



Comments of the Generic Pharmaceutical Association on the Anti-Counterfeiting Trade Agreement

March 21, 2008

The Generic Pharmaceutical Association (GPhA) supports efforts to secure the U.S. drug supply from counterfeit medicines. Currently, due in great part to the vigilance of the U.S. Food and Drug Administration (FDA), the quality of America's prescription medicines is the highest in the world. However, the abundance of counterfeit medicines in the global market and the increasing presence of such medicines in our domestic market threaten to undermine the standards of quality and security that the American public has come to rely upon. Pharmaceuticals represent the fastest-growing area of IPR seizures by U.S. Customs and Border Protection (CBP), accounting for 6 percent by value in FY 2007, up from only 1.5 percent the previous year. Moreover, pharmaceuticals accounted for **40 percent of the domestic value of IPR "Import Safety" Commodities seized by CBP in FY 2007**, making it far and away the #1 public health and safety concern with respect to imported counterfeit goods.¹

GPhA believes that the problem of counterfeit medicines raises a very significant public health concern that must be addressed systemically on a range of levels—from local to global, and throughout the drug supply chain. GPhA applauds the initiative of the Office of the United States Trade Representative (USTR) to pursue an Anti-Counterfeiting Trade Agreement (ACTA) with like-minded countries to establish a common standard for IPR enforcement in terms of international cooperation, enforcement practices, and the legal framework for IPR enforcement. We offer these comments to ensure that the ACTA addresses the growing threat of counterfeit drugs to the security of our drug supply in a balanced, appropriate and effective way, taking account of the IPR peculiarities of the U.S. pharmaceutical sector. In our view, anti-counterfeiting strategies should be centered on strong enforcement of the rights and systems currently in place and the cultivation of proper legal framework in nations where it may be inadequate.

The Focus

In its *Federal Register Notice* of February 15, 2008, USTR stated that a principle goal of the ACTA would be to establish a common standard for IPR enforcement "to combat global infringements of IPR particularly in the context of *counterfeiting and piracy*" (Emphasis added.) As an initial matter, especially given the importance of this undertaking, GPhA urges USTR not to allow the rising momentum behind a global

¹ "Intellectual Property Rights, Seizure Status: FY 2007", U.S. Customs and Border Protection (CBP), December 2007.



anti-counterfeiting strategy to be diffused by deviating into expanded IP protection and enforcement with respect to patents and data exclusivity.

While this may seem a stretch at first glance, the fact is, some confusion does exist regarding just what IP rights are violated by counterfeiting. This may not be too surprising when you consider that the terms “counterfeiting and piracy” are often used in conjunction, just as USTR did in this announcement. Because patent infringement is a form of piracy, some erroneously conclude that counterfeiting is also a form of patent infringement, particularly in the area of counterfeit medicines. Thus, for example, *Wikipedia* in the opening paragraph of its entry on “Counterfeit,” inaccurately states, “[the] word ‘counterfeit’ most frequently describes forged currency or documents, but can also describe clothing, software, *pharmaceuticals*, watches, or more recently, cars and motorcycles, especially when this results in *patent infringement* or trademark infringement.” (Emphasis added.) Even as knowledgeable a group as the Congressional Research Service seems to confuse these two ideas in a recent publication, “*Intellectual Property Rights and International Trade*.” In its discussion of the pharmaceutical industry, CRS juxtaposes an opening paragraph on the prevalence of counterfeit drugs with PhRMA’s annual estimates of U.S. pharmaceutical industry losses from foreign violations of patent protection and data exclusivity, without any indication to the reader that the subject matter has changed.²

Instead, we endorse the approach that USTR has taken in previous free trade agreements (FTAs) where the specific enforcement obligations developed to address infringement by “counterfeit and pirated goods” concern “trademark counterfeiting and copyright or related rights,” and appropriately does not address patent infringement, a different subject altogether. In fact, we note that with respect to border measures, previous FTAs provide definitions for **counterfeit trademark goods** and **pirated copyright goods**.³ (Emphasis added.) This is the context within which we assume that USTR will address “*counterfeiting* and *piracy*” in the ACTA, and we would strenuously object to any effort to expand the focus to include patents (or data protection.) Any effort to do so would risk upsetting the balance found in U.S. law between the intellectual property protections afforded innovative pharmaceuticals and access to affordable medicines.

Specifically in the pharmaceutical area, **counterfeiting is a trademark problem that can affect both branded and generic products**. According to the U.S. Food and Drug Administration, which is the U.S. agency responsible for protecting public health by ensuring the safety and effectiveness of medicines, “U.S. law defines counterfeit drugs as those sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is deliberately and fraudulently mislabeled in a way that suggests that it is the authentic

² Ilias, Shayerah and Fergusson, Ian, “CRS Report for Congress: Intellectual Property Rights and International Trade”, December 20, 2007, Order Code RL34292, p. CRS-12 and CRS-13.

