work as well as judicial briefs, all to help serve the legal community.

Given the breadth of this question however, our views here are narrowed to indicate our support for certain existing U.S. government trade policies that encourage strong IP protection and enforcement abroad, and which in turn aim to prevent and curtail infringement abroad. (We do not address here any actions or policies taken by foreign governments.)

First, one of the most distinct trade developments has been the comprehensive IP Chapters in the various Free Trade Agreements (“FTA”) that the U.S. Government has developed over the last two decades. Recent agreements have incorporated the obligations found in the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPS”) as well as the obligations in the World Intellectual Property Organization (“WIPO”) digital treaties (WIPO Copyright Treaty and WIPO Performances and Phonograms Treaty) as well as treaty obligations in the industrial property arena. Importantly, these FTA chapters include more detailed obligations affecting enforcement measures in the civil, criminal and border context; having our trading partners have strong measures and apply them in-practice is imperative to achieving effective enforcement against IP infringement.

Second, the annual Special 301 process has, since the 1988 Trade Act, invited public input to inform the Office of the U.S. Trade Representative (“USTR”) in identifying countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual

property protection. Special 301 has been a remarkable tool in heightening foreign countries' awareness and attention to their own IP legislative and enforcement landscape.

Third, rights holders may petition the U.S. Government to initiate reviews of other countries' adequate and effective protection of U.S. intellectual property under the Generalized System of Preferences ("GSP"), the Caribbean Basin Initiative ("CBI") and Andean Trade Preferences Act ("ATPA") trade programs. In fact, the CBI preference program was the first trade law (in 1984) that intersected trade law with IP protection. These laws contain mandatory and discretionary criteria on whether the beneficiary country is providing "adequate and effective" protection to holders of U.S. intellectual property. Many of these investigations have proven very useful in elevating bilateral engagement to achieve improvement in the problems at-hand. Having credible trade leverage is an important "carrot" as much as it is a "stick" in bilateral contexts.

Cooperation between Stakeholders and the U.S. Government:

3. Identify specific existing processes involving cooperation between stakeholders and the U.S. Government (or between stakeholders and other governments) that have been particularly effective at curtailing or preventing infringement.

(Question 3, Federal Register Notice, page 8138)

The following activities of U.S. Government Agencies are notable as being cooperative with intellectual property stakeholders in curtailing or preventing infringement:

- The continuous bond option (although further publication of this is required so that more rights holders are aware of it and take advantage of it).
- Online recordation of registered trademarks and copyrights.
- The CBP IPR Center's participation with other countries in the International Internet Week of Action ("IIWA") November 15-20, 2009 which targeted illegal and counterfeit medicines sold over the Internet. In the U.S., the FDA issued 22 warning letters about illegal sales of medicines on 138 independent websites. The websites were posted on the FDA's website, resulting in 136 of the identified websites being permanently suspended.
- Deployment of US International IP Attachés.

New Methods for Providing Useful Information to the CBP:

6. Suggest new methods for rights holders and importers to provide information to U.S. Customs and Border Protection (CBP) on distribution and supply chains. Such information could enable CBP to increase the effectiveness of its process for selecting ("targeting") imports for inspection by creating a segment of trusted imports, which would allow CBP to better focus its targeting on high risk imports and imports for which advance information is lacking.

(Question 6, Federal Register Notice, page 8138)

The following initiatives would be helpful in allowing stakeholders to provide useful information to the CBP:

- Expansion of e-Allegations online reporting system, including better promotion of the system to increase use.
- Linkage of USPTO and U.S. Copyright Office records to CBP's IPR system to allow seizure of goods that infringe registered trademarks or copyrights regardless of whether the registration has been recorded with CBP.
- Creation of a database of importers with exclusive rights to use registered trademarks or copyrights. This would allow the exclusive importer to be treated as the rights holder for the purpose of determining whether detained goods are counterfeit.
- Better coordination, linkage and sharing of data and information among the various agencies within CBP including International Trade Data System ("ITDS") and the use of data contained in Automated Commercial Environment ("ACE") to assist CBP agents inspecting imported goods.

Adequacy and Effectiveness of Reporting by Governmental Agencies:

10. Describe the adequacy and effectiveness of the reporting by the various agencies responsible for enforcing intellectual property infringements, such as the reporting of investigations, seizures of infringing goods or products, prosecutions, the results of prosecutions, including whether any further voluntary reporting of activities should be made, in keeping with other federal law.

(Question 10, Federal Register Notice, page 8138)

In general, it would greatly improve the effort to protect intellectual property rights if all agencies involved increased the reporting of their efforts. The more information shared and disseminated among the agencies, rights holders, other countries and the government, the more effective enforcement procedures will be. More or additional information should be provided in the areas of identifying the importers and manufacturers of counterfeit goods and their country of origin, seizure rates, detention rates and the length of detention. CBP is currently constrained by the Trade Secrets Act which impacts on CBP's ability to communicate with rights holders and provide them with sufficient information to determine whether detained goods are counterfeit. Amendments to the Trade Secret Act to permit the release of information and photographs to rights holders are necessary.

