

ACTA@ustr.eop.gov

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

The undersigned associations and companies appreciate that the United States Trade Representative (USTR) and the Department of Commerce have organized a public meeting to consult with interested parties on the proposed ACTA anti-counterfeiting agreement. We also appreciate the call for additional comments prior to the public meeting. As you may be aware, many of the signatories below have submitted extensive prior comments and expressed a variety of procedural and substantive concerns about the ACTA agreement, which we very much appreciate your considering.

We submit these additional brief comments because we have a strong interest in ensuring that the “Internet provisions,” which we understand will presently be under discussion, not disrupt the delicate balance with respect to Section 512 struck in the Digital Millennium Copyright Act, result in increased liability for intermediaries or adopt solutions that directly or indirectly suggest changes to U.S. law.

We understand that one idea under discussion is the possible inclusion of an abbreviated form of the Digital Millennium Copyright Act into ACTA. Given the complexity of Section 512, and the delicately arrived-at compromise contained in that Section, we think it ill-advised to include this (or any other) provision of the DMCA in the Agreement in the first place. Nevertheless, if the parties decide to incorporate Section 512, we strongly encourage USTR to adhere closely to the DMCA safe harbor language (17 U.S.C. §512) contained in prior FTAs. It is important to keep in mind that each word in Section 512 of the DMCA intentionally appears in the statute as a result of Congressionally-supervised industry negotiations. Removing or altering the substantive provisions of the DMCA could result in significant unintended consequences to U.S. law.

For example, any language relating to the termination of repeat infringers under Section 512(i) should include the FTA/DMCA language that emphasizes that termination occur only “in appropriate circumstances.” Removing the important words “in appropriate circumstances” could lead to arguments that ISPs automatically terminate infringers in all cases without the necessary discretion intended by Congress. Similarly, the obligation for an ISP to comply with “standard technical measures” defines that term as an open and voluntary multi-industry standards process that does not impose substantial costs or burdens on service providers’ networks. It is critical that ACTA make clear that limitations not be conditioned on requiring a service provider monitoring its system or network. Similarly, the wording of Section 512(h) addressing the ability of a copyright owner to issue a subpoena for the identity of an alleged copyright infringer must not be abbreviated in a manner inconsistent with the two circuit court decisions (*RIAA v. Verizon* and *RIAA v. Charter*) that have held that the 512(h) subpoena applies only when the alleged infringing material resides on the service provider’s system or network. These are only a few examples of how changes to the DMCA’s language could affect U.S. law. Finally, it should be noted that if the DMCA is included in ACTA, it

must only apply to copyright and not to the inapplicable areas of trademark law or trademark counterfeiting.

We also understand that there is a possibility that other sections of ACTA may propose the discussion of “best practices” including future government-imposed private sector agreements on subjects that are either inconsistent with existing U.S. laws or would inevitably lead to changes in U.S. law. As you are aware, numerous discussions on best practices are already occurring between companies in many different countries as part of private commercial agreements in the marketplace. Government-led negotiations roping in different private industry sectors are inappropriate for an international trade agreement. These kinds of discussions will result in international governments picking industry winners and losers, accommodating a long list of changes to law at the expense of consumers and other important industry sectors.

Although we can only glean a general idea of what some of these proposed “best practices” might be from the prior submissions of the copyright and trademark communities, it is clear that virtually all these ideas may have significant implications for U.S. law:

1. The “best practices” idea of encouraging government-led discussions on a “graduated response” three strikes approach to termination of repeat infringers re-opens the DMCA. The graduated response could easily take away the discretion ISPs were given by Congress to terminate repeat infringers only “in appropriate circumstances.”
2. Discussions to extend the DMCA’s “take down” requirements beyond copyrighted materials that are hosted on the service providers’ network, including those transmitted over the ISPs’ networks, drastically narrows the DMCA’s “mere conduit” provision in Section 512(a) and expands the take down requirements applicable only to Sections 512 (c) and (d).
3. Any proposal to extend the idea of “take down” to trademarks, including trademark counterfeiting, will require changes to the Lanham Act. Trademark takedowns require a new statutory scheme imposing secondary liability where none exists today. Such an idea would likely require a DMCA-like limitation of liability under the Lanham Act.
4. Any discussion of “best practices” regarding the use or testing of filtering technologies would also require changes to both the DMCA and existing trademark law. No obligation exists today to filter under U.S. law. In fact, Section 512(m) of the DMCA expressly states that none of the obligations in the DMCA are conditioned on the service provider monitoring its service. Filtering obviously has significant privacy, technical, due process and cost concerns that would implicate many other U.S. laws.
5. Discussions regarding “take downs” of words or terms in search engines or marketplace sites raise First Amendment issues and weaken the protections afforded under Section 230 of the Communications Act.
6. Efforts to impose new duties on payment intermediaries to take down, disrupt, monitor or interfere with financial transactions would impose new liabilities for the financial services sector and require changes to U.S. laws.

7. New practices relating to the proposed “right of information” will require amendments to a host of existing federal and state privacy laws, trademark laws and the DMCA. The Section 512(h) subpoena narrowly applies to situations where the content alleged to be infringed is hosted on the service provider’s system or network.

For all these reasons, we believe that it is critical that any discussions of “Internet issues” in ACTA be carefully circumscribed and consistent with U.S. law. We cannot know, at present, whether the current draft actually poses the concerns that we have pointed to. Conversely, there may be other entire and separate areas about which the undersigned will express concern once the draft provisions are known.

All solutions contained in ACTA, whether they be immediately applicable or forward-looking in nature, must avoid the unintended consequences of requiring changes to U.S. laws. USTR, in its important role of seeking a balanced agreement that addresses counterfeiting and piracy, should not be placed in the role of influencing changes, directly or indirectly, to U.S. law.

Thank you for your consideration,

American Association of Law Libraries	Intel Corporation
American Library Association	Internet Commerce Coalition
Association of Research Libraries	Knowledge Ecology International
Center for Democracy & Technology	Medical Library Association
Computer & Communications Industry Association	NetCoalition
Consumer Electronics Association	Public Knowledge
Digital Future Coalition	Special Libraries Association
Entertainment Consumers Association	US Internet Industry Association
Home Recording Rights Coalition	Verizon
Information Technology Association of America	Yahoo! Inc.
IP Justice	



**AMERICAN FREE TRADE ASSOCIATION**  
**(“AFTA”)**

5200 Blue Lagoon Drive, Suite 600

Miami, Florida 33126

Telephone: (305) 267-9200

Fax: (305) 267-5155

[www.aftaus.com](http://www.aftaus.com)

[www.americanfreetradeassociation.com](http://www.americanfreetradeassociation.com)

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September 17, 2008

VIA ELECTRONIC FILING; HARD COPY TO FOLLOW

Ms. Rachel Bae  
Director for Intellectual Property & Innovation  
Office of the U.S. Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, D.C. 20508

**Public Hearing on the Anti-counterfeiting Trade Agreement**  
**Written comments submitted by the American Free Trade Association**

Dear Ms. Bae:

The American Free Trade Association (AFTA) believes that any global effort to eliminate trade in counterfeit goods must be supported by all stakeholders, including rights holders, consumers, consumer groups, trade associations, ISPs, wholesalers, distributors and importers. Only by conspicuously reaching out to all marketplace participants can ACTA effectively target the “bad guys” without inadvertently eliminating or obstructing legitimate international trade to the detriment of consumers across the globe.

AFTA is pleased to offer the following specific discussion and comments in response to the fact sheets and other information provided to date regarding the Anti-counterfeiting Trade Agreement (ACTA):

Background About the American Free Trade Association

The American Free Trade Association was formed more than twenty (20) years ago in order to provide an industry-wide voice for parallel market, or alternative marketplace, traders, distributors and business people. During its entire history, AFTA has remained the single collective voice in Washington and throughout the United States for the parallel market industry.



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The parallel or alternative marketplace provides consumers with genuine brand name products at competitive prices in a wide variety of outlets throughout the United States. Without the competition provided by this industry, U.S. and foreign manufacturers would have no incentive to lower costs and would be able to exclusively control distribution of authentic merchandise, largely to the detriment of middle and lower income U.S. consumers.

AFTA has been and continues to be well-recognized and effective in the debate over parallel market issues. Initially consisting only of members in the fragrance and cosmetic industries, the Association now represents member businesses representative of a broad spectrum of consumer products, including food, electronics and all brand-name FDA-regulated merchandise. AFTA has offered testimony to Congress, filed comments and met with federal agencies, and appeared as *amici curia* in federal and state courts throughout the country, including the two leading Supreme Court cases upholding the legality of the parallel market: the 1988 *Kmart* decision and the 1998 *L'Anza* decision. AFTA has actively defended challenges to laws which permit free competition through the secondary marketplace and it provides its members with information and education regarding the laws governing parallel market trade and related regulations throughout the World.

AFTA and its members consistently support efforts to protect consumers against unsafe or threatening merchandise and carry the message to lawmakers, regulators and the trade that the parallel market can continue to thrive while health, safety and security measures are improved. *However, the Association opposes any initiatives that deny U.S. consumers the benefits of a freely competitive marketplace and unfettered access to unadulterated, safe and genuine consumer goods.*

### Comments Specific to ACTA

1. ACTA, as a multi-national trade agreement, must be premised on a desire to foster and enable legitimate global trade without creation of barriers favoring any one particular market segment over another. As currently presented, ACTA only protects rights holders --- without providing any concomitant protection for the rights of importers, distributors, wholesalers or other legitimate commercial businesses.
2. ACTA should, by its very nomenclature, be a trade agreement focused on stopping global trade in *counterfeit* goods. Specific and unambiguous definitions of “counterfeit” “pirated” and “infringing” goods must be provided within ACTA, clearly exempting from any such definitions those products manufactured under authority from, license by or with the consent of the rights holder, without restriction as to location of manufacture.
3. Distribution of “genuine” products --- those made under authority or license of the rights holder or with its consent --- should not give rise to any of the seizure, forfeiture, damage claims or remedies set forth in the Agreement (although such distribution may be regulated by national laws or regulations in which case such national laws should govern any applicable enforcement action or remedy).
4. ACTA should include a “first sale” provision permitting the rightful owner of a product made under authority, license or consent of the rights holder, without regard to country of



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production, to dispose of that product without further obligation or liability to the initial rights holder.

5. ACTA should restrict disclosure to rights holders of third party trade secrets, or other proprietary business information, only to those cases and in those instances in which that third party has been found definitively to have trafficked in *counterfeit* goods so that the damage caused by such disclosure is clearly offset by the *actual, measurable* damages caused to the rights holder.
6. ACTA should provide for equal securities against unfounded litigation, detention and /or seizure in favor of both the rights holder and the accused party, including storage fees, attorney's fees, court costs, loss of good will and loss of profits.
7. ACTA should definitively state that Customs will not be asked or made to enforce private commercial contractual arrangements at the border as a means of protecting private intellectual property rights holders against lawful third party competition.
8. ACTA should not permit the disclosure to rights holders or other publication of independent third party customs brokers, freight forwarders, warehouse owners, bankers or transporters.
9. ACTA should not encourage or outwardly permit tortuous interference with commercial relations. Unless a rights holder has recorded its registered trademarks or copyrights with Customs and has provided Customs with written, substantive evidence that an incoming shipment contains or is likely to contain *counterfeit* merchandise, ACTA should prohibit rights holders from privately requesting Customs inspections for detentions of specific third party shipments. Any such evidence provided to Customs by a rights holder as the basis for such specific cargo interdiction, must be disclosed to the owner of the arriving goods immediately upon arrival and the owner must be provided a reasonable time to refute such evidence, before being assumed to be guilty of such an offense and/or before the goods are seized or forfeited.
10. In all events other than when an arriving shipment contains CLEARLY counterfeit merchandise, ACTA should insist that importers and distributors be provided with all rights and remedies of due process prior to seizure or other enforcement action and the rights holders should be provided with specific timelines and deadlines for providing Customs and the importer with evidence of the alleged non-genuine nature of the products presented. Any and all information provided to Customs or any other authority by the rights holder attesting to the counterfeit or pirated nature of the subject goods should be fully disclosed to the owner of such merchandise and ample opportunity provided to rebut the veracity of such evidence. Moreover, the confidentiality of such information must be protected so that allegations of infringing activity or counterfeiting activity that are not yet proven do not become known to any other party other than the rights holder in question, Customs and the alleged infringer.



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### Conclusion

AFTA applauds any and all efforts to thwart trafficking in counterfeit goods and looks forward to participating in an ongoing dialog with the USTR to ensure that ACTA appropriately balances the rights of *all* relevant and concerned stakeholders.

AFTA thanks you for this opportunity to participate in this public hearing and invites you to contact the undersigned or Lee Sandler, Esq. ([lsandler@strtrade.com](mailto:lsandler@strtrade.com)) directly at any time to further discuss the issues addressed in these comments.

Sincerely,  
American Free Trade Association

*Lauren V. Perez*

By: \_\_\_\_\_  
Lauren V. Perez

Cc: Lee Sandler, Esq.  
Board of Directors



*Copyright Alliance comments by Executive Director Patrick Ross for the September 22, 2008 public meeting at the U.S. Copyright Office on the proposed Anti-Counterfeiting Trade Agreement.*

“My name is Patrick Ross and I am the Executive Director of the Copyright Alliance. We are a group of individual artists, artist organizations, unions, companies and trade associations that share a conviction that copyright promotes creativity, jobs and growth. Thank you for the opportunity to comment on the U.S. Trade Representative’s efforts toward an Anti-Counterfeiting Trade Agreement.

“At the Copyright Alliance, we know that copyright enforcement is critical to the U.S. economy and to American workers. Consider, for example, the more than 100,000 workers who belong to the International Alliance of Theatrical Stage Employees, better known as IATSE. These “below-the-line” workers – the carpenters, make-up artists, set painters and other laborers you see whizzing by on the screen at the end of a movie – rely on residuals from motion picture sales to fund their pension and health-care plans. They work irregularly, whenever work is available, but IATSE’s management of residuals ensures their health care needs are met and they have nest eggs building for a much-deserved retirement. Piracy and counterfeiting in all forms erodes those residuals and threatens to leave some workers without health care and pensions.

“As Dr. Stephen Siwek noted in a report commissioned by the Institute for Policy Innovation, there are more than 11 million Americans employed in copyright-related jobs, yet the U.S. loses nearly 400,000 jobs every year due to piracy and counterfeiting. More information on the importance of copyright is available on our website at [www.copyrightalliance.org](http://www.copyrightalliance.org).

“This debate has nothing to do with checking iPods at the border. This has to do with vast criminal operations around the globe taking the cultural output of U.S. workers and duplicating it for sale at the expense of our workers and our economy. It is not only appropriate, it is imperative that the nations participating in the Anti-Counterfeiting Trade Agreement proceedings coordinate their law enforcement efforts and find new ways to enforce existing laws on intellectual property infringement.

“Thank you for your efforts to combat copyright infringement and support US workers.”





## **ELECTRONIC FRONTIER FOUNDATION SECOND SUBMISSION TO OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE ON THE PROPOSED ANTI-COUNTERFEITING TRADE AGREEMENT**

The Electronic Frontier Foundation (EFF) appreciates the opportunity to submit the following comments to the Office of the United States Trade Representative (USTR) in response to the Notice of Public Hearing on the Proposed Anti-Counterfeiting Trade Agreement, published in the Federal Register of September 5, 2008 (Volume 73, Number 173, pages 51860-1). These comments supplement the concerns raised in the comments we submitted to the Office of the USTR on March 21, 2008.

### **1. Lack of Transparency and Opportunity for Meaningful Consultation**

EFF remains deeply concerned about the lack of transparency surrounding the contents of the proposed Anti-counterfeiting Trade Agreement (ACTA). While we appreciate the opportunity to provide comments to the USTR, we believe that the effectiveness of this consultation is lessened significantly by the limited information that has been made public on the proposed agreement's content.

EFF is one of over 100 global public interest groups that called upon ACTA negotiators on September 15, 2008 to make public the draft negotiating text of ACTA. We respectfully request that Ambassador Schwab and USTR officials make the draft negotiating text of ACTA and previous background documents available to the public so that we can provide meaningful comments. We hope that the USTR will provide further opportunities for informed public comment once the draft text of ACTA is eventually made public.

In the absence of a draft text or any specific information about ACTA's contents to comment upon, we wish to comment on several matters concerning Internet intermediaries that have been requested by U.S. intellectual property rightsholders in their submissions to the USTR, which raise significant public policy concerns.

### **2. Comments**

Based on submissions to USTR in March 2008 that have been made public on the USTR's website, EFF is concerned that ACTA may require significant changes to several aspects of current U.S. law. We respectfully request that USTR officials address how these matters comport with existing U.S. law in the forthcoming consultation on September 22, 2008.

#### **Monitoring of Internet communications**

We note that the submission of at least one major copyright owner industry group has requested that ISPs and Internet intermediaries be required to adopt "technical measures", including filtering of their networks, and monitoring of customer communications, in order to find evidence of potential copyright infringement.

If adopted in ACTA, these proposals are likely to dramatically alter the Internet's fundamental architecture and require changes to current U.S. law. Section 512 (m) of the U.S. Copyright statute makes it clear that ISPs' ability to avail themselves of the U.S. copyright safe harbors is not conditioned upon ISPs' monitoring their service or affirmatively seeking facts indicating infringing activity, except to the extent consistent with a "standard technical measure" complying with subsection 512(i) of the Copyright statute. That section only requires ISPs to accommodate and not interfere with "standard technical measures" that have been developed by a broad consensus of copyright owners and service providers in an open, fair, voluntary and multi-industry standards process. This does not extend to proprietary copyright filtering technologies and services developed by or for copyright rightsholders in a non-public, and non-transparent process.

These proposals would require ISPs and Internet intermediaries to monitor their networks in an unprecedented manner. This directly threatens citizens' privacy rights and makes it more likely that ISPs will be deemed to have constructive knowledge of online copyright infringement taking place on their networks, thus disqualifying them from the safe harbors that have previously safeguarded their businesses. At the same time, adopting such filtering measures is not likely to be technologically effective because encrypting communications can defeat them. Thus, while mandatory network filtering is not likely to reduce online copyright infringement, it is likely to lead to violation of citizens' privacy rights, particularly if these proposals require the use of Deep Packet Inspection.

### **Termination of Internet Access**

We note that submissions from several intellectual property rightsholder industry groups have called for the ACTA enforcement provisions to clarify the application of national laws to permit use of the so-called "Graduated Response" or "Three Strikes" policy, which would require ISPs to automatically terminate their customers' Internet access upon a repeat allegation of copyright infringement by a copyright owner. The Graduated Response proposal that is currently under discussion in draft French legislation would require ISPs to automatically disconnect Internet users for up to one year. The names of disconnected Internet users would be put on a blacklist and disconnected Internet users would then be precluded from obtaining Internet access from any service provider, for any purpose, for one year.