³ See, for example, Article 16.11 [Enforcement of Intellectual Property Rights] of the U.S.-Peru Trade Promotion Agreement, and especially paragraphs 20-25.



approved product. Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.”⁴ In the international context, the World Health Organization has defined a counterfeit medicine as “a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients or the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”⁵ An anti-counterfeiting trade agreement should therefore not become a platform for addressing patent protections, at least with respect to pharmaceuticals.

a) Improved Cooperation

The consistency of the U.S. and WHO definitions of what constitutes a counterfeit drug should put U.S. negotiators in a strong position when it comes to defining a common scope for the problem, a necessary first step toward improving information sharing and cooperation among enforcement agencies.

The correct definition of the problem can also play an important role in educating the public. Unfortunately, while the counterfeiting of generic drugs is less common than with higher-priced branded drugs, misinformed consumers sometimes confuse high quality generics with unregulated, counterfeit or inferior drugs. To ensure that expanded international efforts to combat counterfeit drugs do not unnecessarily stifle competition between generic and brand drugs, GPhA strongly urges USTR to stress the distinction between generic and counterfeit drugs when it negotiates the ACTA. As FDA consistently affirms, “[a] generic drug is identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.”

Finally, counterfeiting of medicines occurs less frequently in the United States than abroad due to the strict guidelines, regulations, and enforcement that the FDA provides throughout the production and distribution chain. Thus, effective cooperation to counter the counterfeiting of pharmaceuticals should support efforts by regulatory agencies to strictly monitor good manufacturing and distribution practices.

b) Enforcement Practices

GPhA notes that U.S. bilateral free trade agreements contain “cutting edge” provisions in terms of tough penalties for counterfeiting and piracy that should be

⁴ “Counterfeit Drugs Questions and Answers”, U.S. Food and Drug Administration, <http://www.fda.gov/oc/initiatives/qa.html>

⁵ World Health Organization, Fact Sheet No. 275, November 2003.



considered for inclusion in the ACTA.⁶ Among some of the most important deterrent and enforcement tools are:

- Civil judicial proceedings must authorize the seizure, forfeiture, and destruction of counterfeit and pirated goods and the equipment used to produce them.
- Civil judicial proceedings must have the authority to order the infringer to provide information regarding the means of production or distribution channel of counterfeit goods, including the identity of involved third persons, and to provide this information to the right holder, with appropriate sanctions for failure to abide by valid orders.
- Damage determinations must take into account the value of the legitimate goods as well as the infringer's profits for trademark counterfeiting and copyright infringement.
- Both statutory and actual damages are mandated for trademark counterfeiting and copyright infringement, ensuring that monetary damages can be awarded even when it is difficult to assign a monetary value to the violation.
- Simple removal of a trademark unlawfully affixed is not sufficient to permit the release of goods into the channels of commerce.
- The exportation of counterfeit or pirated goods is not permitted.
- *Ex officio* action may be taken in border and criminal cases, thus providing more effective enforcement.
- Willful importation or exportation of counterfeit or pirated goods are subject to criminal penalties to the same extent as the trafficking or distribution of such goods in domestic commerce.

On the other hand, GPhA opposes the inclusion of stronger enforcement protections with respect to patents, such as the recent initiatives in the EU to criminalize patent infringement. Whereas in the pharmaceutical industry, patent infringement is a case-by-case judicial determination based on the merits of a patent challenge in a civil action, copyright and trademark infringements are generally deliberate criminal acts. The two concepts should not be confused. Any provision that seeks criminal penalties for patent infringement would undermine well-established policies and business practices that help to maintain patent quality and support fair competition in the U.S. pharmaceutical industry.

The Legal Framework

GPhA proposes that two concepts that have been applied before in the Telecommunications Chapter of U.S. bilateral trade agreements be adapted by the ACTA in the global fight against counterfeit drugs.

⁶ For greater certainty, any GPhA endorsement of enforcement against piracy in this section refers to the infringement of copyright or related rights.



The first would require Parties to the agreement to establish a competent national drug regulatory authority to ensure medicines are safe, effective and of good quality (much as the Telecommunications Chapter requires an independent regulator to promote competitive market conditions.) While such an authority is likely to already exist in the initial signatories, it sends the appropriate signal to the many countries that still lag in this area.

The second would require the Parties to maintain technology neutrality with respect to the adoption of new anti-counterfeiting technologies in the fight against counterfeits (much as the Telecommunications Chapter gives suppliers of public telecommunication services the flexibility to choose the technologies that they use to supply their services). ACTA should not prevent drug manufacturers or other stakeholders in the supply chain from having the flexibility to choose the anti-counterfeiting technologies that they use to supply their products, so long as their use supports legitimate public policy interests.

Finally, GPhA supports the concept of ending illegal Internet drug sales and better screening of Internet pharmacies, as these sites can be important conduits for counterfeit drugs. The legal framework in this area is only evolving in the United States, but the ACTA could encourage voluntary, private sector driven programs that identify trustworthy web sites through “seal programs” and similar means. For example, the National Association of Boards of Pharmacy’s (NABP) VIPPS program identifies licensed pharmacies where FDA-approved drugs can be purchased. Unless medications have been purchased from a U.S. state license pharmacy website, the safety and efficacy of these medications cannot be guaranteed. It should also be possible to identify some minimal criteria that on-line pharmacies must comply with, such as posting a street address on its Web site and having a toll-free phone number for patients to contact pharmacists if they have questions about their medications.