Also, intellectual property owners who are victims of crimes and entitled to restitution under 18 U.S.C. 3663 often must rely upon relationships and personal contacts in order to be informed of those cases prior to sentencing. It is suggested that a database of criminal indictments be maintained, to which intellectual property owners could subscribe and periodically search and/or be notified of any cases involving their copyrights or trademarks. Early notification would also provide rights owners with an

opportunity to offer their assistance to federal prosecutors, including supplying evidence of the intellectual property rights involved.

Particular Problems Presented by Infringement over the Internet:

14. Suggest specific methods to limit or prevent use of the Internet to sell and/or otherwise distribute or disseminate infringing products (physical goods or digital content).

(Question 14, Federal Register Notice, page 8138)

For obvious reasons, much of the work of CBP and other agencies pertains to physical goods which are imported into the U.S. However, the Internet has created an entire new class of counterfeit goods which come into the country on-line. This is a particular problem for rights holders in the music, arts and film industries. This is one area where enforcement is difficult and lacking and requires new measures. There has been some success under the Digital Millennium Copyright Act (“DMCA”) with take down procedures. However, that is primarily of a civil nature and enforced by the rights holders themselves without government assistance. It is suggested one or more agencies begin considering similar procedures for on-line violations.

The Internet also allows sellers of products that infringe patents and trademarks to advertise those products (including counterfeits and gray market goods) to customers in the U.S. Once the order is placed online, those infringing goods are then shipped into the U.S., often in small packages that are not inspected by CBP. Because of the highly decentralized nature of the Internet, stopping (or even identifying) those transactions at the source is often impossible. However, the link between infringer and customer can be broken by removal of those websites from search results generated by Internet search engines. As mentioned above, the DMCA has permitted such removal of copyright-infringing websites from search results (both sponsored links and organic results) with some success. It is suggested that a similar tool be made available for patent and trademark owners.

Google currently allows reporting of any websites selling counterfeit goods that appear in Google’s sponsored link advertisements (see reporting form at http://services.google.com/inquiry/aw_counterfeit), for investigation and action (including removal). We applaud that voluntary step, and encourage other Internet search engines to implement a reporting system. Such reporting systems should also be expanded to organize search results and possibly also to patent and trademark (e.g., gray market) infringements.

Threats to Public Health and Safety Caused by Infringement:

(Question 17, Federal Register Notice, page 8139)

In the field of human medicine, intellectual property violations present a severe threat to public health and a high cost to the economy. Counterfeit medicines are a growing problem with an estimated 1% of the total market, 50% of medicines sold on-

line, and 10-30% in emerging markets, Latin America, South East Asia, and Africa. The problem is not limited to foreign jurisdictions with increasing reports of counterfeit medicines in the U.S. The following references are representative: *Counterfeit Medicines*, The Parliamentary Office of Science and Technology, www.parliament.uk/parliamentary_offices/post/pubs.2010.cfm; *Counterfeit Drugs Kill*, World Health Organization report of IMPACT (International Medical Products Anti-Counterfeiting Task Force), May 2008; *The Word is Out on Unapproved H1N1 Products*, FDA Consumer Health Information, USFDA, October, 2009.

As in other industries, 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. See, for example, *Safeguarding against Substandard/Counterfeit Drugs: Mitigating a Macroeconomic Pandemic*. Research in Social and Administrative Pharmacy, 5:4-16 (2009).

Specific strategies for reducing threats to public health and safety include the following:

- (1) 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, U.S. and outside of the United States (“OUS”), which enables and threatens a secure manufacture through-market supply chain. Increased transparency would also facilitate enforcement action against unapproved and/or infringing manufacturers.
- (2) Improved export /import regulations and enforcement. Infringing and counterfeit drugs, medical devices, and biologics 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.
- (3) 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.
- (4) Regulation of “rogue” internet pharmacies, which facilitate counterfeit drug distribution, in a manner similar to brick and mortar pharmacies. There are over 35,000 Internet pharmacies that do not meet basic safety standards (see <http://www.legitscript.com>). As explained above, the highly decentralized nature of the Internet makes stopping (or even identifying) rogue Internet

- (5) Leveraging health regulations and approval of a drug as a point to stop infringing drugs, medical devices and biologics. Infringing drugs, medical devices, and biologics 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 IP rights, and also to be exported and sold as substandard or counterfeit medicines in other markets. Regulatory approval pathways should be transparent and permit IP 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.
- (6) Continued efforts by the U.S. to encourage countries to improve their enforcement environment, particularly in the developing countries with a high level of counterfeiting (China, India, Pakistan and Mexico).

Educational Efforts:

20. Provide specific suggestions on the need for public education and awareness programs for consumers, including a description of how these programs should be designed, estimates of their cost, whether they should focus on specific products that pose a threat to public health, such as counterfeit pharmaceuticals, or whether should they be general infringement awareness programs.

(Question 20, Federal Register Notice, page 8139)

Unfortunately, an ever-growing portion of the United States population has come to believe that if material is made available on the Internet, it is free. The IPEC could be particularly helpful in coordinating efforts toward producing educational public service announcements aired on broadcast media and over the Internet. Such announcements should not only inform the public that intellectual property infringement is illegal, it is also harmful to the United States economy. The ABA-IPL Section would be pleased to assist with such efforts as well.