The adoption of such a policy, whether as part of a direct obligation in a "Legal Framework" or a "Best Practices" private party agreement approach, raises serious due process concerns for citizens, and is vulnerable to misuse and mistake. It is also a disproportionate response to the alleged harm involved. Such automatic disconnection also appears inconsistent with current U.S. law. Section 512(i) of the Copyright statute requires ISPs to adopt and implement a policy of terminating subscribers and account holders who are "repeat infringers", but only "in appropriate circumstances." Adopting the "Graduated Response" would remove the discretion currently available to Internet service providers and redraw the balance currently embodied in section 512 of the Copyright statute.

## **Mandatory disclosure of customer data**

We note that submissions to the USTR from several copyright owner industry groups have requested that ACTA include an obligation on ISPs to disclose to rightsholders information about the identity of ISP subscribers who are allegedly engaged in copyright infringement. An extra-judicial mandatory disclosure obligation raises very substantial privacy and due process concerns for citizens.

It would also require changes to U.S. Copyright law and potentially, various Federal and State privacy laws. U.S. copyright law does not provide an extra-judicial mechanism forcing disclosure of the identity of individuals allegedly engaged in infringing activities. As two Appellate Court decisions have made clear, Section 512(h) allows rightsholders to use subpoenas to ISPs to obtain the identity of alleged infringers who post material on an ISPs' network in certain circumstances. It does not require ISPs to divulge customer information about alleged infringers where the allegedly infringing material does not reside on the ISPs' computer network.<sup>1</sup> However the absence of such a mechanism has not provided any obstacle to U.S. copyright holders' ability to enforce their rights against alleged file-sharers, as evidenced by the more than 30,000 lawsuits brought against individuals since 2003<sup>2</sup>.

Unlike current U.S. law, the European Community introduced a mandatory disclosure obligation in the "right of information" enshrined in Article 8 of the 2004 Intellectual Property Enforcement Directive (2004/48/EC). If ACTA were to provide rightsholders with a right of information similar to that in EU law, it would directly or indirectly lead to significant changes to current U.S. law. To protect citizens, at a minimum, any disclosure obligation must incorporate adequate due process safeguards and be conditioned on a process of judicial review.

Finally, we wish to reiterate that ACTA needs to provide balanced solutions that recognize and respect the fundamental rights of *all* stakeholders in the information economy.

We would be pleased to provide further information on any of the above issues once the draft ACTA text is made available.

Thank you for your consideration.

Gwen Hinze  
International Policy Director  
Email: [gwen@eff.org](mailto:gwen@eff.org)

Eddan Katz  
International Affairs Director  
Email: [eddan@eff.org](mailto:eddan@eff.org)

September 17, 2008

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<sup>1</sup> USC §512(h) provides an expedited subpoena process, but this does not extend to obtaining the identity of alleged file-sharers extra-judicially. See *Recording Industry Association of America, Inc. v. Verizon Internet Services, Inc.*, 351 F.3d 1229 (D.C. Cir. 2003); *Recording Industry Association of America, Inc. v. Charter Communications, Inc.*, 393 F.3d 771 (8<sup>th</sup> Cir. 2005).

<sup>2</sup> EFF Report, *RIAA v. The People: Four Years Later*, available at: <[http://w2.eff.org/IP/P2P/riaa\\_at\\_four.pdf](http://w2.eff.org/IP/P2P/riaa_at_four.pdf)>

# Essential Action

P.O. Box 19405

Washington, D.C. 20036

TELEPHONE: 202-387-8030 • FAX: 202-234-5176 • WWW.ESSENTIALACTION.ORG

September 17, 2008

Office of the U.S. Trade Representative  
600 17th Street, N.W.  
Washington, DC 20508  
E-mail: ACTA@ustr.eop.gov

## **Re: Comments for 09/22/08 Public Meeting on the Anti-Counterfeiting Trade Agreement (ACTA)**

To the U.S. Trade Representative:

Essential Action is a project of Essential Information, a non-profit 501(c)(3) organization based in Washington, D.C. We are concerned generally with protecting the public domain and the information commons. A key organizational area of focus is promoting access to medicines, including in the United States and especially in developing countries. We are concerned as well with preservation and protection of the public domain, and consumer protections in general.

On March 21, 2008, we submitted comments on ACTA focused on its potential impact on access to medicines. Those comments are available here:

<http://www.essentialaction.org/access/index.php?/archives/131-Comments-on-Proposed-Anti-Counterfeiting-Treaty.html#extended>

Because USTR and the other ACTA negotiators have failed to release the ACTA negotiating text, or even relevant background documents or meeting agenda, we have no additional substantive comments to add.

We do want to call attention to, and urge correction of, the illegitimate process by which the ACTA talks are proceeding. There is no conceivable rationale for the cloak-and-dagger aura around the talks, and the refusal to disclose draft texts and relevant background documents.

USTR staff have claimed that it is standard for trade talks to be conducted in secrecy. This claim is mistaken. In fact, negotiating texts are commonly made public in multilateral trade negotiations. Examples of negotiations where texts are or were made public include:

The current Doha Round negotiations at the World Trade Organization;

[http://www.wto.org/english/tratop\\_e/dda\\_e/dda\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/dda_e.htm)

The Free Trade Area of the Americas;

[http://www.ftaa-alca.org/FTAADraft03/Index\\_e.asp](http://www.ftaa-alca.org/FTAADraft03/Index_e.asp)

The Multilateral Agreement on Investment (although initial texts were not made public)

[http://www.oecd.org/document/35/0,3343,en\\_2649\\_33783766\\_1894819\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/35/0,3343,en_2649_33783766_1894819_1_1_1_1,00.html)

Draft text at the World Health Organization, where resolutions are published in advance of consideration and treaty or treaty-like negotiations are handled openly, including this example of follow-on negotiations for the Framework Convention on Tobacco Control:

<http://www.who.int/gb/fctc/>

The World Intellectual Property Organization, including this example of a draft Treaty on the Protection of Broadcasting Organizations:

[http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=57213](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=57213)

It is true that some trade talks, including U.S. bilateral free trade negotiations, are conducted in secrecy. But this is no rationale for secrecy in the ACTA context, for several reasons. First, it is illogical for USTR to point to its own practice of demanding secrecy as a justification for secrecy in this case. Second, even if secrecy were the norm, there is no argument to be made for following a bad, self-imposed policy just because of precedent. Third, if there is any logic to the secrecy in bilateral talks (and we do not believe a good case can be made), it is that negotiators necessarily are discussing benefits and sacrifices for different national industry groups, and if the industry groups were able to respond to every proposal, the negotiation might be bogged down. But this argument has no relevance to the ACTA context. Are negotiators worried that counterfeiters might seek to influence the negotiations?

More than 100 organizations from around the world, along with leading academics and other individuals, recently sent Ambassador Schwab and other ACTA negotiators a letter calling for the draft treaty text to be made public.

The letter emphasizes why openness and disclosure is so important in this case. The letter raises a number of potential substantive concerns about the draft treaty, noting that the public cannot assess the validity of such concerns, because the draft terms remain secret. The letter further states,

Equally, because the treaty text and relevant discussion documents remain secret, treaty negotiators are denied the insights and perspectives that public interest organizations and individuals could offer. Public review of the texts and a meaningful ability to comment would, among other benefits, help prevent unanticipated pernicious problems arising from the treaty. Such unforeseen outcomes are not unlikely, given the complexity of the issues involved.

The lack of transparency in negotiations of an agreement that will affect the fundamental rights of citizens of the world is fundamentally undemocratic. It is made worse by the public perception that lobbyists from the music, film, software, video games, luxury goods and pharmaceutical industries have had ready access to the ACTA text and pre-text discussion documents through long-standing communication channels.

We have attached a copy of the sign-on letter to this comment.

Before any further negotiations occur, we strongly urge you to make public the draft text of the Anti-Counterfeiting Trade Agreement, along with pre-draft discussion papers, the agenda for negotiating sessions and treaty-related meetings, and a list of participants in the negotiations.

Sincerely,

A handwritten signature in black ink that reads "Robert Weissman". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Robert Weissman,  
Director

September 15, 2008

Ambassador Susan C. Schwab  
United States Trade Representative  
600 17th Street, NW  
Washington, DC 20508  
U.S.A  
Fax 202-395-4549

Dear Ambassador Schwab,

**Re: Anti-Counterfeiting Trade Agreement Negotiations**

We are writing to urge the negotiators of the Anti-Counterfeiting Trade Agreement (ACTA) to immediately publish the draft text of the agreement, as well as pre-draft discussion papers (especially for portions for which no draft text yet exists), before continuing further discussions over the treaty. We ask also that you publish the agenda for negotiating sessions and treaty-related meetings in advance of such meetings, and publish a list of participants in the negotiations.

There is no legitimate rationale to keep the treaty text secret, and manifold reasons for immediate publication.

The trade in products intended to deceive consumers as to who made them poses important but complicated public policy issues. An overbroad or poorly drafted international instrument on counterfeiting could have very harmful consequences. Based on news reports and published material from various business associations, we are deeply concerned about matters such as whether the treaty will:

- \* Require Internet Service Providers to monitor all consumers' Internet communications, terminate their customers' Internet connections based on rights holders' repeat allegation of copyright infringement, and divulge the identity of alleged copyright infringers possibly without judicial process, threatening Internet users' due process and privacy rights; and potentially make ISPs liable for their end users' alleged infringing activity;
- \* Interfere with fair use of copyrighted materials;
- \* Criminalize peer-to-peer file sharing;
- \* Interfere with legitimate parallel trade in goods, including the resale of brand-name pharmaceutical products;
- \* Impose liability on manufacturers of active pharmaceutical ingredients (APIs), if those APIs are used to make counterfeits -- a liability system that may make API manufacturers

reluctant to sell to legal generic drug makers, and thereby significantly damage the functioning of the legal generic pharmaceutical industry;

\* Improperly criminalize acts not done for commercial purpose and with no public health consequences; and

\* Improperly divert public resources into enforcement of private rights.

Because the text of the treaty and relevant discussion documents remain secret, the public has no way of assessing whether and to what extent these and related concerns are merited.

Equally, because the treaty text and relevant discussion documents remain secret, treaty negotiators are denied the insights and perspectives that public interest organizations and individuals could offer. Public review of the texts and a meaningful ability to comment would, among other benefits, help prevent unanticipated pernicious problems arising from the treaty. Such unforeseen outcomes are not unlikely, given the complexity of the issues involved.

The lack of transparency in negotiations of an agreement that will affect the fundamental rights of citizens of the world is fundamentally undemocratic. It is made worse by the public perception that lobbyists from the music, film, software, video games, luxury goods and pharmaceutical industries have had ready access to the ACTA text and pre-text discussion documents through long-standing communication channels.

The G8's recent Declaration on the World Economy implored negotiators to conclude ACTA negotiations this year. The speed of the negotiations makes it imperative that relevant text and documents be made available to the citizens of the world immediately.

We look forward to your response, and to working with you toward resolution of our concerns.

Sincerely,

Essential Action  
c/o Robert Weissman, Director  
P.O. Box 19405  
Washington, DC, USA 20036  
Tel +1 (202) 387-8030  
Fax +1 (202) 234-5176

Act Up East Bay  
Oakland, CA, USA

Act Up Paris  
Paris, France



African Underprivileged Children's Foundation (AUCF)  
Lagos, Nigeria

AIDS Access Foundation  
Thailand

AIDS Healthcare Foundation  
Los Angeles, CA, USA

AIDS Treatment News  
Philadelphia, PA, USA

American Medical Student Association  
Reston, VA, USA

AIS Colombia  
Bogotá, Colombia

ASEED Europe  
Amsterdam, The Netherlands

Asia Pacific Network of People Living with HIV/AIDS (APN+)

Australian Digital Alliance  
Kingston, Australia

Australian National University  
Canberra, Australia

Australian Privacy Foundation  
Sydney, Australia

Bharatiya Krishakn Samaj  
New Delhi, India

BUKO Pharma-Kampagne  
Bielefeld, Germany

The Canadian HIV/AIDS Legal Network  
Toronto, Canada

The Canadian Internet Policy & Public Interest  
Clinic (CIPPIC)  
University of Ottawa, Faculty of Law  
Ottawa, Canada

The Canadian Library Association  
Ottawa, Canada

The Canadian Treatment Action Council  
Toronto, Canada

Center for Democracy and Technology  
Washington, DC, USA

Center for Digital Democracy  
Washington, DC, USA

Center for Policy Analysis on Trade and Health (CPATH)  
San Francisco, CA, USA

Centre for Safety & Rational Use of Indian Systems of Medicine  
Ibn Sina Academy of Medieval Medicine & Sciences  
Aligarh, India

The Center for Women's Culture & Theory  
Korea

Chinese Domain Name User Alliance  
Beijing, China

Christian Media Network  
Korea

CHOICE (Australian Consumers Association)  
Marrickville, Australia

Community HIV/AIDS Mobilization Project (CHAMP)  
New York, NY, USA

Congress of South African Trade Unions (COSATU)  
Cape Town, South Africa

Consumentenbond  
The Hague, Netherlands

Consumer Action  
San Francisco, CA, USA

Consumer Federation of America  
Washington, DC, USA

Consumers Union (Publisher of Consumer Reports)  
Yonkers, NY, USA

Consumers Union of Japan (Nihon Shohisha Renmei)  
Tokyo, Japan

La Corporacion Opcion por el Derecho a Ser y el Deber de Hacer, NIT  
Bogotá, Colombia

Corporate Europe Observatory  
Amsterdam, The Netherlands

Cultural Action  
Korea

Diverse Women for Diversity (DWD)  
New Delhi, India

Drug Study Group (DSG)  
Thailand

Ecologist Collective (Colectivo ecologista Jalisco A.C.)  
Guadalajara, México

Egyptian Initiative for Personal Rights  
Cairo, Egypt

Electronic Frontier Foundation  
San Francisco, CA, USA

Electronic Frontiers Australia  
Adelaide, Australia

The Electronic Privacy Information Center (EPIC)  
Washington, DC, USA

European AIDS Treatment Group (EATG)  
Brussels, Belgium

Foreign Policy in Focus  
Institute for Policy Studies  
Washington, DC, USA

Foundation for Integrative AIDS Research (FIAR)  
Brooklyn, NY, USA

Fundación Ifarma  
Bogotá, Colombia

Foundation For Consumers (FFC)  
Thailand

Foundation for Media Alternatives  
Philippines

Foundation for Research in Science Technology & Ecology (RFSTE)  
India

Free Press  
Washington, DC, USA

FTA Watch  
Thailand

Global AIDS Alliance  
Washington, DC USA

Global Health through Education, Training & Service (GHETS)  
Attleborough, MA, USA

Global Trade Watch  
Washington, DC, USA

Gram Bharati Samiti Society for Rural Development  
Amber, India

Gyeonggi NGO Network  
Korea

Health Action International (HAI) – Africa  
Nairobi, Kenya

Health Action International (HAI) – Asia Pacific  
Colombo, Sri Lanka

Health Action International (HAI) – Europe  
Amsterdam, The Netherlands

Health Action International (HAI) – Global  
Amsterdam, The Netherlands

Health Action International – Latin America & Caribbean  
Lima, Perú

Health GAP (Global Access Project)  
Philadelphia, PA, USA

HealthWrights (Workgroup for Peoples Health and Rights)  
Palo Alto, CA, USA

Healthy Skepticism Inc.  
Adelaide, Australia

Home Recording Rights Coalition  
Washington, DC, USA

INEGroup  
Atlanta, GA, USA

Information & Culture Nuri for the Disabled  
Korea

Initiative For Health Equity & Society (IHES)  
New Delhi, India

International Federation of Library Associations and Institutions (IFLA)  
The Hague, Netherlands

International Peoples Health Council (South Asia)

Intersect Worldwide  
India, South Africa and USA

IP Justice  
San Francisco, CA, USA

IPLeft  
Seoul, Korea

Knowledge Ecology International (KEI)  
Geneva, Switzerland, London, UK and Washington, DC, USA

Korean Progressive Network Jinbonet  
Seoul, Korea

Labour, Health and Human Rights Development Centre  
Lagos, Nigeria

Lawyers Collective HIV/AIDS Unit  
India

Medsin-UK

Médecins sans Frontières (Doctors without Borders)  
Campaign for Essential Medicines  
Geneva, Switzerland

Media Access Project  
Washington, DC, USA

La Mesa de ONGs Con Trabajo en VIH/SIDA  
Bogotá, Colombia

Misión Salud  
Bogotá, Colombia

National Consumer Council (NCC)  
London, UK

National Working Group on Patent Laws  
New Delhi, India

Navdanya  
New Delhi, India

Netzwerk Freies Wissen  
Berlin, Germany

Open Rights Group  
UK

Paradise Hospital  
Port Moresby, Papua New Guinea

People's Coalition for Media Reform  
Seoul, Korea

Phasuma Consultancy & Training  
Amsterdam, The Netherlands

Positive Malaysian Treatment Access & Advocacy Group (MTAAG+).  
Malaysia

Privacy Activism  
USA

Privacy Rights Clearinghouse  
San Diego, CA, USA

Public Knowledge  
Washington, DC, USA

Rural Reconstruction Nepal (RRN)  
Kathmandu, Nepal

Social movement to combat private media ownership and enhance public media  
Korea

Student Global AIDS Campaign  
USA

Swisslinux.org  
Mayens-de-Chamoson, Switzerland

The Transparency and Accountability Network  
New York, NY, USA

Third World Network  
Malaysia

Universities Allied for Essential Medicines (UAEM)  
UK, USA

U.S. Public Interest Research Group (PIRG)  
Washington, DC, USA

Women & Health ! (WAH ! )  
India

**\*\*Individuals\*\***

Jamie Acosta, PhD, LCSW, CHES  
Miami, FL, USA

Mr. Jose L. Aguilar  
Justice and Peace Commission  
Mexico City, Mexico

Beate Amler  
Trade Union Researcher  
Berlin, Germany

Professor Brook K. Baker  
Northeastern University School of Law  
Program on Human Rights and the Global Economy  
Boston, MA, USA

Gladys Baldew  
Public Health Consultant  
Netherlands  
Laurel Baldwin-Ragaven, MD  
Asylum Hill Family Practice Center  
Hartford, CT, USA

Murtala Bello  
Pharmacist, Ministry of Health  
Sokoto, Nigeria

Jennifer Bruenger  
Reference Librarian & Education Program Coordinator  
Linda Hall Library of Science, Engineering & Technology  
Mission, KS, USA

Erin Burns  
Former National Organizer, Student Global AIDS Campaign (SGAC)  
Jacksonville, FL, USA

Sylvia Caras, PhD  
Santa Cruz, CA, USA

Ramon Certeza  
Director for Education, Research and Industrial Relations  
Confederation of Labor and Allied Social Services (CLASS)  
Manila, Philippines

Sae-Rom Chae  
University of Illinois at Chicago College of Medicine  
Chicago, IL, USA



Jeff Chester  
Executive Director  
Center for Digital Democracy  
Washington, DC, USA

Don Christie  
President, New Zealand Open Source Society

Mark R. Costa  
Clay, NY, USA

Chris Curry  
MD/PhD Candidate, Loyola University Chicago  
Forest Park, IL, USA

Dr Gopal Dabade  
President, Drug Action Forum - Karnataka  
Dharwad, India

Anke Dahrendorf, LL.M.  
Junior Researcher, International and European Law  
University of Maastricht, The Netherlands