Conclusion

Providing over 65% of the U.S. prescription drug supply, the U.S. generic pharmaceutical industry is highly vested in maintaining security of the drug supply chain and is dedicated to taking the measures necessary to protect patients and consumers from the harm caused by counterfeit medicines. Working together with the U.S. and foreign governments and stakeholders to improve security and enforcement practices is a necessity for addressing this global problem.

GPhA appreciates this opportunity to share the concerns of the U.S. generic pharmaceutical industry as USTR begins to pursue trade negotiations with other governments. If there is need of further clarification on any of the issues discussed in these comments, please do not hesitate to contact Kathleen Jaeger, CEO & President, GPhA.



INTERNATIONAL AUTHENTICATION ASSOCIATION
PMB 226
2149 WEST CASCADE
HOOD RIVER, OR 97031

541-490-7920
FAX: 541-386-1654 – ATTENTION PMB 226

info@IntIAA.org

March 21, 2008

Rachel S. Bae
Director for Intellectual Property and Innovation
Office of the United States Trade Representative

Regarding: Anti-Counterfeiting Trade Agreement (ACTA): Request for Public Comments

Dear Ms. Bae:

I am writing on behalf of the International Authentication Association (IAA) for which I am the General Secretary / Americas. The IAA is a practice based, non-profit organization made up of 20 member companies who are users or suppliers of authentication/tracking technologies used in the fight against global counterfeiting. *Today, IAA member technologies protect the currency of the United States and over 100 other countries around the world, the majority of the world's credit cards as well as numerous passports, national ID cards & drivers' licenses.* IAA members are either users or providers of authentication products and services to companies in critical product categories including pharmaceuticals, computer software, electronics and apparel in their constant battle against counterfeiting and piracy.

IAA Member Companies Include:

3M Company
Advanced Coding Systems
American Bank Note Holographics
ARmark Authentication Technologies
Authentix
BP Labels
DuPont Authentication
Hologram Company Rako
Hologram Industries
Honeywell
Ingenia Technology
JDSU

Johnson & Johnson Health Care Systems
Label Systems Authentication
NanoInk
Payne Security
Schreiner ProSecure
Securikett
SICPA
Solos Indentificazione Protezione
Tesa Scribos GmbH
TUV Rheinland Group
Richemont

On behalf of our members, I am writing in response to your request for comments in regards to the development of an Anti-Counterfeiting Trade Agreement (ACTA).



The IAA and its member companies believe strongly that the development and ratification of an ACTA would be a valuable and effective tool in the global battle against counterfeiting and other forms of product fraud. Since those we are fighting are organized as trans-national networks and operate globally, it is essential that we work with other nations to coordinate our efforts in this area.

As you see from the introduction to the IAA above, our members have a great deal of experience with counterfeiting and its effects and are committed to working together to fight it. We believe that one of the most effective tools for fighting counterfeits is the development and implementation of systems for the authentication of genuine products, and its corollary, that being the detection and seizure of counterfeit products. Authentication technologies and systems are performing this important role every day, world-wide, but their support within ACTA could do much to make them more effective and therefore, our collective battle against counterfeiting more effective. Using the stated goals of the agreement, we would like to share our views with you on why authentication should be an important part of the ACTA.

As stated in your Fact Sheet on the ACTA, the goal of the agreement is:

Establish, among nations committed to strong IPR protection, a **common standard** for IPR enforcement to combat global infringements of IPR particularly in the context of counterfeiting and piracy that addresses today's challenges, in terms of **increasing international cooperation**, strengthening the **framework of practices that contribute to effective enforcement** of IPRs, and strengthening relevant IPR enforcement measures themselves.

Common Standards

To effectively hinder the flow of counterfeit products of all kinds, enforcement personnel (customs, police, private investigators) need methods to determine whether or not goods are genuine. Today, no consistent process or tools are available for these personnel to examine suspect goods and make a reasonable determination of their validity, and therefore many shipments of likely counterfeit products must be passed since company experts are not available to assist in the inspection. While authentication technologies are increasingly used by companies to assist and facilitate this objective, the fact that there is no global infrastructure for training and support in the use of these tools limits their effectiveness in the field. The development of standards for the process of examining suspect goods, along with the support needed to effectively utilize the existing authentication technologies in place, would provide countries belonging to the ACTA with a significantly improved system for detecting, intercepting and seizing counterfeits. Such a system would, we believe, be a improved barrier to counterfeiters.

Increasing International Cooperation

Improved international standards for authentication practices and process could and would be a focus for international cooperation, coordination and communication as these would be a common language that would allow countries to exchange information on the source and nature of known or suspected counterfeits. Examination and analysis of counterfeits typically reveals the 'fingerprints' of the counterfeiter and often, these counterfeiters attempt to simulate authentication technologies as well.

Rather than compromising the validity of the product, such attempts, and their detection by examining and comparing them against the originals, has become one of the most efficient and effective methods for determining the origin of counterfeit attempts.

Strengthening the framework of practices that contribute to effective enforcement

Using authentication technologies to determine genuine products and detect counterfeits is today a standard practice for governments in areas such as currency, passports and other identification documents as well as other vital government documents. Governments regularly cooperate on practices for the examination and authentication of these items but such efforts have yet to be developed for the authentication of products. An ACTA, containing appropriate language relative to the development of authentication standards and practices could utilize the existing framework for cooperation which exists for these items, but also intensify and expand it into these new threats.

Our recommendations:

Clearly, we firmly believe that cooperation and development on common standards and practices for the authentication of products must be a fundamental part of any multi-country agreement that seeks to develop an effective response to counterfeit products. We propose that the following language, or the concepts contained within it, be a part of any draft ACTA:

“In order to improve their effectiveness in identifying genuine products and detecting counterfeit products, all parties to this agreement will work toward the development and implementation of standardized procedures and processes for the use and examination of authentication devices and technologies designed to identify genuine products. The parties will encourage industries to support this activity through the implementation of multi-layered authentication systems & technologies on those lines of their products which are susceptible to counterfeiting. The parties agree to commit to the development of an infrastructure and means to share information on authentication tools between their customs and law enforcement agencies.

Such infrastructure should include:

- 1. The ability for companies to identify standard points of entry for their products with custom’s agencies whose governments are parties to the agreement.*
- 2. The creation and maintenance of a global internet database tool for customs inspectors whose countries are parties to the agreement which includes information on product appearance and instructions for the examination of any overt authentication feature or technology applied to a product for use in the examination of products at entry. Such database shall be centrally updated not less than every six (6) months.*
- 3. The ability for companies to identify their qualified providers of shipment and forwarding for their goods.*



4. *Regular opportunities for the training of customs personnel by companies on the examination of their products to improve their effectiveness at authenticating genuine, and spotting counterfeit products.”*

I want to make it clear that while we support the development of standards for procedures and processes for authentication, we **do not** favor the selection of specific technologies or types of technology, nor of standards which recommend specific technologies. Given the wide range of products which will fall under the scope of this agreement, and the physical limitations of different product types, it is literally impossible to find technologies which are equally applicable and effective on any product which might be at risk. In addition, implementing standards or selecting particular technologies would, in point of fact, make it easier for the counterfeiters by providing a common target for them to aim at. There are many credible and effective options for authenticating products in use today and to limit this range through an arbitrary standard would be anti-competitive as well.

On behalf of the IAA and its members, we appreciate the opportunity to contribute to development of this important and vital agreement towards countering this growing global threat. If we can provide further insight or explanation of our views on this matter, or elements of a potential ACTA, I, or our members would appreciate the chance to contribute.

Sincerely,

Edward Dietrich
General Secretary / Americas
International Authentication Association



March 21, 2008

VIA ELECTRONIC MAIL ACTA@ustr.eop.gov

Ms. Rachel S. Bae
Director for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

**Re: Anti-Counterfeiting Trade Agreement (ACTA): Request for Public
Comments, 73 Fed. Reg. 8910 (February 15, 2008)**

Dear Ms. Bae:

The International AntiCounterfeiting Coalition, Inc. ("IACC") submits the enclosed comments in response to the request by the United States Trade Representative ("USTR") for written comments from the public concerning specific matters that should be the focus of the proposed Anti-Counterfeiting Trade Agreement ("ACTA").

IACC commends the United States Government for its leadership in proposing to negotiate ACTA. As the largest organization representing exclusively the interests of companies concerned with product counterfeiting and copyright piracy, IACC hopes that these comments will be useful in pursuing successful negotiations with our trading partners and improving enforcement against trademark counterfeiting and copyright piracy.

Respectfully submitted,

A handwritten signature in black ink, which appears to read "Travis D. Johnson". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Travis D. Johnson
Vice President – Director of Legislative Affairs and Policy

Enclosure (via e-mail): IACC ACTA Comments



Comments of the

International AntiCounterfeiting Coalition

To the

United States Trade Representative

On the Anti-Counterfeiting Trade Agreement

March 21, 2008

INTRODUCTION

The International AntiCounterfeiting Coalition, Inc. (“IACC”) submits the enclosed comments in response to the request by the United States Trade Representative (“USTR”) for written comments from the public concerning specific matters that should be the focus of the proposed Anti-Counterfeiting Trade Agreement (“ACTA”).¹

Anti-counterfeiting is a moving target, and there is a constant need to review laws and the sufficiency of government resources allocated to criminal enforcement and training. New technologies, and the increasing sophistication of counterfeiters and pirates, require that government and industry work ever more closely in assessing not only the adequacy of laws but also their effectiveness in practice.