Daniel de Beer, PhD  
Lecturer in Law  
Université Saint Louis  
Brussels, Belgium

Dr. Gilles de Wildt  
Jiggins Lane Medical Centre  
Birmingham, UK

John Dillon  
Program Coordinator  
KAIROS: Canadian Ecumenical Justice Initiatives  
Toronto, Canada

Dr. David Egilman, MD, MPH  
Clinical Associate Professor  
Brown University  
Attleboro, MA, USA

Professor Peter Evans  
Department of Sociology  
University of California, Berkeley, USA

Thomas Alured Faunce  
Assoc. Professor, College of Law  
Assoc. Professor, Medical School, College of Medicine and Health Sciences  
Australian National University  
Canberra, Australia

Professor Brian Fitzgerald  
Professor of Intellectual Property and Innovation  
Law Faculty  
Queensland University of Technology  
Brisbane, Australia

Professor Sean Flynn  
Associate Director  
Program on Information Justice and Intellectual Property  
American University Washington College of Law  
Washington DC, USA

Maurice J. Freedman  
Past President, American Library Association  
Mount Kisco, NY, USA

Michael Geist  
Canada Research Chair in Internet and e-commerce Law  
University of Ottawa, Canada

Jonathan Walter Giehl  
Ocala, Florida, USA

Johnny Jesus Guaylupo  
PLWHA  
Brooklyn, NY, USA

Dr. Chandra M. Gulhati  
Editor, Monthly Index of Medical Specialities (MIMS)  
New Delhi, India

Mark W. Heffington, MD  
Cashiers, NC, USA

Matthew Herder  
Visiting Professor of Law  
Loyola University Chicago  
Chicago, IL, USA

Maggie Huff-Rousselle  
Chair, Pharmaceuticals Interest Working Group  
American Public Health Association  
Boston, MA, USA

Doug Ireland,  
Journalist  
New York, NY, USA

Professor S. Jayasundar, PhD  
Pharmacology  
Chennai, India

Dr. K.R. John  
Dept. of Community Health  
Christian Medical College  
Vellore, India

Puja Kapai  
Assistant Professor  
Faculty of Law  
The University of Hong Kong

Alison Katz  
People's Health Movement and Centre Europe Tiers Monde  
Geneva, Switzerland

Niyada Kiatying-Angsulee, Ph.D.  
Chair, Social Pharmacy Research Unit (SPR)  
Faculty of Pharmaceutical Sciences  
Chulalongkorn University  
Bangkok, Thailand

Professor Heinz Klug  
University of Wisconsin Law School  
Madison, WI, USA  
Senior Honorary Research Associate, University of the Witwatersrand  
Johannesburg, South Africa

Adam M. Kost  
University of Illinois at Chicago College of Medicine  
Chicago, IL, USA

Professor Joel Lexchin, MD  
York University  
Toronto, Canada

Jiraporn Limpananont, PhD  
Social Pharmacy Research Unit  
Faculty of Pharmaceutical Sciences  
Chulalongkorn University  
Bangkok, Thailand

Nicholas J. Lusiani  
International Network for Economic, Social and Cultural Rights  
ESCR-Net / Red-DESC / Réseau-DESC  
New York, NY, USA

Hamish MacEwan  
Open ICT Consultant  
Wellington, New Zealand

Dr. Duncan Matthews  
Reader in Intellectual Property Law  
School of Law  
Queen Mary, University of London  
United Kingdom

Eduardo Mayorga  
ALAFAR (Ecuadorian Generic Pharmaceutical Association)  
Quito, Ecuador

Dr. Jeni McAughey  
Whitehead, Northern Ireland

Prof. David Menkes  
Waikato Clinical School  
University of Auckland  
Hamilton, New Zealand

Mr. T. Mikindo, B.Pharms, MSc  
Pharmacist  
Ifakara Health Institute  
Dar Es Salaam, Tanzania

Adrienne Mishkin  
Tulane University School of Medicine and School of Public Health and  
Tropical Medicine MD/MPH candidate, Class of 2009  
New Orleans, LA, USA

Isameldin M.A. Mustafa, B.Pharm  
The Director of Pharmaceutical Services Department  
National Health Insurance Fund  
Khartoum, Sudan

Ibraheem Naeem  
Medical student  
Lahore, Pakistan

Dr. Pat Neuwelt  
Public Health Physician and Professor  
Mt. Albert, Auckland, New Zealand

Ahti Ojala  
Espoo, Finland

Frank Ottey  
Media, PA, USA

Kevin Outtersen  
Associate Professor of Law & Director of the Health Law Program  
Boston University School of Law  
Boston, MA, USA

Dr. Carol Parlow  
Oakville, Canada

Dr. Peter Parry  
Consultant Child & Adolescent Psychiatrist  
Senior Lecturer, Flinders University  
Oaklands Pk, Australia

Ngufor Forkum Polycarp, BA, MEd, MA, DEA, Dip-ENSP, LLM  
Human Rights Training Unit  
Police Training School  
Yaounde, Cameroon

Joana Ramos, MSW  
Cancer Resources & Advocacy  
Seattle, WA, USA

Nicolas Rasmussen, MPhil, PhD, MPH  
Associate Professor  
National Drug and Alcohol Research Centre  
University of New South Wales  
Sydney, Australia

Dr. Amitrajit Saha  
New Delhi, India

A. Sankar  
Executive Director  
EMPOWER  
Tuticorin, India

Dr. Canan Sargin, MD  
UNICEF  
Ankara, Turkey

Dr. Gordon Schiff  
Associate Director, Center for Patient Safety Research and Practice  
Division of General Internal Medicine, Brigham and Women's Hospital  
Boston, MA, USA

Claudio Schuftan, MD  
People's Health Movement Vietnam

Professor Susan K. Sell  
George Washington University  
Washington, DC USA

Melissa Serrano  
Researcher  
University of the Philippines  
Manila, Philippines

Aaron Shaw  
Berkman Center for Internet and Society  
Harvard University  
Cambridge, Massachusetts, USA

Dr. Mira Shiva, MD  
Coordinator, Initiative for Health, Equity and Society  
Founding Member, People's Health Movement  
New Delhi, India

Dr. Vandana Shiva  
Navdanya  
New Delhi, India

Beverley Snell  
Essential Medicines and Community Health Specialist  
Centre for International Health  
Macfarlane Burnet Institute for Medical Research and Public Health  
Melbourne, Australia

Wilma Teran  
Pharmaceutical Biochemist, Public Health  
Platform on Access to Medicines and Intellectual Property  
La Paz, Bolivia

Clinton Henry Trout, MPH  
Candidate for Doctor of Public Health  
Boston University, USA

Karolina Tuomisto  
Medical Student  
Helsinki, Finland

Mike Waghorne  
Retired  
Former Assistant General Secretary  
Public Services International  
Esquibien, France

Richard Walther  
Alexandria, Virginia, USA

Professor Kimberlee Weatherall  
TC Beirne School of Law  
The University of Queensland  
Brisbane, Australia

Patricia Whelehan, PhD  
Professor, Anthropology  
State University of New York-Potsdam  
Potsdam, NY, USA

Edlira Xhafa  
Researcher, Education International  
Nyon, Switzerland

Julie M. Zito, PhD  
Professor, Pharmacoepidemiology  
University of Maryland, Baltimore  
Baltimore, MD, USA

**BEFORE THE  
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE  
Washington, D.C.**

**ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)**

**Written Comments**

**on behalf of**

**G.G. Marck & Associates, Inc.**

**September 17, 2008**

**Edmund Maciorowski  
Edmund Maciorowski, P.C.  
33 Bloomfield Hills Parkway, Ste. 250  
Bloomfield Hills, MI 48304**

**Attorney for:**

**G.G. Marck & Associates, Inc.  
300 Phillips Avenue  
Toledo, OH 43612**



## **I. COMPANY HISTORY AND EXPERIENCE AS A REGIONAL TRADER**

On behalf of our client, G.G. MARCK & ASSOCIATES, INC. (“Marck”) we make this submission in furtherance of its previous brief, as filed on March 20, 2008, before the Office of the United States’ Trade Representative (“USTR”), and herein attached as EXHIBIT 1. Marck offers the following comments for consideration and integration into the ongoing negotiations of the Anti-Counterfeiting Trade Agreement (“ACTA”) in order to amplify the stark impact the flood of counterfeit Chinese ceramic drink and tableware exerts on the ceramic market.

## **II. RECOMMENDATIONS FOR CONTINUING NEGOTIATIONS FOR STRONG ENFORCEMENT AGAINST CERAMIC COUNTERFEITING**

Despite extensive efforts to prevent their importation into the domestic market, Marck has been directly aggrieved by the prolonged importation of counterfeit ceramic goods. These efforts include continuous availment of domestic and international court actions and agency procedures, and despite minor victories, certain competitors continue to use China as a platform for aggressive trademark infringement of ceramic drink and tableware that is subsequently imported into the United States.

The focus of discussions about counterfeiting in both the media and other government venues tends to be about pirated movies, software, pharmaceuticals, or counterfeit apparel and accessories. However, merchandise that is not as high-profile as these are targeted just as heavily by counterfeiters who wrongfully profit from the industry goodwill and quality reputation justly earned by smaller trade community members. Efforts undertaken by Marck under the current

international anti-counterfeiting regime have proven ineffectual and difficult to enforce, and so counterfeiters continue to benefit from Marck's years of experience and marketing efforts. Marck, as a manufacturer and importer of fine porcelain and ceramic drink and tableware, is one company that is routinely targeted by counterfeiters who seek to sell low quality products – that are identical in appearance – under hijacked, internationally recognized trademarks, through deceitful and fraudulent methods.<sup>1</sup> These methods include the blatant copying of ceramic patterns and molds and shipment of goods under stolen trade names; in blatant and unlawful acts of theft these products are marketed and shipped under protected trademarks owned by Marck and recorded with U.S. Customs.

It is needless to restate here in great detail the critical problem that this counterfeiting creates, causing lost tax revenue, careers, business, and in some cases threatening both health and safety while at the same time funding organized crime.<sup>2</sup> These problems are documented, well-known, and have been the focus of comments previously received by the U.S. Trade Representative in connection with this treaty. It is Marck's belief that ACTA must make aggressive efforts to provide a suitable and proportional international response to the economic, health, and safety dangers created as a result of rampant counterfeiting.

Marck's hope and expectation is that ACTA is successful where previous efforts have failed. To that end, Marck endeavors to help achieve that success by offering the following

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<sup>1</sup> Often these methods not only involve deceit and fraud by their marketing under these trademarks, but unfortunately many of these same goods are manufactured through the use of forced prison labor provided by Chinese political and social prisoners. This activity is seemingly in direct violation of 15 USC § 1124, 19 USC § 1307, and 19 USC § 1526.

<sup>2</sup> Office of the United States Trade Representative, *Trade Facts: Anti-Counterfeiting Trade Agreement (ACTA)*, August 4, 2008.

recommendations gained through its over twenty years of operations and its attempts to encourage and strengthen enforcement efforts in an industry increasingly plagued by counterfeiting,

**A. The ACTA should unify and harmonize existing efforts at the member-government level for each signatory and build on existing international enforcement measures.**

Marck recommends that a primary objective and result of ACTA must be the consolidation and harmonization of existing anti-counterfeiting institutions' efforts instead of merely an additional institution or mechanism that stakeholders must contact when attempting to stop counterfeiters. The ACTA must harmonize the competing efforts in the international community to defeat the ever-expanding number of counterfeiters that governments and stakeholders face when trying to level the international playing field. A review of current enforcement and negotiating efforts reveal that there are as many institutions committed to anti-counterfeiting activities as there are sources of counterfeit goods. This creates an over-expansive enforcement scheme that is endemically shallow and seemingly powerless to help. Marck is of the view that using the ACTA to redirect resources currently expended into these existing efforts would be an aggressive and proactive means of attaining an acceptable level of enforcement. Implementing the ACTA as truly a "new kind of agreement" by bridging "the gap between laws on the books and strong enforcement on the ground" is a sorely needed effort in a field of enforcement that is populous but too often rendered anemic.<sup>3</sup> Therefore, ACTA should require that all member governments focus their anti-counterfeiting efforts into the ACTA and away from existing structures.

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<sup>3</sup> Office of the United States Trade Representative, *Trade Facts: Anti-Counterfeiting Trade Agreement (ACTA)*, August 4, 2008.

To achieve aggressive enforcement, the ACTA should incorporate a heightened standard of enforcement based on the framework established by the World Trade Organizations' TRIPS Agreement. The ACTA should apply the same anti-counterfeiting laws and penalties to companies who utilize fraudulently produced and/or obtained quality-assurance seals (such as ISO compliance emblems) and certification indicators for factories (such as China Commodity Inspection Bureau certifications), which work to ensure internationally accepted health and safety standards, as well as compliance with the domestic laws of the destination countries. Deceptive practices such as these are routinely used by Marck's competitors to flout the laws on the books and mislead inspectors and consumers into believing that their products are produced in accord with international standards.

To work against these counterfeit or misleading markings, a basic inspection of merchandise entering or leaving each member country should include procedures to verify the authenticity of any such marking and ensure that the source of the goods corresponds to the authorized user of the CCIB or ISO standard certification. In addition to these problems, containers of counterfeit goods are often marked with registered and recorded trademarks. In the ceramic industries, these trademarks are often mistaken for product numbers and not trademarks; therefore, enforcement for packing and shipping containers bearing trademarks should equally severe in its penalties as counterfeit goods themselves.

Accordingly, counterfeiting is not a problem limited to the latest movie releases or the latest popular fashion labels. The emphasis to those industries is rightly given. However,

maintaining a narrow focus on high-profile counterfeit goods only encourages counterfeiters to target low-profile goods which are not currently subject to the same heightened scrutiny. Because counterfeiters sense the opportunity to make a buck and avoid detection, this results in an increased flow of low-profile counterfeit goods. While large corporations have far greater opportunities to staunch the flow of counterfeit goods, smaller corporations, often those depended on by local communities, are left with what seem like only vague promises of brighter days. Therefore, enforcement measures need to be stepped up in all areas of imported products.

Given the variety of goods at issue, a port inspector trained to recognize counterfeit copies of computer software would have difficulty identifying counterfeit ceramic drinkware and tableware. To begin righting this wrong, counterfeit merchandise should be categorized by ACTA members according to product type. This would allow specially trained inspectors to more readily recognize and remove counterfeit goods from the supply chain. Currently, many inspectors are not aware that there is a trade in counterfeit ceramics because of the focus into high-profile areas of counterfeiting.

Therefore, establishing methods of categorizing merchandise and assigning specially trained teams to remove counterfeit goods from the supply chain before they reach consumers should be part of the final version of the ACTA enforcement procedures. This border enforcement measure would be easily integrated into existing procedures providing for the inspection of goods. After entry, audits using information from a central clearinghouse, as

proposed below, would facilitate the recognition of counterfeit goods by referencing a database of authorized users of the trademarks.<sup>4</sup>

In addition to acting as a means of consolidating existing efforts, the ACTA should require that signatories establish a high level position within their government who would serve as the Chief Counterfeiting Prevention Officer. The person in this position would coordinate domestic and international enforcement and work to strengthen the anti-counterfeiting provisions of the ACTA. This kind of commitment by all signatories of the ACTA to unify their anti-counterfeiting efforts under the aegis of the ACTA is the logical result of the trend toward international harmonization of customs issues. Such a unitary institution for redressing counterfeiting, founded on the principles of open cooperation and communication, would dramatically increase accountability, efficiency, and enforcement. This gives third parties, whether stakeholders or governments, a clear means of raising concerns, sharing knowledge, and achieving compliance.

**B. Increased cooperation and communication via an international electronic clearinghouse accessible to member-governments and governments acceding to the ACTA.**

Another keystone to achieving successful harmonization of anti-counterfeiting efforts is to increase the information flow through direct and open channels of communication between stakeholders and member governments. The current negotiations planned on international cooperation are rightly premised on both capacity-building and increasing the technical

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<sup>4</sup> U.S. Immigration and Customs Enforcement, *Fact Sheet: Strategy Targeting Organized Piracy (STOP!)*, 2004.

assistance available to enforcement.<sup>5</sup> Increased communication will increase cooperation among member governments and between those governments and their business communities. In keeping with the recommendations given above, the creation of a harmonized method of documenting and sharing information must be implemented to further those goals. A harmonized system should allow registered stakeholders to track and report incidences of counterfeiting. If member governments participated in a system like this that allowed input from stakeholders, it would increase the success of anti-counterfeiting investigations and prosecutions. Stakeholders have the best operational intelligence and technical assistance to combat suspected counterfeiters and their methods of circumventing detection.

In order to accomplish this, the ACTA should provide that members participate in ACTA-created centralized electronic clearinghouse. This system would assist the recognition of counterfeit material by providing access to the responsible enforcement agencies in each ACTA member country. Procedures for detecting counterfeit merchandise could be added into the database by stakeholders to better enhance enforcement measures by members of ACTA. In this way, these stakeholders would have an ongoing means of keeping the proper agencies informed of suspected counterfeiters.

This information clearinghouse would be accessed through the internet to provide the best means of sharing information between member governments and the agencies responsible for enforcing their customs and trademark laws. This direct pipeline of communication would help in the fight against counterfeiters by giving member nations the capability of recognizing

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<sup>5</sup> Office of the United States Trade Representative, *Trade Facts: Anti-Counterfeiting Trade Agreement (ACTA)*, August 4, 2008.

trends in counterfeit practices and sources, and providing instantaneous information exchange between members.

This system would provide increased identification of counterfeit activities in certain goods or in certain regions, akin to the USTR's "priority watch" criteria.<sup>6</sup> This data could be provided and manipulated in the same way the Interactive Tariff and Trade Dataweb is currently provided by the U.S. International Trade Commission.<sup>7</sup> Making this data available for statistical calculations to governments and to stakeholders would help fight against counterfeit goods by developing new procedures, technologies, and analytical techniques to counter recognized trends and practices. It would also allow for risk-based assessments to create more efficient enforcement procedures.

In addition to the development of these procedures, the Strategy Targeting Organized Piracy program (STOP) should be integrated into this system by adding a database of certifications of authenticity from manufacturers in suspect countries and maintaining a database of known counterfeiters.<sup>8</sup> Providing system access to governments who are not yet members of the ACTA would significantly help them improve compliance with the provisions of the ACTA by giving them the same access to information on potential sources of counterfeiting. This would allow potential members to increase their own domestic enforcement efforts, improve the effectiveness of domestic investigations, and better prepare them for membership in ACTA.

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<sup>6</sup> U.S. Immigration and Customs Enforcement, *Fact Sheet: Strategy Targeting Organized Piracy (STOP!)*, 2004.

<sup>7</sup> Accessible at <http://dataweb.usitc.gov>.

<sup>8</sup> Id.