IACC commends the United States Government for its leadership in launching negotiations on ACTA. As the largest organization representing exclusively the interests of companies concerned with product counterfeiting and copyright piracy, IACC hopes that its comments will be useful in pursuing successful negotiations with our trading partners and the goal of improving enforcement against trademark counterfeiting and copyright piracy.

IACC and Its Mission

The IACC, based in Washington, D.C., is the largest and oldest association representing exclusively the interests of trademark and copyright owners concerned with product counterfeiting and copyright piracy. Our members consist of approximately 250 corporations, trade associations, and professional firms and represent total annual revenues estimated at over \$750 billion. Our brand- and copyright-owner members represent a broad cross-section of industries, and include many of the world’s best known companies in the apparel, automotive, consumer goods, entertainment, pharmaceutical, personal care and other product sectors.

The mission of the IACC is to combat trademark counterfeiting and copyright piracy by promoting laws, regulations, and directives designed to make intellectual property theft unprofitable. At the heart of this mission is the belief that counterfeiting causes severe economic harm to trademark and copyright owners and also creates hazards to public health and safety.

¹ As published in 73 Fed. Reg. 8910, Feb. 15, 2008.

To carry out its mission, the IACC is committed to working with government and industry partners in the United States and abroad to strengthen intellectual property protection and enforcement by encouraging improvements in the law, allocation of greater political priority and resources, and raising awareness regarding the enormous—and growing—harm caused by IPR violations. IACC also conducts training in counterfeit identification for law enforcement and border control authorities in the U.S. and abroad, and conducts educational programs in product security and infringement prevention for rights holders.

Anti-Counterfeiting Needs Identified

As detailed in IACC's recent "Special 301" comments, trademark counterfeiting and piracy pose an ever-increasing threat to the sustainable development of the world economy. In addition to depriving legitimate businesses and their workers of income, counterfeiting and piracy discourage innovation and creativity, threaten consumer health and safety, provide an easy source of revenue for criminals (including organized crime) and deprive governments of much-needed tax revenue.

Despite the considerable resources applied by both the public and private sector to address the global problems of counterfeiting and piracy, there is substantial anecdotal and statistical evidence indicating that these problems continue to grow in size and scope. Information from industry and government sources, including Interpol, the World Customs Organization, and the World Intellectual Property Organization confirms that this growth is due in part to the increasing involvement of more sophisticated organized criminal networks operating across national boundaries.

As explained in its recent Special 301 comments, IACC believes that improving the fight against trademark counterfeiting and copyright piracy requires the following steps:

- Substantially greater political will and resources to combat counterfeiting and piracy;
- Greater cooperation and coordination among different government enforcement bodies, including police, Customs, and other administrative enforcement bodies;
- Greater use of criminal enforcement to create substantially greater deterrence, rather than relying excessively on administrative measures that are limited to economic sanctions;
- Sentencing and other guidelines that will lead to stronger criminal and administrative sanctions;

- Providing IPR owners with earlier access to information needed to pursue investigations and legal actions;
- Greater use of “creative” enforcement tools, including landlord liability strategies; and
- Greater transparency regarding the results of government enforcement work.
- Adequate resources and personnel to fight the problems of trademark counterfeiting and copyright piracy

The proposed ACTA offers the opportunity to address a number of these needs in a multilateral instrument among countries with a common interest in deterring trademark counterfeiting and copyright piracy.

Suggestions for the Focus of the Anti-Counterfeiting Trade Agreement

The goal of the ACT Agreement, developed by the United States Government and a group of key trading partners, is to establish a common global enforcement standard to combat IPR infringements. It calls for addressing today's unique challenges by increasing international cooperation and strengthening the framework of effective enforcement practices and relevant enforcement measures.

In pursuing these goals, IACC believes that the focus of ACTA should include the following specific matters in the three main areas detailed in the request for comments – international cooperation, enforcement practices, and legal framework for IPR enforcement:

International Cooperation

Counterfeit Identification Training: ACTA should provide an ongoing program to bring together administrative, law enforcement, and customs authorities from ACTA signatories for training presented by right holders in identifying trademark counterfeit and pirated copyright goods.

Counterfeit Identification Database: ACTA should establish a database available to administrative, law enforcement, and customs authorities in signatory countries that includes reports and information concerning production and distribution of counterfeit trademark and pirated copyright goods, and images of these goods.

Enforcement Practices

While leaders and policy makers in our trading partners are more cognizant of the negative implications tied to the trade of illicit goods, the need for greater priority to be given to anti-counterfeiting efforts remains dire. Counterfeiting and piracy pose serious threats to public health and well being, cause substantial losses in tax revenues, hinder development of both domestic and international markets, and diminish incentives for global innovation.

Political Commitment: To succeed, ACTA should be coupled with a commitment by each country to make anti-counterfeiting enforcement a high priority and to provide the necessary resources to fight and deter counterfeiting. ACTA parties should acknowledge that a decision that a party makes concerning distribution of enforcement resources shall not excuse that party from complying with its obligations under ACTA.

Domestic Coordination: ACTA should require signatory countries to require greater cooperation and coordination among different government enforcement bodies, including police, Customs, and other administrative enforcement bodies.

International Investigations. ACTA should provide an ongoing means for administrative, law enforcement, and customs authorities in signatory countries to exchange information and to organize and conduct cooperative investigations and enforcement actions.

Legal Framework for IPR Enforcement

An important goal of ACTA is to provide a legal framework so that law enforcement agencies, the judiciary and private citizens have the most up-to-date tools necessary to effectively bring counterfeiters and pirates to justice.

In preparing its comments in this respect, IACC has relied on the series of Free Trade Agreements negotiated by the United States Government with a number of trading partners. These FTA agreements include obligations for intellectual property rights enforcement that should be the focus of ACTA, including the following:

Publication of Decisions and Rulings: Each party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights shall be in writing and shall state any relevant findings of fact and the reasoning or the legal basis on which the decisions or rulings are based. Each party shall provide that such decisions shall be published, including by making the decision available to the public on the Internet.

Enforcement Statistics: Each party shall collect and publish enforcement statistics from administrative agencies, civil and criminal courts, law enforcement, and customs agencies on an annual basis. Statistics should be available on the Internet and in English.

Injunctions – Import and Export: In civil judicial proceedings concerning enforcement of intellectual property rights, each party shall provide that its judicial authorities have authority to order a party to desist from an infringement, *inter alia* to prevent, immediately after they clear customs, the entry into the channels of commerce in the jurisdiction of those authorities of imported goods that involve the infringement of an intellectual property rights, or to prevent their exportation.

Civil Damages and Infringer's Profits: Each party shall provide judicial authorities with authority to order infringers to pay the right holder damages adequate to compensate for the injury the right holder has suffered as a result of the infringement, and the profits of the infringer attributable to the infringement that are not taken into account in computing the amount of damages. In determining the damages for infringement of intellectual property rights, each party shall require its judicial authorities to consider, *inter alia*, any legitimate measure of value of the infringed-on good or service submitted by the right holder, including the suggested retail price.

Pre-Established Civil Damages: Each party shall establish or maintain pre-established damages, which shall be available on the election of the right holder, in an amount sufficient to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement.

Costs and Attorney's Fees: Each party shall provide that its judicial authorities shall have the authority, except in exceptional circumstances, to order, at the conclusion of civil judicial proceedings, at least for copyright infringement and trademark counterfeiting, that the prevailing party shall be awarded payment of court costs and fees and reasonable attorney's fees by the losing party

Seizure of Infringing Items and Related Materials: In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each party shall provide that its judicial authorities shall have authority to order the seizure of suspected infringing goods, any related materials, implements, labels, and packaging, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

Destruction of Infringing Items and Related Materials, Labels, and Packaging: In civil judicial proceedings, each party shall provide that, at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional circumstances. Each party shall also provide that its judicial authorities shall have authority to order that materials and implements that have been used in the manufacture or creation of pirated or counterfeit goods, or labels and packaging used or intended to be used in connection with pirated or counterfeit goods, be promptly destroyed without compensation of any sort to the infringer. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of goods into the channels of commerce.

Landlord Liability: Each party shall provide judicial authorities with authority to impose liability for copyright piracy and trademark counterfeiting on landlords in appropriate circumstances.

Right of Information: Each party shall provide that, in civil judicial proceedings concerning enforcement of intellectual property rights, its judicial authorities shall have authority to order the infringer to provide any information that the infringer possesses regarding any person involved in any aspect of the infringement and regarding the means of production or distribution channel of such goods, including the identification of such third persons, and to provide this information to the right holder's representative in the proceedings.

Penalties for Violation of Judicial Orders. Each party shall provide that its judicial authorities shall have authority in judicial proceedings concerning the enforcement of intellectual property rights to fine or imprison, in appropriate cases, a party to a litigation who fails to abide by valid orders issued by such authorities, and to impose sanctions on parties to a litigation, their counsel, experts, or other persons subject to the court's jurisdiction, for violation of judicial orders regarding the protection of confidential information produced or exchanged in a proceeding.

Administrative Authorities. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each party shall provide that such procedures conform to principles equivalent in substance to those provided to judicial authorities pursuant to ACTA.

Expeditious Consideration of Provisional Measures: Each party shall act on requests for relief *inaudita altera parte* expeditiously and shall, except in exceptional circumstances, execute such requests within 10 days.

Application for Suspension of Release by Customs Authorities – Export, Goods-in-Transit, and Free Trade Zones: Each party shall provide that an application to suspend the release of goods shall remain in force for a period of not less than one year from the date of application, or the period that the goods are protected by copyright or the relevant trademark registration, whichever is shorter. Requirements for the right holder to provide information in support of an application to suspend release of the goods shall be limited to information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods recognizable by competent authorities, and any such requirements for information and to provide security or equivalent assurance to protect the defendant shall not unreasonably deter recourse to these procedures.

Ex Officio Authority of Customs Authorities: Each party shall provide that its competent authorities may initiate border measures *ex officio*, with respect to imported, exported, or in-transit merchandise, including such merchandise in free trade zones, suspected of

infringing an intellectual property right, without the need for a formal complaint from a private party or right holder.