This system would also provide a single visible means of redress which stakeholders in the business community could supply with their practical operational information to help detect counterfeit goods; this, in turn, would provide customs officials with the best and most current means of combating counterfeit trade. The creation of such a system would reduce the need for resource-heavy advisory groups which are now currently proposed for ACTA negotiations, while still imparting specialized expertise from the same government and industry sources regardless.<sup>9</sup> Most importantly, this system would put the information directly into the hands of those charged with enforcement and it would provide superior operational intelligence for any joint enforcement actions contemplated by the ACTA.

### **III. CONCLUSION**

These recommendations would be powerful additions to the ACTA framework and would strengthen topics still being negotiated. Making the ACTA a capstone that organizes the successful elements of various existing institutions and providing a framework for effective enforcement all under one harmonized mechanism is a pragmatic solution to current problems. In this way, this proposal allows for unrestrained flexibility in implementing various methods of detecting and stopping counterfeit goods while simultaneously establishing an accountable and highly visible framework for implementing successful, as well as theoretical, means of counterfeit detection. It would give a clear contact in each member-government to which all anti-counterfeiting resources may be directed. It would provide industry members with a single institution to which they can bring their knowledge. It would give nations that currently flout

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<sup>9</sup> Office of the United States Trade Representative, *Trade Facts: Anti-Counterfeiting Trade Agreement (ACTA)*, August 4, 2008.

anti-counterfeiting laws a single institution with which to negotiate meaningful reforms. Likewise, a single institution can hold those governments accountable for their non-compliance and actively discourage such behavior with better operational intelligence. This will allow for greater cooperation among nations, among governments and their business communities, and greater enforcement of existing laws. Marck stands ready to provide any additional information which might be useful to support these important negotiations.

# **EXHIBIT 1**

**BEFORE THE  
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE  
Washington, D.C.**

**ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA)**

**Written Comments**

**on behalf of**

**G.G. Marck & Associates, Inc.**

**March 20, 2008**

**Edmund Maciorowski  
Edmund Maciorowski, P.C.  
33 Bloomfield Hills Parkway, Ste. 250  
Bloomfield Hills, MI 48304**

**Attorney for:**

**G.G. Marck & Associates, Inc.  
300 Phillips Avenue  
Toledo, OH 43612**

## I. BACKGROUND

G.G. Marck & Associates, Inc. (“Marck”) was founded in 1986 to provide products to the decorating industry. Marck’s headquarters is located in Toledo, Ohio, and has an additional office in Mira Loma, California. Marck began importing ceramic mugs and has expanded its product offerings over time. With over 30 established years in the decorating industry, Marck is a leading wholesaler of ceramic, glass, stainless steel and plastic products to the decorating industry in the United States.

The decorating industry, comprising manufacturers, decorating, marketing professionals and design and industry suppliers, relies on Marck’s experience as a resource for quality products in the North American market. More recently, Marck has become an exclusive distributor of glass and crystal ware for prominent companies such as ARC International, O-I Cristar and Anchor Hocking.<sup>10</sup> With sourcing and market access throughout the Asia region and beyond, Marck imports products from China, Columbia, France, India, Taiwan, and Thailand. In 2004, Marck acquired an ownership interest with the Shandong Zibo Niceton-Marck Huaguang Ceramic Factory, to be Marck’s primary supplier. The factory is China’s largest manufacturer of premium quality stoneware ceramic products and has the capacity to produce in excess of 140 million ceramic pieces annually.

As a leading supplier of ceramic articles to retail markets, Marck is aware of certain domestic competitors which are infringing Marck’s protected trademarks. Likewise, Marck is aware that ceramic factories in China are producing and exporting these infringing articles to the

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<sup>10</sup> Additional information on Marck is available at <http://www.marckassoc.com>

United States. Through its industry resources, Marck has identified Shandong Zibo Maolong Ceramics Co., Ltd. in Zibo City, Shandong Province, China as a significant source of the prison made goods being exported into the United States.<sup>11</sup> This factory produces ceramic articles that share common characteristics with Marck's products. The infringing articles have the same physical characteristics and bear the identical word marks as the articles protected under Marck's U.S. trademarks. Additionally, the products of this factory then enter the same market in the United States, which includes consumers, retail outlets, concession sales, promotional product distributors, food service industry providers, etc. This activity is seemingly in direct violation of 15 USC 1124, as well as 19 USC 1526.<sup>12</sup>

In response to The United States Trade Representatives Request for written comments relative to the proposed Anti-Counterfeiting Trade Agreement (ACTA) published in the Federal Register on February 15, 2008, Marck is providing this information for your consideration in adopting the provisions of the agreement.<sup>13</sup> Marck has felt the impact as a wholesaler of imported ceramic mug and dinnerware to the decorator industry in the domestic market. Competitors importing and selling similar, albeit inferior, counterfeit ceramic articles domestically have a competitive advantage despite the import laws prohibiting such goods.

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<sup>11</sup> Marck has additionally identified this same factory as a prison labor factory in its testimony before the International Trade Commission's Investigation 331-492, "China: Government Policies Affecting U.S. Trade in Selected Sectors."

<sup>12</sup> 15 USC 1124 states "[N]o article of imported merchandise which shall copy or simulate the name of any domestic manufacturer...shall be admitted to entry at any customhouse of the United States...." Likewise, 19 USC 1526 requires that "[a]ny such merchandise bearing a counterfeit mark...imported into the United States in violation of section 42 of the Lanham Act ... (15 USC 1124), shall be seized and , in the absence of the written consent of the trademark owner, forfeited for violations of the Customs Laws." 19 USC 1526 (d).

<sup>13</sup> 73 FR 8910, February 15, 2008

China stands as the world's largest exporter of counterfeit goods. Moreover, exports of counterfeit product from China are expected to increase.<sup>14</sup> U.S. enforcement of IPR law has demonstrated that over 80 percent of IPR seizures are exports from China.<sup>15</sup> Despite U.S.-China bilateral trade negotiations and strong Customs enforcement efforts, the staggering influx of counterfeit goods from China into the domestic market, amongst other condemned international trade practices, continues to cause harm to U.S. economic interests. Based on the trends reflecting the likely increase of counterfeit goods from China, there is reason to believe that counterfeit exporters view global markets as potential revenue streams waiting to be exploited. Accordingly, Marck is of the view that strengthening the global enforcement of trademark prohibitions through the ACTA is a meaningful progression in continuing efforts to effectively remedy IPR violations worldwide through cooperative multilateral enforcement of these ongoing illegal trade practices.

## **II. COUNTERFEIT EXPORTS ARE AN INTEGRAL PRACTICE OF CHINA'S GLOBAL TRADE OBJECTIVES**

Marck concurs with the ongoing view that China's global economic strategy is to "maintain access to the open multilateral trading system on which its rapid export driven growth now depends."<sup>16</sup> The objectives appear; however, to be fostered by a variety of unfair trade practices. China is projecting itself as a "more attentive and profitable alternative to the U.S." both regionally and globally because of the U.S. preoccupation with terrorism and security

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<sup>14</sup> *Intellectual Property Rights Issues and Imported Counterfeit Goods Hearing before the U.S.-China Economic and Security Review Commission* 109<sup>th</sup> Cong. June 7-8, 2006, at p.6

<sup>15</sup> <http://cbp.gov>, *U.S. Customs and Border Protection Office of International Trade, 2007 Top Trading Partners for IPR Seizures*, November, 2007.

<sup>16</sup> *China's Growth as a Regional Economic Power: Impacts and Implications*, December 4, 2003, at page iii

relations.<sup>17</sup> It would appear that China's global approach is intended to further its national policy of rapid global trade dominance through its export driven growth.

Counterfeit exports from China fit into this growth objective of the Chinese government. "While most Chinese local governments do not appear to have the will to enforce IPR, the central government's resolve to address the issue is not much stronger."<sup>18</sup> The U.S. administration's bilateral negotiations with the Chinese government have been consistently premised on the strong belief that "China needs to do a much better job of protecting and enforcing IPR."<sup>19</sup> The reluctance to effectively enforce IPR by the Chinese government is primarily economic. Where counterfeit goods have saturated local Chinese markets, some in the central government see enforcement as damaging to local economies. Moreover, these Chinese government parties likewise take the view that trade in counterfeit goods serve a viable means of fostering economic development.<sup>20</sup> Thus, despite the aggressive negotiation efforts of the United States with the Chinese government, an agreement of worldwide partnership on global enforcement cooperation and strategies would increase the prospects of reducing the counterfeit trade through heightened enforcement of offending articles being distributed by China into the world market.<sup>21</sup>

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<sup>17</sup> *Id.*

<sup>18</sup> *Intellectual Property Rights Issues and Imported Counterfeit Goods Hearing before the U.S.-China Economic and Security Review Commission* 109<sup>th</sup> Cong. June 7-8, 2006, at p.4

<sup>19</sup> *Office of the United States Trade Representative Trade Facts, USTR's Mission to Protect U.S. Intellectual Property Rights*, November, 2007

<sup>20</sup> *Id.*

<sup>21</sup> It is noteworthy that the timing of a global commitment to IPR enforcement is opportune in view of the recently signed U.S.-China Memorandum of Cooperation on intellectual property rights.



### **III. EFFECT OF CHINA COUNTERFEIT IMPORTS ON MARCK'S BUSINESS AND MARKET POSITION**

The influx of counterfeit goods into the United States from China is a continuing and damaging reality in the domestic market place. The effect on Marck's business in their sales to the United States market arises from the overall volume of counterfeit imports of ceramic articles that flood the market. The impact is felt financially in millions of dollars of lost sales; the costs to routinely pursue litigation against competitors who purchase counterfeit product; and, the cost of extensive efforts to work with relevant agencies responsible for the enforcement of IPR statutes and regulations prohibiting entry of such articles.

When domestic companies follow the laws of the United States, they are immediately placed at a competitive disadvantage. In the absence of adequate measures to ensure a level playing field, agencies responsible for enforcement appear to have inadequate resources, acting alone, for protecting the domestic market. Consequently, the flood of counterfeit goods into the domestic market provide competitors purchasing counterfeit articles a significant competitive advantage over Marck. The advantage in buying cheap counterfeit product permits these counterfeit articles to displace products that are otherwise protected under trademark law, resulting in decreased sales.

Accordingly, Marck asserts that enhancing agency remedies will assist the effective enforcement of existing laws and regulations by prohibiting the entry of counterfeit products into the domestic market. In its continuing efforts to make direct and extensive efforts to bring these violative practices to the attention of appropriate agencies for investigation and enforcement of current laws, Marck is of the view that the ACTA provides the opportunity for a unified global

participation which will enhance domestic agency remedies by providing a more effective enforcement of IPR matters where countries choose to evade compliant participation.

In line with the USTR's goal of establishing a common standard for IPR enforcement to combat global infringements through international cooperation, strengthening the framework of enforcement practices, and the strengthening of relevant IPR enforcement measures, Marck considers the global implementation of the initiatives developed under the Strategy Targeting Organized Piracy (STOP!) also relevant in a global application of IPR enforcement.<sup>22</sup> Accordingly, Marck is of the view that global infringement enforcement would be significantly enhanced by:

1. Establishing an international offending country list patterned on the USTR's "Priority Watch" list criteria;<sup>23</sup>
2. Certifications of authenticity from the manufacturers of all items produced in countries identified on the Priority Watch List imported to participating countries, verifying that the items being exported are not counterfeit;<sup>24</sup>

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<sup>22</sup> *Bush Administration Strategy for Targeting Organized Piracy*, April 2006

<sup>23</sup> *Intellectual Property Rights Issues and Imported Counterfeit Goods Hearing before the U.S.-China Economic and Security Review Commission* 109<sup>th</sup> Cong. June 7-8, 2006, at p.6.

<sup>24</sup> *Id.*

3. Implementing New procedures and risk assessments that will allow the Bureau of Customs and Border Protections (CBP) to better identify firms routinely trafficking in fake goods;<sup>25</sup>
4. Conducting Post-entry product audits to verify that an importer is authorized to use trademarks and copyrights;<sup>26</sup>
5. Empowering U.S. District Courts to issue injunctions against pirated and counterfeit goods entering any U.S. port;<sup>27</sup>
6. Department of Homeland Security (DHS) and CBP application of new technologies and new analytical techniques to combat counterfeiting in combination with identification of high-risk companies and shipping techniques, and;<sup>28</sup>
7. Conduct Joint enforcement actions, and actively share information on the movement of suspected fake products.<sup>29</sup>

Marck is of the view that these recommendations and initiatives remain a viable approach to what has otherwise become a frustration of the import laws with regard to China's counterfeit goods flooding U.S. and global markets.

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<sup>25</sup> *U.S. Immigration and Customs Enforcement Fact Sheet, Strategy Targeting Organized Piracy (STOP!)*, 2004

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

#### IV. CONCLUSION

Chinese exports of counterfeit goods flooding into the domestic market adversely affects G.G. Marck & Associates, Inc. because prohibitions against the entry and importation of these goods under U.S. law are routinely skirted. This has had the obvious effect of giving the offending companies the ability to sell products cheaper than their competitors and to produce a higher margin of profit. These companies are doubtlessly encouraged by the seeming lack of resolve of industry and government to take effective preventative measures to change the status quo. Marck appreciates the opportunity to present these materials in furtherance of its continuing efforts to address the continuing harm from these trade realities.

The Government of China has a long history of effectively encouraging production of counterfeit products in its country. These policies of the Chinese government accomplish two goals. First, they strengthen their global position through profiteering from economies driven by counterfeit goods manufacturing and distribution, and second, they decrease the competitiveness of U.S. businesses. To this end, Marck continues to take measures to combat the exportation of counterfeit goods from China and to raise industry and government awareness of the extent of the problems such exports are creating.

Marck reiterates its support of the global enforcement proposed under the ACTA. As discussed, Marck is of the view these enforcement efforts could be further enhanced through incorporation of the STOP! initiatives and a certification and inspection process as effective means of deterring both supply and demand for Chinese counterfeit goods. United States'

companies competing and sourcing products from the various trading regions are painfully aware of the reality these Chinese products have on their day to day operations and their profitability. For these reasons, we would welcome the opportunity to discuss any aspect of these matters as may be necessary in furtherance of the USTR's goals in establishing its Anti-Counterfeiting Trade Agreement.



**Comments Submitted by Google Inc.  
Regarding the Anti-Counterfeiting Trade Agreement  
In Response to USTR Public Notice of September 5, 2008 (73 FR 51860)  
September 17, 2008**

Google Inc. appreciates the opportunity to comment on the pending negotiations for the proposed Anti-Counterfeiting Trade Agreement (ACTA). We have three areas of concern: (1) the scope of the issues proposed to be covered in the agreement and the competency of an Executive agreement to address such issues; (2) the alacrity with which the agreement is being negotiated and the need for transparency and openness to ensure a balanced agreement reflective of the balance in U.S. law; (3) specific substantive provisions affecting intermediaries, such as Internet Service Providers (ISPs) and other innovative companies. We address these below.

**I. The Scope of ACTA**

The ACTA should not address issues beyond border and customs enforcement issues. Internet companies and other intermediaries, like Google, telecom companies and ISPs more generally, do not engage in counterfeiting and piracy; they are legitimate businesses critical to the U.S. economy. To impose potential liability and obligations on them, or to dictate terms of substantive intellectual property law that affect Internet intermediaries, is shooting at the wrong target, potentially contrary to U.S. law, and in any event not appropriate subject matter for an Executive agreement not submitted to the Congress.

U.S. law regarding ISP/intermediary obligations and liability is sensitive and carefully balanced; there are ongoing legislative debates and litigation in domestic courts that seek to balance the interests of right holders according to the Congressional policy of encouraging innovation. Indeed, a decision this summer from the Second Circuit (the *Cablevision* case) calls into doubt what prior U.S. FTAs had assumed was U.S. law on temporary copies. A trade agreement should not affect or freeze these developments (especially one that will not even be submitted to the Congress). For this reason, provisions on obligations and liability of Internet intermediaries, such as ISP safe harbors, technological protection measures, and statutory damages, have no place in ACTA.

## II. Process and Transparency

If, despite the concerns of a number of intermediaries, ACTA is to cover issues beyond border and customs enforcement issues, we believe it will be challenging to secure a balanced agreement based on full consultation with all stakeholders in the ambitious time frame signaled by the Administration (the end of the year). Given the complexity of the issues and range of U.S. economic interests at stake, such an agreement should not be negotiated on a rushed, artificial schedule.

Whatever the schedule, it is critical that U.S. negotiators pursue this agreement in a transparent, consultative manner. The issues under consideration are actively disputed and are of tremendous economic importance to Internet intermediaries like Google. We appreciate USTR' and Commerce's invitation for comments and the September 22 public meeting as a good first step. Given the critical economic interests at stake and the careful balance reflected in U.S. law, the key affected industries need an opportunity to review and comment on the specific proposals before they are offered and with sufficient time to comment constructively and intelligently. Consultation should be meaningful and genuine.

We in particular want to emphasize the importance that this agreement not tilt the balance of interests, even inadvertently, among key U.S. economic stakeholders. Google Inc. and other Internet companies contribute significantly to the U.S. economy and represent one of the United States' strongest areas of growth. Google alone has approximately 20,000 employees in the United States and throughout the world. Google is the world's leading search engine; YouTube is the world's leading video hosting service. In addition, Google is a leading provider of email and many other Internet services. Much of Google's success is founded upon its partnerships with small businesses, as Google last year provided \$4.5 billion to its online advertising partners. There are of course many other Internet companies and other companies that provide products and services related to the Internet. A 2007 study showed that these products and services accounted for \$4.5 trillion in revenues and \$2.2 billion in value added for the United States in 2006. They are directly responsible for more than 18% of US economic growth, significant U.S. exports, and nearly 11 million American jobs.<sup>1</sup>

Indeed, the United States economy has led investment in the growing Internet space and U.S. Internet companies are leaders in Internet e-commerce in part because of the balance of U.S. law – a position that should not be put in jeopardy through an overbroad trade agreement.

The interests of Internet and other intermediary companies therefore need to be carefully factored in as the U.S. government formulates its negotiating positions for ACTA. Internet intermediary companies should have a seat at the table and receive the same consideration in negotiating positions that right holders do.

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<sup>1</sup> Computer & Communications Industry Association, Fair Use in the U.S. Economy.

### III. Core Issues Affecting Internet Companies

As noted above and already expressed to USTR, Google believes strongly that Internet issues should not be addressed in ACTA. But recognizing that U.S. officials are seeking to develop negotiating positions on Internet issues, we outline below some particular bright lines that should not be crossed. Whether other provisions may negatively affect Internet companies can only be determined if Internet companies are closely consulted about proposed ACTA text/positions. Moreover, given the distinct U.S. legal frameworks between copyright and trademark, for example, one must be careful not to over-generalize an intellectual property agreement seeking to address counterfeiting and piracy (and be sensitive to how such terms are defined).

#### Temporary Copies

ACTA should not address substantive issues of copyright law, including the issue of temporary copies. U.S. law regarding temporary copies is unsettled, and how it is resolved will have significant implications for Internet companies, Internet users, and other intermediaries. Indeed, in August 2008, a key U.S. court rejected a view of U.S. law on temporary copies that had been previously considered by some to be prevailing.<sup>2</sup> The United States should not agree in ACTA, or in any other trade agreement, to provisions dictating legal protection of temporary copies.<sup>3</sup>

If, on the other hand, substantive provisions of copyright law are ultimately included in ACTA despite the objection of a number of intermediaries, the agreement should make clear that indexing, buffering, caching and similar activity that is incident to the ordinary operations of the Internet do not amount to infringing activity.