Right of Inspection and Information: Where its competent authorities have made a determination that the goods are counterfeit or pirated, a party shall provide its competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer, and the consignee and of the quantity of goods in question.

Customs Remedies: Each party shall provided that goods that have been determined to be pirated or counterfeit by its competent authorities, as well as any labels or packaging used or intended to be used for such goods, shall be destroyed, except in exceptional circumstances. In regard to counterfeit trademark goods, labels, and packaging, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized to permit the exportation of counterfeit or pirated goods, labels, or packaging, or permit such goods to be subject to movement under customs control.

Border Measure Fees: Each party shall provide that any application fee or merchandise storage fee assessed in connection with border measures to enforce an intellectual property rights shall not be set in an amount that unreasonably deters recourse to these measures.

Criminal Penalties: Each party shall provide criminal remedies that include sentences of imprisonment and monetary fines sufficiently high to provide a deterrent to infringements, consistent with a policy of removing the infringer's monetary incentive, and shall establish policies or guidelines that encourage judicial authorities to impose those remedies at levels sufficient to provide a deterrent to future infringements.

Criminal Import and Export: Each party shall treat willful importation or exportation of counterfeit or pirated goods as unlawful activities subject to criminal penalties to the same extent as the trafficking or distribution of such counterfeit or pirated goods in domestic commerce.

Criminal Seizure Orders. In criminal judicial proceedings, each party shall provide that its judicial authorities have authority to order the seizure of suspected counterfeit or pirated goods, any related materials and implements used in the commission of the offense, labels and packaging used or intended to be used in connection with infringing goods, any assets traceable to the infringing activity, and any documentary evidence relevant to the offense. Each party shall provide that items that are subject to seizure pursuant to any such judicial order need not be individually identified, so long as they fall within general categories specified in the order.

Criminal Forfeiture and Destruction Orders: In criminal judicial proceedings, each party shall provide that its judicial authorities have authority to order the forfeiture of any

assets traceable to the infringing activity for at least criminal offenses, and shall have authority to order the forfeiture and destruction of all counterfeit or pirated goods, materials and implements that have been used in the manufacture or creation of infringing goods, or labels and packaging used or intended to be used in connection with infringing goods, without compensation of any sort to the infringer.

Counterfeit Labels and Packaging: Each party shall provide for criminal procedures and penalties to be applied to knowing trafficking in counterfeit labels and goods affixed to or used for, or designed to be affixed to or used for, goods even absent willful counterfeiting or piracy.

Ex Officio Authority: Each party shall provided that the appropriate authorities, as determined by each Party, shall have the authority to initiate criminal legal action *ex officio* with respect to the offences described herein without the need for a formal complaint by a private party or right holder.

Conclusion

The growing sophistication and global reach of trademark counterfeiters require heightened anti-counterfeiting efforts that do not stop at national border. ACTA promises to give countries committed to effective intellectual property enforcement a framework for taking greater action against trademark counterfeiting.

The global counterfeiting problem can only be addressed successfully by fostering cooperation at all levels – within industries, between industry and government, and between governments – to ensure that governments and right holders have the legislative tools and resources needed to fight trademark counterfeiting and copyright piracy more effectively.

In closing, IACC once again commends the United States Government for its leadership in launching negotiations on ACTA. IACC hopes that its comments will be useful in pursuing successful negotiations with our trading partners and the goal of improving enforcement against copyright piracy and trademark counterfeiting.



March 18, 2008

Rachel S. Bae
Director for Intellectual Property and Innovation
Office of U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

**Re: Anti-Counterfeiting Trade Agreement (ACTA): Request
for Public Comments**

The Internet Commerce Coalition (ICC) appreciates the opportunity to share its views regarding the United States Trade Representative's (USTR) intention to negotiate an anti-counterfeiting trade agreement (ACTA).

The ICC consists of leading Internet Service Providers (ISPs), e-commerce companies, and technology trade associations. Our members oppose counterfeiting and piracy and support appropriately targeted efforts to improve international cooperation and enforcement against counterfeiters and pirates.

At the same time, we note that the USTR's fact sheet on ACTA lists Internet distribution as a particular area that the treaty effort will address. U.S. industry enjoys a leading position in Internet distribution models and global communications. What is more, recent fluctuations in the value of the dollar create significant opportunities for exports from the United States to regimes with higher currency values, and for importing goods from other countries whose currencies are lower.

We are concerned that ACTA not have the unintended consequence of undermining this leadership position by justifying discriminatory or protectionist application of laws against U.S. Internet intermediaries or Internet distribution models. For example, some nations' laws treat parallel imports as counterfeits. In fact, these goods are not counterfeits at all, but rather legitimately manufactured, lawfully branded with the trademark, and intended for a different market. Because the Internet is frequently an alternative distribution channel, bringing the strong penalties envisioned in ACTA to bear against these items would have the unintended consequence of hurting both consumers and U.S. businesses which are world leaders in Internet distribution.