#### Technological Protection Measures (TPM)

TPMs that control access to works do not relate to enforcement of copyright and should not be included in ACTA. Instead, such TPMs are often used towards anti-competitive ends and do little to deter counterfeiting (in the correct use of that term).<sup>4</sup> If trade

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<sup>2</sup> See *Cartoon Network LP, LLLP v. CSC Holdings, Inc.*, --- F.3d ----, 2008 WL 2952614, (2d Cir. August 4, 2008).

<sup>3</sup> While some U.S. trade agreements have addressed the issue of temporary copies (mirroring the prior "prevailing" view that the Second Circuit recently rejected), that was a mistake that should not be repeated. See, e.g., U.S.-Korea FTA § 18.4.1; U.S.-Australia FTA § 17.4.1. At the time the U.S.-Australia FTA was negotiated, there was one line of cases from the Ninth Circuit that involved a specific set of facts: a computer program that was fixed and that was being serviced by a third party in alleged violation of a maintenance contract. Those facts have nothing to do with buffering and caching on the Internet. The Ninth Circuit line of cases has been criticized by scholars and questioned by the Copyright Office – and now rejected by the Second Circuit – as applying to buffering and caching.

<sup>4</sup> The Digital Millennium Copyright Act (DMCA) prevents a wide range of legitimate activity that has nothing to do with counterfeiting (e.g., TPMs are the reason that you cannot: load a lawfully purchased DVD on to your iPod; play a legitimate DVD bought in the U.K. at full-price on your DVD at home in the U.S.; transfer songs lawfully purchased on iTunes to a different music service; operate a device like a DVD player on Linux, an open source program, even though there is no question of copying a single work of authorship). Indeed, the DMCA was used by original equipment manufacturers of printer toner cartridges and electric garage door openers to shut out cheaper substitutes.



agreements are generally intended to remove barriers to trade, TPMs are just such a barrier that ought to be scrutinized carefully.

To the extent that ACTA nevertheless includes provisions on TPMs, only those measures required by the 1996 WIPO Treaty – and not TPMs for access – should be included.<sup>5</sup>

### Safe Harbors

In addition to fair use and implied license, safe harbor regimes are critical to the ability of Internet companies like Google to function and for the United States to continue its global leadership in the Internet economy. However, there are wide divergences in approaches that evolve as the Internet evolves. In light of the diversity of approaches, no provisions involving safe harbors should be included. They are, at any rate, well beyond the scope of an anti-counterfeiting enforcement initiative.

If the Administration persists in pursuing provisions on safe harbors, at a minimum those provisions must cover passive carriers, e.g., Internet services that act as conduits; the ordinary operations of search engines such as hyperlinking and other information location tools such as indexing and caching; copying incidental to search results that is fair use or otherwise lawful hosting sites; and blogs. At the same time, the agreement should not address in any way controversial issues such as the nature of the knowledge and financial benefit that might disqualify one from safe harbors.

### Filtering Mandates

Google appreciates USTR's assurances that filtering will not be addressed in ACTA, whether cast as "voluntary" or explicitly as mandatory. Filtering is a truly nascent area globally, fraught with legal, technological, and commercial controversy and uncertainty, and should not be imposed or encouraged in any Executive agreement.

### Statutory Damages

Countries around the world vary in their approaches toward statutory damages. In the United States, the House Judiciary Committee has stated that it intends to undertake a much-needed review next year of the entire U.S. legal regime regarding statutory damages in intellectual property cases. Under these circumstances, the Executive should not seek to or agree to include provisions on statutory damages in ACTA.

If nevertheless a provision were to be included, it must do no more than state that parties may provide a statutory damage regime without any details on that regime.

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<sup>5</sup> The WIPO Copyright Treaty provides: "Contracting Parties shall provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors in connection with the exercise of their rights under this Treaty or the Berne Convention and that restrict acts, in respect of their works, which are not authorized by the authors concerned or permitted by law." (Art. 11)



September 17, 2008

Rachel S. Bae  
Director for Intellectual Property and Innovation  
Office of U.S. Trade Representative  
600 17th Street, N.W.  
Washington, DC 20508  
[ACTA@ustr.eop.gov](mailto:ACTA@ustr.eop.gov)

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

The Internet Commerce Coalition (ICC) appreciates the opportunity to respond to the United States Trade Representative's (USTR's) request for comments regarding the proposed ACTA anti-counterfeiting agreement.

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.

We very much appreciate USTR's expressed interest in crafting a trade agreement that improves enforcement against counterfeiting and piracy activities in a balanced fashion that both avoids curbing commerce that is entirely lawful under US law and reflects the balance struck in other U.S. Free Trade Agreements with respect to service provider liability.

As the words suggest, "piracy" and "counterfeiting" are not subtle activities, and are already clearly illegal under U.S. law. If ACTA is actually to be an anti-counterfeiting trade agreement that promotes free trade and U.S. exports, it is critical that it apply to counterfeiting and not to trade in parallel imports or other sales of lawfully purchased items outside of manufacturer distribution restrictions. The *LVMH v. eBay* decision issued this summer in France that limits the availability and sale of legitimately manufactured goods offered on a U.S. e-commerce site underscores the importance of clarifying that ACTA does not countenance this sort of anti-competitive restriction.

With regard to criminal liability, we request that USTR clarify that seizure/forfeiture authority applies only to the property of individuals or entities that engage in counterfeiting or piracy or that aid and abet or conspire with such violators. Providing for broad seizure/forfeiture authority against innocent intermediaries whose property or service is simply used by a third party in violation of a national IP law creates unacceptable legal uncertainty and risk of a discriminatory action against foreign competitors.

While we understand that the "Internet provisions" of the Trade Agreement will not track analogous provisions in U.S. FTAs *verbatim*, we urge that USTR adhere closely to the balance in the FTAs on these issues. As the *LVMH* decision demonstrates, there is a very real threat of discriminatory and extra-territorial application of foreign laws against U.S. Internet intermediaries. ACTA must not inadvertently sanction or encourage such trade barriers by weakening the protections for service providers that have been a standard feature of the IP provisions of U.S. FTAs and are part of U.S. law through title II of the Digital Millennium Copyright Act (17 U.S.C. § 512).

For example, any service provider provisions should be framed as limitations on liability/remedies and make clear that these limitations may not be conditioned on requiring a service provider to monitor its system or network. Because technology mandates present a significant barrier to entry into national markets, if the issue of technology protection measures is addressed, it is critical that it preclude technology mandates and use the FTA/DMCA formulation regarding an "open, voluntary process," rather than leaving the door open to national governments picking winners and losers by government fiat.

Any language relating to termination of repeat infringers should include the FTA/DMCA language that termination should occur only "in appropriate circumstances" to avoid mandates, for example, to cut off an entire business' Internet access because one or two employees have engaged in repeat infringement.

Furthermore, ACTA should not delve into "best practices" for government regulation or government-imposed private sector "agreements" that are inconsistent with U.S. law. To do so would likely result in effectively requiring changes in U.S. law. Furthermore, discussions over best practices are occurring on a company-to-company and country-by-country basis without the sort of government intervention contemplated by best practices proposals. For example, a "graduated response" best practice idea is an entirely appropriate subject for private sector negotiations, but requiring it would place governments around the world in the middle of these sorts of negotiations and potentially re-open the DMCA.

Thank you for considering our views.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jim Halpert".

Jim Halpert  
General Counsel

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

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Susan C. Schwab  
U.S. Trade Representative  
600 17<sup>th</sup> Street, N.W.  
Washington DC, 20508  
United States of America

17 September 2008

**Re: Comments on the Anti-Counterfeiting Trade Agreement**

Dear Ambassador Schwab,

On behalf of the member companies of the International Chamber of Commerce's BASCAP initiative and the International Trademark Association (INTA), we would like to express our continued support for the United States' involvement in the negotiations for the Anti-Counterfeiting Trade Agreement (ACTA). Thank you also for providing the opportunity for the business community and other stakeholders to learn more about the progress on ACTA negotiations and to provide relevant comments at the upcoming public meeting to be held in Washington D.C. on September 22, 2008. Our representatives look forward to attending the public meeting.

Since our last letter dated March 19, 2008, and the start of the ACTA negotiations, we have coordinated business input for your negotiations with more than twenty industry associations worldwide – many of which are located in ACTA negotiating countries. Along with ourselves, these groups are dedicated to the fight against counterfeiting and piracy on behalf of businesses large and small. Collectively, we have sought to provide a global, common, business perspective on relevant topics under discussion at each meeting of the ACTA negotiators. Thus far, we have participated in submitting recommendations to the relevant national governments of the negotiating countries on the general framework of the trade agreement as well as considerations for border measures and civil enforcement. We enclose copies of these submissions for your reference and encourage you to share them with your counterparts in the negotiations. We are currently working with our international group of associations on recommendations for criminal enforcement and hope to finalize them prior to the next meeting of ACTA negotiators in October 2008.

INTA and ICC BASCAP reiterate our strong support for the negotiators to create an ACTA that will significantly deter intellectual property (IP) theft and strengthen guidelines and standards for more effective national IP enforcement regimes. We believe this can be accomplished only if the negotiating countries take a comprehensive approach to creating ACTA and devote the necessary time and resources to ensure that it becomes a truly higher standard for governments. INTA and ICC BASCAP continue to stand ready to provide additional assistance and comments to the negotiations. We look forward to future opportunities to share our thoughts and those of the business response groups where appropriate. Thank you for your kind attention and consideration.

Sincerely,

Guy Sebban  
Secretary General  
International Chamber of Commerce

Alan C. Drewsen  
Executive Director  
International Trademark Association

Enclosures

**Memorandum to:** ACTA Negotiators  
**Subject:** Anti-counterfeiting Trade Agreement (ACTA)  
**From:** Concerned business groups operating in ACTA nations  
**Date:** 3 June 2008

As you initiate your negotiations and begin to frame the provisions of the Anti-Counterfeiting Trade Agreement (ACTA), the undersigned associations wish to provide our views on what we consider to be the essential elements upon which ACTA should be constructed. These are indispensable to your stated objective to significantly deter intellectual property (IP) theft and strengthen guidelines and standards for more effective national IP enforcement regimes.

Once the basic framework emerges and you begin to focus on specific aspects and details, we are prepared to provide additional recommendations drawn from the expertise of our member companies operating across sectors and across ACTA borders. Such engagement, which will generate broad business support for ACTA as negotiated, will only be possible if you provide details on the progress of the negotiations and create frequent opportunities for us to comment.

Finally, while we appreciate your aim to conclude the negotiations on an accelerated schedule, we urge you to maintain a comprehensive approach to creating ACTA, avoid compromises that will limit the scope and effectiveness of the final agreement, and devote whatever time is necessary to permit ACTA to become a truly higher standard for government performance.

### **Essential Elements of ACTA**

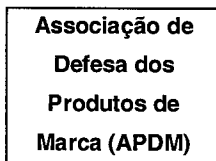
1. Intellectual property theft is no less a crime than physical property theft. An effective ACTA should therefore establish clear and transparent standards for the calculation and imposition of effective criminal penalties for IP theft that: reflect the magnitude of the crime; at a minimum match existing legal penalties for theft of physical merchandise; provide real deterrents to IP theft; remove incentives for infringement; escalate penalties for repeat infringers; and, apply to both online and off-line IP transactions.
2. Law enforcement and customs authorities must have expanded power to investigate criminal infringements of intellectual property rights and initiate criminal actions, both at the request of rights holders and on their own initiative. An effective ACTA must include provisions that train, resource and enable these authorities to: significantly increase inspections of exports/imports to find shipments of counterfeit or pirated goods; refer such findings to appropriate authorities for investigation and prosecution; seize clearly infringing copyright

and trademark materials and seize and/or place under seal equipment or materials suspected of being used to produce such infringing copies; and seize other physical and financial assets of violators.

3. In civil proceedings, an effective ACTA should establish minimum standards for prosecutors to bring charges and for judges to assess penalties in counterfeiting and piracy cases presented to authorities. Such civil sanctions should provide for: deterrent damages; destruction of infringing goods and machines used in their manufacture; closure of establishments used for production and sale; injunctive relief; compensation to rights holders for damages suffered; and, deprive infringers of any profits or other gain from the infringement.
4. While free trade zones are recognized as important and valuable for reducing barriers to global free trade, transshipment and transit of goods through these areas now contribute significantly to the trafficking of counterfeit goods around the world. An effective ACTA must disrupt the flow of counterfeit goods through Free Trade Zones and other transshipment sites by extending greater authority and effective powers to local customs and enforcement authorities to inspect all shipments, detain suspicious shipments, and seize and destroy all goods identified by rights holders as infringing.
5. Recognizing the real and growing link to organized crime and that organized criminals are behind commercial level counterfeiting trade, an effective ACTA must treat acts of counterfeiting and piracy crossing national borders as transnational crimes.
6. Counterfeiters and pirates are increasingly using the Internet to conduct illicit activity. An effective ACTA should address the growing problem of copyright infringements and the sale of counterfeit items on the Internet and encourage all relevant actors to play a responsible role and to cooperate in the fight against counterfeiting and piracy on the Internet.
7. Cooperation, both internationally and among national agencies, is imperative to curb the global nature of counterfeiting and piracy. International enforcement cooperation, especially in the areas of information exchange, capacity building and best practice exchange, is vital. An effective ACTA must create mechanisms for international cooperation, both among the ACTA parties and with countries who are not party to the agreement. It should also establish national coordination mechanisms, such as designating a chief intellectual property enforcement officer with high-level authority to raise the profile of the issue, oversee coordination of relevant government officials and agencies, and allocate necessary financial and personnel resources.

8. Educated consumers and constituencies that understand harms associated with purchasing and consuming counterfeit and pirate goods are better able to act against counterfeiting and piracy. An effective ACTA should include the establishment of public awareness campaigns to warn constituencies and consumers about the harms of counterfeit products and the immediate and extenuating dangers and risks of producing, distributing, marketing, purchasing and consuming counterfeit and pirate products.
9. The parties negotiating ACTA have an important opportunity to educate other countries on the harms associated with counterfeiting and piracy and the economic opportunities associated with creating a system that promotes and protects innovation and creativity. Parties should assist other countries with developing assessments of the economic and social benefits of participating in the ACTA process.

**On behalf of:**



*Portugal*



*Spain*



*United Kingdom*



*Canadian IP Council, Canada*



*European Union*



*Finland*



*Germany*



*USA*



*Mexico*



*Switzerland*



*Italy*



*United Kingdom*



*European Union*

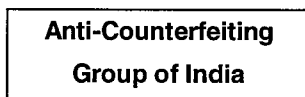


*Sweden*



*Japan*

**Also supported by:**



*India*



*Russia*



*China*



*Norway*



*Ukraine*

**Memorandum to: ACTA Negotiators**

**Subject: Business Perspectives on Border Measures and Civil Enforcement**

**From: Concerned business groups operating in ACTA nations**

**Date: July 28, 2008**

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For your consideration during the meeting of the negotiators of the Anti-Counterfeiting Trade Agreement (ACTA) scheduled for July 29-31 in Washington D.C., the undersigned business associations would like to provide additional input and perspectives on various provisions expected to be included in the final Agreement with respect to border measures and civil enforcement.

Collectively, we remain hopeful that the result of your negotiations will significantly deter intellectual property (IP) theft and strengthen guidelines and standards for more effective national IP enforcement regimes.

Furthermore, we would like to express our appreciation to the negotiating nations that have engaged the business community in collecting comments on ACTA. We look forward to more opportunities to engage with you and to receive additional details on the negotiations so that we can better provide relevant comments and information.

**Recommendations for Border Measures**

ACTA, at a minimum, should include provisions for border measures that:

1. Extend greater authority and effective powers to local customs and enforcement authorities and provide *ex officio* authority for customs authorities to suspend import, export and trans-shipment of goods, including merchandise in free trade zones, which are suspected of being counterfeited or pirated. Significantly increase inspections of exports/imports to find shipments of counterfeit or pirated goods and refer such findings to appropriate authorities for investigation and prosecution.
2. In cases where relevant authorities have seized goods that are counterfeit or pirated, require authorities to inform the right holder of the names and addresses of the consignor, importer, exporter or consignee. Authorities should: (a) provide right holders access to relevant documents and information for use in conducting private investigations or filing complaints to the courts or other government agencies; (b) provide right holders with sufficient time to commence a proper



action pursuant to a seizure/suspension of clearance by customs authorities by introducing provisions that require a time period of at least 20 business days or 31 calendar days from the date of suspension or seizure, whichever is longer, for right holders to commence such action.

3. Establish clear procedures for right holders to initiate suspension by customs authorities of import, export and trans-shipment of suspected IPR infringing goods, including (a) all relevant and reasonably available evidence that is in its control, which is needed to establish a *prima facie* case for the party's claims or defenses; (b) reasonable security or equivalent assurance sufficient to protect the defendant and the competent authorities to prevent abuse. Bond requirements, however, should be eliminated as a condition to processing counterfeiting cases by customs. At the very least, the requirements should be established at a reasonable level so as not to deter the procedures. Governments should also take appropriate steps to reduce or eliminate the burdens on trademark owners of suffering costs of storage and destruction of counterfeit goods.
4. Require authorities to take appropriate steps to ensure that all counterfeit goods are compulsorily destroyed, definitively removed from channels of commerce, or disposed of with the rights holders' consent where there is no health or safety risk. The simple removal of the unlawfully affixed trademark should not be considered a sufficient course of action.
5. Ensure close cooperation between national customs authorities and the special authorities of their free trade zones or free ports in order to provide for the efficient enforcement of anti-counterfeiting and anti-piracy laws to check the offences of trafficking in counterfeit and pirated goods. This would include the seizure of equipment or materials suspected of being used to produce infringing merchandise.

### **Recommended ACTA Provisions for Civil Enforcement**

ACTA, at a minimum, should include provisions for civil enforcement that:

1. Encourage governments to develop calculation methods that lead to fines against counterfeiters and pirates commensurate to the harms caused in order to increase the deterrent impact of fines, and impose sanctions, such as contempt of court, for failure of violators to pay such fines. Calculation methods can be based on information provided by right holders. Right holders should be allowed to elect award of either actual damages suffered or pre-established damages.
2. Allow right holders to recover costs incurred in the detection, investigation and prosecution of acts of counterfeiting and piracy. Costs that can be recovered by the right holder can include court costs or fees, reasonable attorneys' fees, and storage and destruction fees.

3. Grant officials authority to order and/or execute seizure of the infringing goods, and materials and implements used to manufacture and/or package the infringing goods, as well as other physical and financial assets of violators. Counterfeit and pirated goods should be destroyed and definitively removed from the channels of commerce, or disposed of with the rights holders' consent where there is no health or safety risk. Destruction of the seized goods and materials and implements used to manufacture them should be conducted in a manner that minimizes risks of further infringements.
  
4. Provide rights holders who are victims of counterfeiting and piracy the right to obtain information regarding the infringer, including their identities, means of production or distribution, and relevant third parties.

**On behalf of:**



*United Kingdom*



*European Union*



*Spain*



*Germany*



*Germany*



*Canada*



*France*



*Russia*



European Communities Trade Mark Association

*European Union*



*USA*



*Germany*



*Morocco*



*Mexico*



*Japan*



*Korea*



*The European Association of Trade Mark Owners*



*USA*



*France*



*Austria*



## Memorandum

Date: 21 September 2008

To: Stanford McCoy USTR  
Rachel Bae USTR  
Amanda Wilson, DOC

From: James Love and Manon Ress, KEI

### ACTA provisions on Injunctions and Damages

#### **Will the European EPAs or ACTA restrict or outlaw TRIPS Part III compulsory licenses?**

One of the most important developments in patent law has been the growth of compulsory licenses in the United States, following the 2006 *eBay* Supreme Court Decision. Now nearly every proceeding to enforce a patent in the United States is a possible compulsory licensing case, under the four element test for injunctions set out by the U.S. Supreme Court. These compulsory licenses seem to be consistent with the TRIPS, but not under Part II of the TRIPS, which requires either that the exception satisfy the Article 30 three step test, or provisions of Article 31, including obligations for prior negotiation with the patent owners on reasonable commercial terms and conditions, and limits on the exports (Article 31), but under Part III of the TRIPS, the part that deals with enforcement.

In particular, the US is using the provisions in Part III of the TRIPS dealing with injunctions (Article 44) to issue compulsory licenses in ways that would not be possible under Part II of the TRIPS.

For example, the United States already used the injunction provision in the TRIPS to justify its 28 USC 1498 automatic compulsory licenses of copyright, patents and plant variety rights, for uses "by or for the government." These operate under a liability rule -- the U.S. government can give private firms the freedom to use patents, copyrights or plant variety rights, subject to an obligation that the U.S. government will pay for that use.<sup>1</sup>

What was new with the *eBay* decision was the expanded use of the injunction provisions in the TRIPS, in cases where the courts grant compulsory licenses for any private sector uses. A lot of big name companies have received compulsory licenses on patents under the *eBay* decision, including Toyota, Abbott Laboratories and Johnson & Johnson, to mention a few. Microsoft has benefited from two compulsory licenses. These authorizations are done in cases where there is no assertion of market power by the patent owner, no evidence of prior negotiation on reasonable commercial terms, and no restrictions on exports. For example, in a recent case involving

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<sup>1</sup> For discussion of Article 44 in the context of copyright, see "Compulsory licensing of copyright under Article 44.2 of the TRIPS, in light of *eBay*," *KEI Research Note 2007:5*.

Innogenetics and Abbott Laboratories, the royalties paid by Abbott were calculated in Euros, the export currency.

United States Court of Appeals for the Federal Circuit, 2007-1145, -1161.  
*Innogenetics, N.V., v. Abbott Laboratories* . “While the market entry fee was based upon the projection that Abbott could sell its product through 2019, even Abbott acknowledges that such future sales would be subject to the running royalty, a compulsory license. We remand to the district court to delineate the terms of the compulsory license, such as conditioning the future sales of the infringing products on payment of the running royalty, the 5-10 Euros per genotyping assay kit.”

The evolving case law in the United States is consistent with a growing consensus that the reform of patent rights should include greater role for “soft” intellectual property protection, where the exclusive rights of patents are weakened, and patent owners are only entitled to reasonable royalty payments.

The economy and these issues are complex, and there certainly will be areas and circumstances where strong exclusive rights for patents or copyrights are the best policy. However, as we are learning, having the option to weaker rights for some situations is quite important. It is almost impossible to make some products and services today without the infringement of patents, and the use of liability rules offers a useful compromise that gives businesses greater freedom to innovate, while providing valuable rewards to inventors.

The European Union Economic Partnership Agreements include several articles that would restrict if not outlaw the practices that U.S. Courts are exploring under the *eBay* decision. These include the EC's proposals on Injunctions, Alternative Measures and Damages (See below). The EC has reportedly proposed these articles in negotiations for a new Anti-Counterfeiting Trade Agreement (ACTA). Taken together, these provisions would narrow the circumstances under which the Part III compulsory licenses are available, such as where a “person acted unintentionally.”

The TRIPS plus Damages section is also problematic, as it requires consideration of “lost profits, which the injured party has suffered, any unfair profits made by the infringer.” These provisions go further than the TRIPS, and further than many courts have in the current U.S. Legal environment. To appreciate the differences, you might want to review for example the remuneration ordered in the most recent Microsoft compulsory license. Moreover, by introducing these provisions into the EPAs and possibly the ACTA, the new tougher and more restrictive provisions would be subject to dispute resolution.

Countries asked to sign the EU EPAs should reject to revise these Articles, and the ACTA negotiators should reject them. It is better to more clearly understand and evaluate the evolving U.S. practice under the *eBay* decision, and to more fully appreciate the role that liability rules should play in an economy where dozens if not hundreds (or thousands) of patents may be relevant for high tech products and services.

*The following provisions were proposed by the EC in both the CARIFORUM and the China EPA negotiations. We believe the EC has proposed this language also in the ACTA negotiation.*

#### **Article        Injunctions**

The EC Party and the Signatory CARIFORUM States shall ensure that, where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction aimed at prohibiting the continuation of the infringement. Where provided for by national law, non-compliance with an injunction shall, where appropriate, be subject to a recurring penalty payment, with a view to ensuring compliance. The EC Party and the Signatory CARIFORUM States shall also ensure that right holders are in a position to apply for an injunction against intermediaries whose services are used by a third party to infringe an intellectual property right.

#### **Article        Alternative Measures**

The EC Party and the Signatory CARIFORUM States may provide that, in appropriate cases and at the request of the person liable to be subject to the measures provided for in Part III of the TRIPS Agreement and in this Chapter, the competent judicial authorities may order pecuniary compensation to be paid to the injured party instead of applying the measures provided for in Part III of the TRIPS Agreement or in this Chapter if that person acted unintentionally and without negligence, if execution of the measures in question would cause him disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory.

#### **Article        Damages**

1. The EC Party and the Signatory CARIFORUM States shall ensure that when the judicial authorities set the damages:

a) they shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors; or

b) as an alternative to (a), they may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of royalties or fees which would have been due if the infringer had requested authorisation to use the intellectual property right in question.

2. Where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity, the EC Party and the Signatory CARIFORUM States may lay down that the judicial authorities may order the recovery of profits or the payment of damages which may be pre-established.

Kevin Outterson & Ryan Smith, *Counterfeit Drugs: The Good, The Bad, and the Ugly*, 16 ALBANY L. J. OF SCIENCE & TECHNOLOGY 525 (2006) (<http://ssrn.com/author=340746>).

As described in the article that follows, the term “counterfeit” is imprecise when describing pharmaceuticals. That term has inappropriately been used to conflate very different categories of drugs:

- Safe and effective drugs imported in parallel trade
- Safe and effective drugs purchased abroad for personal use
- Drugs of unknown safety and effectiveness purchased abroad or over the internet
- Deliberately mislabeled drugs containing the correct dose of the active ingredient
- Deliberately mislabeled drugs which do not contain the correct dose, or which also contain dangerous contaminants
- Completely fraudulent drugs, mislabeled and containing no active ingredient and possibly dangerous contaminants
- Drugs not produced under GMP, but otherwise safe and effective

Each situation is unique, with diverse causes and solutions. More precise terminology is needed to avoid poor policy choices, as the following article describes in detail. The article can also be found online at: <http://ssrn.com/author=340746>.

Kevin Outterson  
Boston University School of Law

# COUNTERFEIT DRUGS: THE GOOD, THE BAD AND THE UGLY

*Kevin Outterson\* & Ryan Smith\*\**

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\* Associate Professor of Law, West Virginia University College of Law. I am grateful to Albany Law School for the invitation to present at this symposium, and to the symposium participants for their excellent comments and questions. I also thank my research assistant, David Davis, for his work.

\*\* J.D. candidate, West Virginia University College of Law.

## I. INTRODUCTION

When I chose the title, *Counterfeit Drugs: The Good, the Bad and the Ugly*,<sup>1</sup> some of my colleagues at this symposium blanched. They understood counterfeit drugs as *Bad* and *Ugly*, but resisted categorizing any counterfeit drug as *Good*. This article is intended to be provocative; challenging some of the conventional wisdom concerning counterfeit drugs.

We start with the fact that reports about the scope of pharmaceutical counterfeiting are remarkably anecdotal rather than empirical. As a professor once chided me, the plural of anecdote is not data. The Food and Drug Administration (FDA) and the World Health Organization (WHO) must undertake comprehensive market surveillance to establish the true scope of the counterfeiting problem.

We also must speak more clearly about counterfeit drugs; with an improved lexicon. It is misleading to pretend that cross-border drugs from Canada and contaminated water passed off as erythropoietin (Epoetin alfa) by criminal gangs are similar issues. They have quite distinct causes, effects and indicated solutions.

Finally, and perhaps most controversially, this article identifies the underlying cause of drug counterfeiting as the legal system of intellectual property laws. We briefly explore alternative systems which would accomplish recovery of R&D expenditures without the patent rents which attract counterfeiting.

## II. THE DATABASE ON COUNTERFEIT MEDICINES IS UNRELIABLE

Information about counterfeit medicines is everywhere: press reports,<sup>2</sup> WHO fact sheets,<sup>3</sup> FDA press releases,<sup>4</sup> U.S.

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<sup>1</sup> With apologies to Clint Eastwood and Sergio Leone (1967).

<sup>2</sup> Associated Press, *FDA: Al-Qaida Could Poison Medicines*, MSNBC, Aug. 12, 2004, available at <http://msnbc.msn.com/id/5682351>.

<sup>3</sup> See WORLD HEALTH ORG., FACT SHEET No. 275, SUBSTANDARD AND COUNTERFEIT MEDICINES (Nov. 2003), available at <http://www.who.int/mediacentre/factsheets/2003/fs275/> (reporting that the FDA estimates that 10% of the global medicine market is made up of counterfeits and “up to 25% of the medicines consumed in poor countries are counterfeit or substandard.”) [hereinafter WHO FACT SHEET].

<sup>4</sup> Press Release, U.S. Food and Drug Admin., FDA Alerts U.S. Residents to Recall of Counterfeit “Lipitor” Sold in the United Kingdom (July 29, 2005), available at <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01216.html>; Press Release, U.S. Food and Drug Admin., FDA Takes Action Against Foreign



government task forces,<sup>5</sup> law review articles,<sup>6</sup> medical journals,<sup>7</sup> and international trade associations.<sup>8</sup>

Statistics are one thing; useful statistics are quite another. Empirical, reliable and transparent statistics about drug counterfeiting are virtually non-existent. In an excellent article, Robert Cockburn and his co-authors examined the paucity of transparent data and called for mandatory public reporting.<sup>9</sup> Drug companies are reluctant to release information that might harm the marketing efforts for their branded products.<sup>10</sup> The only comprehensive global collection point for counterfeit drug information is the Pharmaceutical Security Institute (PSI), a trade organization established by the security directors of 14 major global drug companies.<sup>11</sup> In October 2004, one of us (KO) asked PSI for access to their database as a researcher, but was told they do not release information to the public.<sup>12</sup> Instead, I

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Websites Selling Counterfeit Contraceptive Patches (Feb. 12, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01023.html>.

<sup>5</sup> HHS TASK FORCE ON DRUG IMPORTATION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, REPORT ON PRESCRIPTION DRUG IMPORTATION IX-X (Dec. 2004), available at <http://www.hhs.gov/importtaskforce/Report1220.pdf>.

<sup>6</sup> See Anthony F. Andrisano, Jr., *To the U.S. Government: Whether or not Reimportation Is the Answer, Something Must Be Done to Help Americans Afford Their Necessary Prescription Drugs!*, 23 PENN STATE INT'L L. REV. 897, 900 (2005) (discussing generally the advent of counterfeit drug sales over the Internet); see also Bryan A. Liang, *International Drug Importation: Issues in Public Policy, Patient Safety, and the Public Health*, 36 CAL. W. INT'L L.J. 1, 4-5 (2005) (explaining that Americans spend approximately \$800 million in medicines from across the Mexican border, much of which is counterfeit).

<sup>7</sup> See Liza Gibson, *Drug Regulators Study Global Treaty to Tackle Counterfeit Drugs*, 328 BRIT. MED. J. 486 (2004), available at <http://bmj.bmjournals.com/cgi/content/full/328/7438/486-c> (stating that the counterfeit drug trade affects between 5% and 7% of the worldwide market).

<sup>8</sup> See, e.g., Judith A. Oulton, Commentary, *Counterfeits Kill—What Are We Doing About Them?*, 52 INT'L NURSING REV. 91 (2005), available at <http://www.icn.ch/INR/INR52-2%20InsideView.pdf> (stating that “[c]ounterfeit medicines make up more than 10% of today’s global medicines”).

<sup>9</sup> Robert Cockburn et al., *The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers*, 2 PLOS MEDICINE 302, 303 (2005), available at [http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371\\_journal.pmed.0020100-L.pdf](http://medicine.plosjournals.org/archive/1549-1676/2/4/pdf/10.1371_journal.pmed.0020100-L.pdf).

<sup>10</sup> *Id.* at 302-04. See Robert Cockburn, *Death by Dilution*, AM. PROSPECT, Dec. 20, 2005, available at <http://www.prospect.org> (describing a situation where GlaxoSmithKline refused to release information about potential counterfeits because of the negative effect it would have on business).

<sup>11</sup> Pharmaceutical Security Institute, About PSI, <http://www.psi-inc.org/about.cfm> (last visited Oct. 1, 2006).

<sup>12</sup> See E-mail from Dr. Sebastian J. Mollo, Pharmaceutical Security Institute, to Kevin Outtersson (on file with author).

was directed to the FDA, WHO and news reports.<sup>13</sup> The “data” begins to resemble a house of mirrors as each group cites the other as the source of the information.

For example, one widely-cited “fact” attributed to the WHO is the claim that “[c]ounterfeit medicines make up more than 10% of today’s global medicines” available in the market.<sup>14</sup> Further, “[WHO] estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever.”<sup>15</sup> Yet another statistic is that “[i]n developing countries, up to 25% of the medicines used are counterfeit or substandard.”<sup>16</sup> In fact, the WHO reports that “[s]ome estimates place the annual earnings from counterfeit medicines at over \$32 billion globally.”<sup>17</sup> Another example is the often-repeated claim that “World Health Organization . . . figures suggest that developing countries account for around 60% of all reported cases of counterfeit and substandard drugs.”<sup>18</sup> But the WHO doesn’t really defend this figure when pressed, and generally cites figures from the U.S. FDA.<sup>19</sup>

In the U.S., the FDA cites the WHO figures for global counterfeiting estimates.<sup>20</sup> Domestically, the FDA estimates that less than 1% of U.S. drugs are counterfeit, but “officials admit that this figure is not based on any scientific studies.”<sup>21</sup>

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<sup>13</sup> *Id.*

<sup>14</sup> Oulton, *supra* note 8; Press Release, Int’l Council of Nurses, Nurses Raise the Alarm: Counterfeit Medicines Kill (May 11, 2005), *available at* [http://www.icn.ch/PR09\\_05.htm](http://www.icn.ch/PR09_05.htm) [hereinafter Nurses Raise the Alarm].

<sup>15</sup> Nurses Raise the Alarm, *supra* note 14.

<sup>16</sup> *Id.*; Int’l Perspectives, ICN asks Nurses to Help Protect Patients From Counterfeit Medicines, 52 INT’L NURSING REV. 85 (2005), *available at* [http://www.icn.ch/fr\\_INRsubscribe.htm](http://www.icn.ch/fr_INRsubscribe.htm).

<sup>17</sup> Nurses Raise the Alarm *supra* note 14.

<sup>18</sup> INT’L COUNCIL OF NURSES, NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES, *available at* <http://www.icn.ch/indkit2005.pdf> (Providing an “Information and Action Tool Kit” for International Nurses day 2005).

<sup>19</sup> *Compare, e.g.*, U.S. Food & Drug Admin., Counterfeit Drugs Questions and Answers, <http://www.fda.gov/oc/initiatives/counterfeit/qa.html> (last visited Oct. 1, 2006) (“It is estimated that upwards of 10% of drugs worldwide are counterfeit, and in some countries more than 50% of the drug supply is made up of counterfeit drugs.”), *with* WHO FACT SHEET, *supra* note 3 (“[E]stimates put counterfeits at more than 10% of the global medicines market. . . . In some countries, the figure [of counterfeit medicines consumed in developing countries] is thought to be as high as 50%.”).

<sup>20</sup> *See id.*

<sup>21</sup> Elizabeth Cady Brown, *Pharmaceutical Fakery*, LONG ISLAND PRESS, June 9, 2005, *available at* [http://www.longislandpress.com/?cp=188&show=article&a\\_id=4250](http://www.longislandpress.com/?cp=188&show=article&a_id=4250).

European officials also rely on the WHO estimates.<sup>22</sup> The Deputy Secretary General of the Council of Europe said “WHO estimates that counterfeit medicines make up for 8% to 10% of the European pharmaceutical market and in some countries even as much as 12%.”<sup>23</sup>

The pharmaceutical industry historically was reticent to discuss counterfeiting, for obvious reasons.<sup>24</sup> With the advent of consumer drug purchasing over the Internet, suddenly the industry was faced with cross-border arbitrage pressure.<sup>25</sup> After consumer focus groups identified safety as a primary concern with Internet drug purchases, the industry and the FDA began to publicly discuss the problem.<sup>26</sup> Publicly discussing counterfeiting is an important tool to enforce the industry’s price discrimination structures across borders, enhancing overall industry profits.

To remedy this insufficient data, the federal government should fund independent market surveillance to identify and describe problems with the U.S. drug supply chain. Randomized purchases should be made across the U.S. market, in various channels, and the purchased drugs should be tested in all regards for compliance with U.S. law. When non-compliance is found, investigators should track the problems back to the source. The full results must then be transparently available to all researchers and the public. Similar undertakings could occur in other countries on a recurring basis. Market surveillance on this level would provide the basic facts necessary to truly understand the threat to our drug supply, and to separate public relations campaigns from genuine threats to public health.

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<sup>22</sup> See Maud de Boer-Buquicchio, Deputy Secretary of the Council of Europe, Opening Speech on the Occasion of the Seminar “Counteract the counterfeiters!”, (Sept. 21, 2005) (transcript available at [http://www.coe.int/T/E/Com/press/News/2005/20050921\\_disc\\_sga.asp](http://www.coe.int/T/E/Com/press/News/2005/20050921_disc_sga.asp)).

<sup>23</sup> *Id.*

<sup>24</sup> See Vivienne Parry, *A Lack of Chemistry*, TIMES ONLINE, July 9, 2005, available at <http://www.timesonline.co.uk/article/0,,8122-1684914,00.html> (stating that pharmaceutical companies are wary of discussing topics that may hurt consumer confidence or open the door to litigation).

<sup>25</sup> Kevin Outtersson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 277–79 (2005) [hereinafter *Pharmaceutical Arbitrage*].