Amazon
AT&T Services, Inc.
Comcast
eBay Inc.
ITAA
Monster Worldwide
USTelecom
Verizon Communications

500 8th Street N.W., Washington, D.C. 20004
tel: 202.799.4000 fax: 202.799.5000

We urge USTR to ensure that ACTA:

(1) is consistent with copyright intermediary liability rules that USTR has negotiated in Free Trade Agreements;

(2) in no way suggest that the U.S. will alter well-settled doctrines of secondary and intermediary liability that apply in piracy and counterfeiting cases under U.S. law;

(3) avoids discriminating against online distribution models; and

(4) avoids restricting parallel imports of lawfully purchased, non-counterfeit goods, and if it addresses substantive law, includes a statement that such goods are exempt from the scope of the Treaty and should be permitted under signatories' national laws.

I. Enforcement and Cooperation

We agree that it is desirable to establish best practices and a legal framework to ensure that nations cooperate and deploy adequate enforcement resources to curb counterfeiting and piracy that occurs both online and offline.

However, this in no way requires substantive changes in U.S. law. It is very important that ACTA target purveyors who intentionally traffic in counterfeited and pirated items, rather than legitimate intermediaries, such as ISPs, online marketplaces, payment services and online distribution models are critical to U.S. leadership in the Internet economy.

ACTA should emphasize measures that can appreciably enhance the enforcement of existing intellectual property rights, rather than issues of substantive law such as secondary liability, limitations and exception or creating new substantive rights that could cause serious harm to electronic commerce in the United States. To this end, USTR should emphasize improved international cooperation and harmonization of enforcement mechanisms, which vary considerably by country.

ACTA should also follow the principle of technology neutrality. A counterfeited good is no less counterfeited merely because it is sold in a street kiosk than if it is sold online. Therefore, in establishing a uniform enforcement mechanism for those who traffic in counterfeited and pirated goods, ACTA should not distinguish between goods that are sold through online marketplaces versus offline marketplaces. Similarly, ACTA should not establish a penalty regime that would impose materially different sanctions based solely on the fact that the Internet is the distribution channel. This type of enforcement scheme could set a dangerous precedent that would create significant barriers to online commerce as other nations attempt to curb otherwise lawful competition from U.S. Internet companies.

II. Legal Framework

A. Parallel Imports

Trademark law rightly helps vindicate the rights of trademark owners where similar or identical goods create confusion regarding the source of the goods. However, trademark law in the United States does not authorize trademark owners to assert control over the secondary distribution of goods or secondary distribution channels. *See e.g. NEC Electronics v. CAL Circuit Abco*, 810 F.2d 1506, 1511 (9th Cir. 1987) (“If [NEC] chooses to sell abroad at lower prices than those it could obtain for the identical product here, that is its business. In doing so, however, it cannot look to United States trademark law to insulate the American market or to vitiate the effects of international trade.”)

Parallel imports are an entirely different animal than counterfeiting, and the First Sale doctrine provides that a trademark owner exhausts its rights in a genuine good after it has sold the good. Accordingly, U.S. law recognizes the general principle that a trademark owner may not rely on trademark law to prevent a parallel import of the same good into the United States. This authority should not be disturbed, and ACTA should in no way adversely affect parallel imports.

Laws in European jurisdictions are sometimes very different, and restrict the importation, export or distribution of lawfully purchased, non-counterfeited goods in ways that support price maintenance plans of European manufacturers. ACTA should not be utilized as a vehicle to disrupt legitimate distribution models and channels of commerce for non-counterfeited goods that are lawfully purchased.

In the event that ACTA does address substantive laws, for example, through an agreed definition of a “counterfeit good,” the ICC urges USTR to advocate for adoption of a statement that parallel imports are exempt from the scope of the Treaty and should be permitted under signatories’ national laws.

B. Intermediary Liability

To the extent that ACTA addresses substantive law, it is of great importance to U.S. leadership in the Internet economy that it contain the standard service provider copyright exception language in the Free Trade Agreements that USTR has negotiated with Singapore, Chile, South Korea and Oman, and that follow the framework set forth in § 512 of the Digital Millennium Copyright Act, 17 U.S.C. § 512. This is true of to *all* elements of the FTA agreement, including the provision specifying that service providers not be required proactively to monitor their services, as it is unfortunately not possible for ISPs and e-commerce sites that allow third party users to post content effectively to screen such postings, and leaving room for such a requirement risks discriminatory enforcement against U.S. Internet industry leaders.

Moreover, given the large body of well-developed U.S. law on copyright and trademark rights and liabilities, to the extent that it addresses substantive law, ACTA should not suggest or require modification of U.S. law governing secondary liability or the scope of intellectual property rights. This should not be difficult to avoid. As the words suggest, “piracy” and

“counterfeiting” are not subtle activities, and are already clearly illegal under U.S. law. As such, addressing them in an international framework does not and should not require modifications to U.S. substantive laws.

Thank you for considering our views.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Halpert". The signature is stylized and somewhat cursive, with a prominent "J" and "H".

Jim Halpert
General Counsel