<sup>26</sup> For example, the FDA recently announced a new prescription drug information format that will help healthcare professionals find information regarding prescription dosage and administration, boxed warnings, and other prescribing information. See Press Release, FDA Announces New Prescription Drug Information Format to Improve Patient Safety (Jan. 18, 2006), available at <http://www.fda.gov/bbs/topics/news/2005/NEW01272.html>.

## III. A NEW PHARMACEUTICAL LEXICON IS NEEDED

One of the most important challenges is unpacking what is meant by the terms *fake* or *counterfeit* drugs. The WHO has a widely-disseminated definition which emphasizes deliberate mislabeling as to identity or source.<sup>27</sup> Less precise terms are used in press accounts<sup>28</sup> and by the U.S. and E.U. drug regulatory agencies.<sup>29</sup> In some cases, the terms *fake* or

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<sup>27</sup> See WHO FACT SHEET, supra note 3:

“Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals. The difference is that they are 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 but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.”

The FDA definition is broader, including drugs with improper dosages, sub-potent or super-potent ingredients, or contamination. COUNTERFEIT DRUG TASK FORCE, U.S. FOOD DRUG AND ADMIN., COUNTERFEIT DRUG TASK FORCE INTERIM REPORT (Oct. 2003), available at [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html) [hereinafter COUNTERFEIT DRUG TASK FORCE INTERIM REPORT]. This definition conflates counterfeits with poorly manufactured or stored products.

<sup>28</sup> See, e.g., *Prescription for Danger Counterfeit Drug Trade Grows*, CBS NEWS, Aug. 2, 2001, available at <http://www.cbsnews.com/stories/2002/01/31/health/main327265.shtml> (“There’s no single definition for counterfeit drugs. They may contain dangerous substitutes instead of the real ingredients. Or they may be much like ‘the real thing’—only expired, or not approved for sale in the [United States].”).

<sup>29</sup> See *Importation of Prescription Drugs into the U.S. and the use of the Internet: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2004) (statement of William K. Hubbard, U.S. FDA Associate Comm’r for Policy and Planning), available at <http://www.fda.gov/ola/2004/importeddugs0714.html> [hereinafter William K. Hubbard]; Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead: One is Busted for Selling Bogus Pharmaceuticals; New Vendor Grabs Address*, WALL ST. J., Aug. 10, 2004, at D4 (describing generic versions which were substituted for brand name drugs still patented in the United States as counterfeits); see also *Options for Safe and Effective Prescription Drug Importation: Hearing Before the S. Comm. on Commerce, Science & Transportation*, 108th Cong. (2004) (statement of Mark McClellan, Comm’r of the Federal Drug Administration), available at [http://commerce.senate.gov/hearings/testimony.cfm?id=1105&wit\\_id=3132](http://commerce.senate.gov/hearings/testimony.cfm?id=1105&wit_id=3132) (discussing “unapproved, imported pharmaceuticals,” “unsafe and illegal drugs,” and “ineffective, counterfeit drugs”) [hereinafter Mark McClellan]; COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, supra note 27 (“Counterfeit drugs pose significant public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated.”); Position Paper, Eur. Fed’n of Pharm. Indus. & Ass’ns, *International Exhaustion of Trade Mark Rights* (Apr. 2001), available at [http://www.efpia.org/4\\_pos/legal/protecpatients.pdf](http://www.efpia.org/4_pos/legal/protecpatients.pdf) [hereinafter EFPIA] (describing the range of products that may be considered counterfeit by

*counterfeit* have included a wide range of drug products, from those resulting in criminal acts of homicide, to placebos, to safe and effective drugs from Canada.<sup>30</sup>

These terms are frequently conflated in unhelpful ways. For example, an August 10, 2004 article on Internet drug purchases in the Wall Street Journal used the words *fake* or *counterfeit* many times before mentioning that FDA lab tests “showed that most of the drugs contained too much active ingredient, making the fakes potentially harmful.”<sup>31</sup> These drugs may be poorly produced, or too strong by U.S. standards, but they should not be lumped together with criminal counterfeits.<sup>32</sup> Each of these categories feature distinct causes, effects, and potential remedies. Conflating these categories needlessly confuses the issues. The following sections begin the process of building a pharmaceutical lexicon that is more descriptive and helpful.

#### A. *The Good*

Good drugs are safe, effective and less expensive, but can violate some technical requirement of U.S. law.<sup>33</sup> A prime example is prescription drugs purchased by U.S. citizens from

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the WHO and the European Pharmaceutical Trade Association and those groups' corresponding concerns).

<sup>30</sup> See Paul N. Newton et al., Editorial, *Murder by Fake Drugs: Time for International Action*, 324 BRIT. MED. J. 800, 801 (2002), available at <http://bmj.bmjournals.com/cgi/content/full/324/7341/800>; Carmen Catizone & Peter Wyckoff, *Should Consumers be Allowed to Buy Drugs From Canada?*, AARP BULLETIN, May 2003, available at <http://www.aarp.org/bulletin/faceoff/a2003-06-25-shouldconsumers.html>.

<sup>31</sup> Tesoriero, *supra* note 29, at D4; see also Mark McClellan, *supra* note 29 (discussing “unapproved, imported pharmaceuticals” and “unsafe and illegal drugs” with “ineffective, counterfeit drugs”). McClellan was the Commissioner of the Food and Drug Administration at the time; he currently heads the Centers for Medicare and Medicaid Services.

<sup>32</sup> The trade association of European pharmaceutical research companies and the WHO use the broader definition. EFPIA, *supra* note 29 (explaining that “[c]ounterfeiting can apply to both branded and generic products and ... may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging’”). My point is not to argue whose definition is “right,” but to demonstrate the analysis which is possible when using a narrower definition.

<sup>33</sup> See *Internet Drug Sales: Hearing Before the H. Comm. on Gov't Reform*, 108th Cong. (2004) (statement of William K. Hubbard, Associate Comm'r, Federal Drug Administration), available at <http://www.fda.gov/ola/2004/internetdrugs0318.html> (noting that legitimate Internet pharmacies provide important services to patients but some sell unapproved drugs, drugs without a required prescription or drugs to patients without valid health problems).

brick and mortar pharmacies in Canada.<sup>34</sup> The purchase is legal, but the FDA states that bringing these drugs back into the United States violates federal law.<sup>35</sup> These are safe and effective drugs purchased in person in Canada, but the consumer violates the U.S. personal importation rule by bringing them back to the United States for personal use.<sup>36</sup>

In many important respects these drugs should not be confused with contaminated products peddled by criminal gangs. The first difference is safety and efficacy.<sup>37</sup> Canadian drugs are just as safe and effective as drugs sold in the U.S. market.<sup>38</sup> In fact, they are cheaper which makes them more effective because patient compliance with prescription drug regimes is higher when the drugs are affordable.<sup>39</sup>

The FDA studiously avoids this important point about financial access to drugs, despite the fact that financial access is the primary reason for the Canadian cross-border prescription

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<sup>34</sup> Donna Young, *FDA Clarifies Importation Law As Internet Pharmacies Proliferate*, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS, April 15, 2003, available at <http://www.ashp.org/news/ShowArticle.cfm?id=3365> (last visited Oct. 30, 2006).

<sup>35</sup> *Id.*; 21 U.S.C. § 331(a), (d), (t) (2000 & Supp. III 2004); 21 U.S.C. § 381(d)(1) (2000 & Supp. III 2004).

<sup>36</sup> Young, *supra* note 34; 21 U.S.C. § 331(a), (d), (t); 21 U.S.C. § 381(d)(1); see also OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMIN., REGULATORY PROCEDURES MANUAL CH. 9: IMPORT OPERATIONS/ACTIONS, SUBCHAPTER: COVERAGE OF PERSONAL IMPORTATIONS (2002), available at [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html). (Chapter 9 is currently under revision as of Jun. 21, 2006). Many critics conflate this foot-traffic market, which is undoubtedly safe, with purchasing from Internet sites claiming to be from Canada. These are entirely different markets, with very different profiles on safety and efficacy.

<sup>37</sup> See Patricia Barry, *Prescription Drugs: The Rush to Buy Canadian*, AARP BULLETIN, May 2004, available at <http://www.aarp.org/bulletin/prescription/a2004-05-12-buycanadian.html> (reporting that a recent study revealed no difference in the active ingredients in drugs purchased from a Canadian Internet pharmacy and those purchased in the U.S.).

<sup>38</sup> *Id.* Drugs purchased from Canada may actually be safer than similar drugs purchased in the U.S. RAM KAMATH & SCOTT MCKIBBIN, OFFICE OF SPECIAL ADVOCATE FOR PRESCRIPTION DRUGS, ILL. DEP'T OF CENT. MGMT. SERVICES, REPORT ON FEASIBILITY OF EMPLOYEES AND RETIREES SAFELY AND EFFECTIVELY PURCHASING PRESCRIPTION DRUGS FROM CANADIAN PHARMACIES 18 (2003) (finding Canadian and U.S. systems equivalent for most aspects, but finding the Canadian system superior in preventing the introduction of counterfeit drugs and incident reporting for internal process errors).

<sup>39</sup> See *In re Petition: to Provide Certification to Congress Under Section 804(l) of Chapter VII of the Federal Food, Drug and Cosmetics Act, and to Authorize a Pilot Program for Importation of Prescription Drugs in the State of Illinois: Before the Dep't of Health and Human Services*, 108th Cong. (2004) (aff. of Alan Sager, Ph.D.).

drug trade.<sup>40</sup> This leads to the second distinction: this trade is not driven by criminals.<sup>41</sup> United States residents fill prescriptions in Canada because the products appear fungible with a transparent price differential.<sup>42</sup>

The primary negative effect of Canadian cross-border foot traffic is the lost pharmaceutical patent rents.<sup>43</sup> The patent-based pharmaceutical companies make a smaller profit when the prices are lower.<sup>44</sup> Evaluation of whether this trade is socially positive must balance the benefits from more affordable drug access (static gains) against the potential dynamic losses from reduced patent rents.<sup>45</sup> The dynamic effects may be positive if indeed current U.S. prices are supra-optimal.<sup>46</sup> Social welfare is improved if the market expands by selling therapeutically-equivalent drugs to lower-income populations with highly elastic demand curves.<sup>47</sup> Whether parallel trade is a net gain is

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<sup>40</sup> See Young, *supra* note 34 (noting that consumers will continue to purchase drugs from Canada until the United States can lower drug prices).

<sup>41</sup> See *id.* (indicating that professional organizations made up of physicians and pharmacists are among those promoting the purchase of prescription drugs from Canada).

<sup>42</sup> See Christopher Rowland, *U.S. Steps Up Seizures of Imported Drugs; Warnings Sent for Prescriptions*, BOSTON GLOBE, Mar. 26, 2006, at A1 (discussing how one American consumer was purchasing prescription drugs from a Canadian Internet pharmacy because it was less expensive, even with Medicare coverage).

<sup>43</sup> See Kevin Outtersson, *Nonrival Access to Pharmaceutical Knowledge*, Submission to the WHO Commission on Intellectual Property Rights, Innovation & Public Health, (Jan. 3, 2005), available at <http://www.who.int/intellectualproperty/submissions/KevinOuttersson3january.pdf> (indicating that patents allow drugs to be priced above the marginal cost of production).

<sup>44</sup> See Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 CAN. MED. ASS'N J. 1451 (2004) available at <http://www.cmaj.ca/cgi/reprint/171/12/1451.pdf> (stating “[e]xcess profits are, of course, the result of excess prices”); see also Barry, *supra* note 37 (quoting U.S. Senator Chuck Grassley who reported that drug companies “do not want to see their lower-priced products from other countries coming into the U.S. It undermines their profits here, and they will want to do everything they can to stop drug importation.”).

<sup>45</sup> See *Drug Importation: Would the Price Be Right?: Hearing Before the S. Comm. on Health, Education, Labor and Pensions*, 109th Cong. (2005) (statement of Kevin Outtersson, Associate Professor, West Virginia University College of Law), available at [http://help.senate.gov/Hearings/2005\\_02\\_17/outtersson.pdf](http://help.senate.gov/Hearings/2005_02_17/outtersson.pdf) (last visited Oct. 1, 2006).

<sup>46</sup> *Pharmaceutical Arbitrage*, *supra* note 25, at 197.

<sup>47</sup> *Id.* at 195; see generally Outtersson, *supra* note 43 (explaining how charging higher prices to low-income populations often results in mortality for those unable to afford the drugs).

unknown.<sup>48</sup> Most studies ignore the effect of lower prices in improving access,<sup>49</sup> as well as the larger question of global optimality of pharmaceutical patent rents.<sup>50</sup>

A second example of a good drug is the unlicensed generic antiretroviral (ARV) drugs produced to address the AIDS treatment crisis in low- and medium-income countries. The Brazilian health minister threatened to issue a compulsory license for a second generation AIDS drug, Kaletra.<sup>51</sup> US trade officials responded with quite intemperate language. A compromise was reached before the compulsory license was issued.<sup>52</sup> Likewise, access to ARVs in Africa and other low-income populations was made possible when several companies and groups produced and used unlicensed generic ARVs.<sup>53</sup> Many of these drugs were pre-qualified by the WHO.<sup>54</sup> Some have now even been approved by the FDA,<sup>55</sup> and yet they violate intellectual property (IP) law. These drugs provide affordable access to millions of people with AIDS.<sup>56</sup>

### B. *The Bad*

Bad drugs include blatant attempts to defraud consumers by selling placebos lacking the correct active ingredient and drugs

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<sup>48</sup> Pharmaceutical Arbitrage, *supra* note 25, at 195–96, 206.

<sup>49</sup> PETER WEST & JAMES MAHON, YORK HEALTH ECON. CONSORTIUM, BENEFITS TO PAYERS AND PATIENTS FROM PARALLEL TRADE (May 2003), at [http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade\\_ExecSumm.pdf](http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf) (estimating direct savings of 631 million in 2002 from legal pharmaceutical arbitrage (parallel trade) within the EU); Panos Kanavos et al., *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* 15–16 (London Sch. of Econ. Political Sci., Special Research Paper, Jan. 2004), available at <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>.

<sup>50</sup> See Outtersson, *supra* note 43.

<sup>51</sup> Todd Benson, *Brazil to Copy AIDS Drug Made by Abbott*, N.Y. TIMES, June 25, 2005, at C12.

<sup>52</sup> Todd Benson, *Brazil and U.S. Maker Reach Deal on AIDS Drug*, N.Y. TIMES, July 9, 2005, at C2.

<sup>53</sup> See Kevin Outtersson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 74 (2005) [hereinafter *Vanishing Public Domain*]; Ben Hirschler, *Generic Drugs Key to Uphill AIDS Fight, WHO Says*, REUTERS NEWMEDIA, June 21, 2005, available at <http://www.aegis.org/news/re/2005/RE050646.html>.

<sup>54</sup> See *Vanishing Public Domain*, *supra* note 53, at 73; Hirschler, *supra* note 53.

<sup>55</sup> Hirschler, *supra* note 53.

<sup>56</sup> *Vanishing Public Domain*, *supra* note 53, at 73–74.



containing negligent or deliberate contaminants or poisons.<sup>57</sup>

Bad drugs are produced and marketed by criminals. The products are at best placebos and at worst positively dangerous. Patients derive no therapeutic benefit whatsoever; all money spent on them is wasted. Nothing of social value is produced. This trade deserves the enhanced criminal sanctions that Bryan Liang and others call for.<sup>58</sup> However, applying these criminal laws to Good or Ugly drugs would be a mistake, and would misdirect resources to attack a market with some social value.

### C. *The Ugly*

Ugly drugs are generally safe and effective but come to the consumer through an insecure supply chain or with other deficiencies which may or may not represent a safety risk.<sup>59</sup> Ugly drugs are intended to be therapeutic and legitimate, but are sub-standard in some way, such as labeling which complies with Canadian or EU law but not U.S. FDA standards.<sup>60</sup>

Ugly drugs present an entirely different profile than Bad drugs. These manufacturers and wholesalers are not criminals. They may be resource-constrained or require enhanced procedures at the plant and in the supply chain.<sup>61</sup> They may even be negligent by US standards; but they are not criminals.

Foreign drugs which are imported into the US with foreign-language labeling present an example of an Ugly drug with possibly positive social value. About 12 million people in the United States are linguistically isolated.<sup>62</sup> For limited English proficiency (LEP) populations, receiving a prescription with the proper U.S. FDA labels is practically useless.<sup>63</sup> For example, it

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<sup>57</sup> Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. (forthcoming 2006).

<sup>58</sup> *Id.*

<sup>59</sup> See William K. Hubbard, *supra* note 29.

<sup>60</sup> See Press Release, U.S. Food and Drug Admin., Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004) available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html> [hereinafter FDA Press Release].

<sup>61</sup> See *id.*

<sup>62</sup> US CENSUS BUREAU, LANGUAGE USE AND ENGLISH-SPEAKING ABILITY: 2000 (Oct. 2003). A linguistically isolated person is one who lives in a household in which no person over age 14 speaks English "very well." *Id.*

<sup>63</sup> See 21 C.F.R. § 201.15(c) (2004) (requiring labels to appear in English); see also Leighton Ku & Glenn Flores, *Pay Now Or Pay Later: Providing Interpreter Services In Health Care*, 24 HEALTH AFF. 435, 436 (Mar/Apr 2005); Leighton Ku

would be better for a recent LEP immigrant from the Philippines to import a drug from home because not only is it cheaper, but the label in Tagalog is both readable and culturally competent. The indicated solution here would either be to permit importation in foreign language labels for LEP communities or to permit dual-language labeling for these communities.<sup>64</sup>

Ugly drugs might also include products imported from legitimate Internet pharmacies.<sup>65</sup> Empirical evidence suggests that virtually none of the Internet drugs arriving in the United States are non-functional counterfeits; their importation simply violates technical restrictions on parallel importation, FDA labeling, or similar rules.<sup>66</sup> Instead, most of the non-functional counterfeit drugs in the United States appear to have domestic origins or domestic networks.<sup>67</sup> The cause of this trade is simply the price differentials across borders.<sup>68</sup> The preferred solution of the FDA is to shut the trade down.<sup>69</sup> Criminal counterfeiting must be recognized as a major threat to the integrity of our health care system and must be shut down. But the Ugly drug trade is not necessarily a criminal enterprise. An alternative is to legalize and regulate it, bringing this trade out of the grey market. The Dorgan-Snowe Bill in Congress<sup>70</sup> and State-based

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& Sheetal Matani, *Left Out: Immigrants' Access to Health Care and Insurance*, 20 HEALTH AFF. 247, 254 (Jan./Feb. 2001) (noting that language problems are "the leading barrier to child health services" by Latino parents and this may increase medical errors due to "misdiagnosis and misunderstanding of physicians' orders").

<sup>64</sup> See Ku & Flores, *supra* note 63, at 437 (pointing out that LEP patients with interpreters or bilingual providers are better informed and, sometimes, have less pain and better physical functioning).

<sup>65</sup> See National Association of Boards of Pharmacy, VIPPS, <http://www.nabp.net/vipps/intro.asp> (last visited Oct. 1, 2006) (providing certification for legitimate pharmacy practices on the Internet).

<sup>66</sup> See, e.g., FDA Press Release, *supra* note 60 (mentioning many categories of unapproved drugs but never indicating that any of them contained no active ingredient); COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, *supra* note 27 (noting that counterfeit drugs may "pose significant public health and safety concerns," as they "may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated."); EFPIA, *supra* note 29 (describing the range of products that may be considered counterfeit by the WHO and the European pharmaceutical trade association and corresponding concerns).

<sup>67</sup> Gilbert M. Gaul & Mary Pat Flaherty, *U.S. Prescription Drug System Under Attack: Multibillion-Dollar Shadow Market Is Growing Stronger*, WASH. POST, Oct. 19, 2003, at A1.

<sup>68</sup> See Pharmaceutical Arbitrage, *supra* note 25, at 277-80.

<sup>69</sup> See William K. Hubbard, *supra* note 29.

<sup>70</sup> Pharmaceutical Market Access and Drug Safety Act of 2005, S. 334, 109th

importation plans, such as I-Save Rx,<sup>71</sup> are prominent examples of this approach. Mindlessly conflating criminal placebos with importation under Dorgan-Snowe only serves the interest of drug company profits rather than a serious discussion of public health.

#### IV. INTELLECTUAL PROPERTY LAWS ARE AN UNDERLYING CAUSE OF COUNTERFEIT DRUGS

One outcome of enhanced lexical precision will be a sharper focus on the most dangerous areas of concern: bad drugs sold by criminals. It also permits us to focus on an underlying cause, which is the legal system of intellectual property (IP) for patented drugs.

An underlying cause of counterfeit drugs is the IP system, particularly patents and trademarks.<sup>72</sup> Criminals follow the money. They typically counterfeit expensive patented drugs rather than generics.<sup>73</sup> The IP system creates the opportunity that counterfeiters exploit.<sup>74</sup>

The marginal cost of producing most name-brand drugs is a small fraction of the commercial price. An annual supply of a well-known anti-retroviral triple combination drug regime in the United States costs over \$12,000.<sup>75</sup> The marginal price is not publicly known, but can be estimated. Unlicensed generic companies sell the same drugs in sub-Saharan Africa for under \$200 per year.<sup>76</sup> These drugs are sold at 60 times their marginal

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Cong. (2005) (A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes).

<sup>71</sup> See 29 Ill. Reg. 7108 (2005) (discussing the I-Save Rx program).

<sup>72</sup> See Vanishing Public Domain, *supra* note 53, at 91.

<sup>73</sup> See Parry, *supra* note 24. In some uncompetitive generic drug markets, even generics might sell at a substantial premium over the marginal cost of production, and thus attract counterfeiters. This uncompetitive market may well be related to a hang-over effect from related pharmaceutical laws, even with the expiration of the patent. See Pharmaceutical Arbitrage, *supra* note 25, at 254–55 (citing an example of a generic drug which has been counterfeited and sold at a price considerably above the actual value).

<sup>74</sup> Vanishing Public Domain, *supra* note 53, at 91 (discussing how the Medical R&D Treaty would diminish exploitation of the IP system by counterfeiters by lowering the cost of pharmaceuticals).

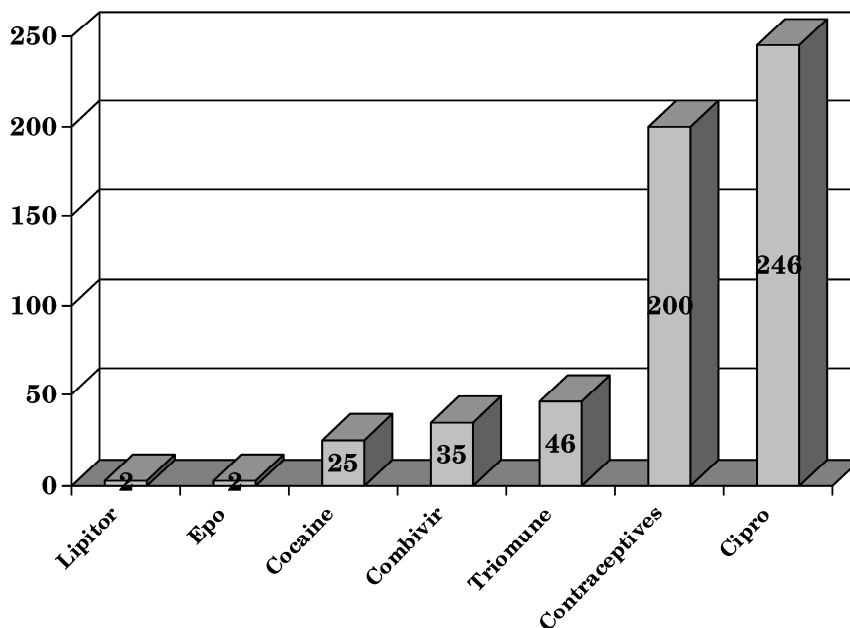
<sup>75</sup> Drugstore.com, Trizivir, <http://www.drugstore.com/pharmacy/prices/drugprice.asp?ndc=00173069100&trx=1Z5006> (last visited Oct. 1, 2006) (listing the price of the antiviral anti-HIV medication Trizivir® based on a two pill per day dosage as \$12,773.56).

<sup>76</sup> MEDECINS SANS FRONTIERES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES 9 (8th ed. 2005), available at <http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf>.

cost (a “pricing ratio” of 60:1).<sup>77</sup> This ratio would not be possible absent IP laws and the related branding efforts of drug companies. High pricing ratios attract counterfeiters.

This is not an isolated example. Many patented drugs exhibit this profile (see Table 1). Industry estimates suggest that the average variable cost of patented drugs accounts for an average of 15% of the final price,<sup>78</sup> yielding an average pricing ratio of more than 6:1. Some pricing ratios are much higher: generic ciprofloxacin is sold in some places at less than 0.4% of the price of the most expensive sources in the U.S., a pricing ratio of 264:1.<sup>79</sup> Others have found pricing ratios of 200:1 in global markets for vaccines and contraceptives.<sup>80</sup>

Table 1. Rx Pricing Ratios



Outterson, Pharmaceutical Arbitrage, 5 Yale J H Pol’y, L & Ethics 193 (2005).

<sup>77</sup> See Drugstore.com, *supra* note 75; MEDECINS SANS FRONTIERES, *supra* note 76 (showing that the price charged in the United States is approximately sixty times the price charged in sub-Saharan Africa for the same drug).

<sup>78</sup> Tomas J. Philipson & Anupam B. Jena, *Dividing the Benefits from Medical Breakthroughs: The Case of HIV/AIDS Drugs*, THE MILIKEN INSTIT. REV. 46, 51 (2006).

<sup>79</sup> Pharmaceutical Arbitrage, *supra* note 25, at 254.

<sup>80</sup> Ellen ‘t Hoen & Suerie Moon, *Pills and Pocketbooks: Equity Pricing of Essential Medicines in Developing Countries* 222 (Medecins Sans Frontieres, DND Working Group 2001), available at <http://www.accessmed->

By way of comparison, one of us (KO) has previously estimated the pricing ratio for cocaine at 25:1.<sup>81</sup> The potential returns from parallel importation of some patented drugs are higher than cocaine by an order of magnitude.<sup>82</sup> Patented drugs are especially attractive if the markets are less crowded and law enforcement is less diligent.<sup>83</sup>

The story gets worse. These ratios are built by comparing safe and effective versions of a drug sold in different markets.<sup>84</sup> All of these pricing ratios assume that the criminal intends to deliver actual functional pharmaceuticals.<sup>85</sup> This assumption is generally true in illegal narcotic markets. When criminals market cocaine, they need to deliver the expected (and observable) biochemical effect: customers want to get high. Delivering a placebo will not only destroy customer loyalty and repeat business, but it may also result in violence.

However, many patented drugs do not deliver an effect that is immediately observable to the patient. If a patient takes a placebo instead of a drug such as atorvastatin calcium (Lipitor), the patient may not notice the lack of therapeutic effect for months.<sup>86</sup> By the time it is noticed, it may be very difficult to retrace the supply chain to the point where the counterfeit was introduced.<sup>87</sup> Some commentators reluctantly acknowledge that

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[msf.org/prod/publications.asp?scentid=20920021811218&contenttype=PARA&](http://msf.org/prod/publications.asp?scentid=20920021811218&contenttype=PARA&)  
(last visited Oct. 1, 2006).

<sup>81</sup> See Pharmaceutical Arbitrage, *supra* note 25, at 262 (comparing the street price in producing countries and the street price in the US).

<sup>82</sup> See *id.* at 254 (showing that the Cipro pricing ratio is 246:1 as opposed to cocaine at a ratio of 25:1).

<sup>83</sup> Liang, *supra* note 57. Brian Liang and others have decried the poor law enforcement resources dedicated to pharmaceutical counterfeiting.

<sup>84</sup> See Pharmaceutical Arbitrage, *supra* note 25, at 263–64 (discussing a case where patented drugs were packaged for the African market but sold to the European market).

<sup>85</sup> Liang, *supra* note 57.

<sup>86</sup> See, e.g., Brown, *supra* note 21 (recounting an incident where it took several weeks before a patient became aware that the Epogen he was taking was counterfeit, even where there were noticeable side effects). For other drugs, such as analgesics or erectile dysfunction drugs, it may well be possible for the patient to quickly identify the therapeutic failure. But if the counterfeit drug was introduced into the supply chain at an unknown point, it might still be difficult to find the counterfeiter. Gaul & Flaherty, *supra* note 67, at A1, A15.

<sup>87</sup> See Brown, *supra* note 21 (noting that one victim's counterfeit drugs changed hands "at least 11 more times" after it first entered the marketplace).

counterfeit drugs are something of a “perfect crime.”<sup>88</sup>

For drugs that do not produce an immediately observable therapeutic effect, criminals need not go to the trouble to procure and ship the actual drugs. Any placebo will do, at a fraction of the cost of either obtaining the correct API to manufacture pills, or obtaining cheaper versions of the medicine via parallel trade.<sup>89</sup> Criminal enterprises may be increasingly involved in pharmaceutical counterfeiting.<sup>90</sup>

At this point the reader may complain that blaming the IP system for counterfeiting is akin to blaming the law for crime.<sup>91</sup> That position may not be as controversial as it may first appear. The Apostle Paul, writing to the Church in Rome said: “And where there is no law there is no transgression”<sup>92</sup> and “Indeed I would not have known what sin was except through the law. For I would not have known what coveting really was if the law had not said, ‘Do not covet.’”<sup>93</sup> However, we are not opening a discussion of law and sin. The narrower point is that if the ostensible goal of pharmaceutical IP law is to promote innovation, then counterfeiting demonstrates that the law is ill-suited to achieving that goal.<sup>94</sup> This is especially true if alternatives are available which fund R&D without creating the pricing ratios found attractive by counterfeiters.

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<sup>88</sup> LEW KONTNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 1, available at [http://www.fffenterprises.com/web\\_pages/anticounterfeiting.html](http://www.fffenterprises.com/web_pages/anticounterfeiting.html), at 1 (last visited Oct. 1, 2006).

<sup>89</sup> Brown, *supra* note 21 (discussing methods used to create counterfeit drugs). See Pharmaceutical Arbitrage, *supra* note 25, at 205–06 (explaining that parallel trading involves purchasing drugs in lower-priced markets and re-selling them in higher-priced markets).

<sup>90</sup> *FDA Eyes New Tactics Against Fakes*, CBS NEWS, Oct. 3, 2003, available at <http://www.cbsnews.com/stories/2003/09/26/health/main575354.shtml> (last visited Oct. 1, 2006) (indicating that organized crime groups are attracted to the sale of counterfeit pharmaceuticals because of financial incentive).

<sup>91</sup> ALLIANCE AGAINST COUNTERFEITING & PIRACY, PROVING THE CONNECTION 7, available at <http://www.allianceagainstiptheft.co.uk/Proving-the-Connection.pdf> (last visited Oct. 1, 2006) (noting various incentives for selling counterfeit products).

<sup>92</sup> *Romans* 4:15 (New International Version).

<sup>93</sup> *Id.* at 7:7.

<sup>94</sup> See Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, TRADE NOTE 20 (World Bank Group/Int'l Trade Dep't) Feb. 7, 2005, at 9, available at <http://siteresources.worldbank.org/INTRANET/TRADE/Resources/Pubs/TradeNote20.pdf> (explaining that the lack of flexibility when attempting to overcome drug patents “can have a detrimental impact on public health.”).

A. *Counterfeiting Is A Major Threat To Pharmaceutical Innovation*

Counterfeits are an imminent danger to innovation. While the FDA still considers it a relatively rare practice,<sup>95</sup> counterfeiting is nevertheless growing rapidly in the United States and in other high-income markets.<sup>96</sup> In 2000, the estimated value of EU pharmaceutical counterfeiting was more than 1.5 billion Euros.<sup>97</sup> In 2003, the United Kingdom-based Anti-Counterfeiting Group estimated that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting,<sup>98</sup> and recent estimates range even higher.<sup>99</sup> Given a pharmaceutical global market exceeding \$500 billion, the total lost to counterfeiting may exceed \$30 billion per year.<sup>100</sup> If true, counterfeiting is a major threat not only to public health, but also to innovation, far outstripping the limited potential damage from government reimbursement systems and equitable access programs.

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<sup>95</sup> COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, *supra* note 27.

<sup>96</sup> The FDA estimates that pharmaceutical counterfeiting has increased in the past few years. *See, e.g.*, Mary Pat Flaherty & Gilbert M. Gaul, *Anti-Counterfeit Steps by Drugmakers Sought: Legislators' Goal Is To Halt Illegal Sales*, WASH. POST, Jan. 17, 2004, at A11; Mary Pat Flaherty & Gilbert M. Gaul, *Miami Man Charged with Selling Counterfeit Lipitor*, WASH. POST, Dec. 6, 2003, at E1; Mary Pat Flaherty & Gilbert M. Gaul, *Lax System Allows Criminals to Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A1. These articles were part of a series of articles on counterfeit drugs by Mary Pat Flaherty and Gilbert M. Gaul that ran in the Washington Post during Fall 2003/Winter 2004. The Wall Street Journal has also covered the story. Anna Wilde Mathews & Heather Won Tesoriero, *Bogus Medicines Put Spotlight on World of Drug Distributors*, WALL ST. J., Sept. 29, 2003, at A1.

<sup>97</sup> Pharmaceutical Arbitrage, *supra* note 25, at 269–70.

<sup>98</sup> THE ANTI-COUNTERFEITING GROUP, WHY YOU SHOULD CARE ABOUT COUNTERFEITING 14 (2003), available at [http://www.a-cg.com/guest\\_frames.html](http://www.a-cg.com/guest_frames.html).

<sup>99</sup> *See* Bryan A. Liang, *supra* note 57 (stating that expenditures in the U.S. for prescription drugs is about \$230 billion, while the worldwide sales of counterfeit drugs equals approximately \$32 to \$35 billion dollars annually, meaning an average loss of 13% of sales revenues to the counterfeit markets).

<sup>100</sup> *See* David Greising & Bruce Japsen, *Pharmaceutical Companies Feeling Potent Effect of Fakes*, CHICAGO TRIB., Nov. 20, 2005, available at <http://www.chicagotribune.com/business/chi-0511200306nov20,1,2099145.story?coll=chi-business-utl> (last visited Oct. 1, 2006) (citing a World Health Organization study finding that counterfeit drugs cost the pharmaceutical industry \$32 billion a year; *Global Pharmaceutical Market Grew 7% in 2005 to \$602 Billion; Emerging Markets in Asia, Latin America and Eastern Europe Gain Strength*, FINFACTS IRELAND, Mar. 22, 2006, available at [http://www.finfacts.com/irelandbusinessnews/publish/printer\\_1000article\\_10005271.shtml](http://www.finfacts.com/irelandbusinessnews/publish/printer_1000article_10005271.shtml)).

*B. Government Reimbursement Systems In High-Income Countries Are A Less Significant Threat*

The patent-based drug industry argues that European-style government reimbursement systems threaten pharmaceutical innovation.<sup>101</sup> The industry and the US Department of Commerce have attacked high-income countries for their price-conscious reimbursement systems for drugs, labeling these efforts as “price controls.”<sup>102</sup> Name calling of this sort ignores the fact that many US government programs employ similar or more restrictive techniques, including Medicaid, the US Public Health Service, the Veterans’ Administration, or the Federal Supply Schedule.<sup>103</sup> The sum of the allegedly lost patent rents equals no more than \$7.5 billion per year,<sup>104</sup> and is likely to be much smaller, as low as \$355 million.<sup>105</sup> In any case, these numbers are much smaller than the pharmaceutical patent rents lost to counterfeiting.<sup>106</sup>

*C. Alternatives To Patent-Based R&D Cost Recovery May Eliminate The Incentive To Counterfeit*

A possible solution to reduce the incentive to counterfeit would be to remove R&D costs from the retail pricing system. Generally, these proposals fund R&D as a global public good through a variety of approaches. A prominent example of this approach is the Hubbard-Love R&D Treaty.<sup>107</sup> Broadly similar

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<sup>101</sup> See innovation.org, Preserving Incentives for Innovation, [http://www.innovation.org/index.cfm/InnovationToday/KeyIssues/Preserving\\_Incentives\\_for\\_Innovation](http://www.innovation.org/index.cfm/InnovationToday/KeyIssues/Preserving_Incentives_for_Innovation) (last visited Oct. 1, 2006).

<sup>102</sup> INT’L TRADE ADMIN., U.S. DEP’T OF COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION viii (2004), available at <http://trade.gov/td/chemicals/drugpricingstudy.pdf>.

<sup>103</sup> Kevin Outtersson, *supra* note 45 at 55–56.

<sup>104</sup> *Id.* at 58.

<sup>105</sup> *Id.* at 59 (stating that a report based on industry data estimates increased revenues from raising foreign prices would result in \$5.3 to \$8 billion in additional Research and Development (R&D), but pointing out the controversial nature of the feasibility of raising prices and predicting the potential revenue increases will be limited to approximately ¼ of that estimated by the industry).

<sup>106</sup> See *infra* Part III.A. (stating that approximately \$30 billion is spent annually on counterfeit medication which could otherwise be spent on licensed pharmaceuticals which would increase R&D funds by approximately \$9 billion, assuming, as the Department of Commerce did, that 1/3 of profit increases will be reinvested into R&D).

<sup>107</sup> See, e.g., Tim Hubbard, Remarks at Colombia Univ.: Alternatives to the Price System (Dec. 4, 2003), available at



approaches are currently being discussed at the WHO Executive Board.<sup>108</sup> Supporters generally seek to enhance financial access to patented pharmaceuticals by low and medium income populations.<sup>109</sup>

If R&D cost recovery is removed from the retail price system, then the pricing ratios described above collapse. All medicines would be sold essentially as generics. This result satisfies the access needs of the poor, and it also destroys the vast majority of the incentive to counterfeit. The best solution to the scourge of counterfeit drugs may involve radical examination of our society's reliance on IP law for recovery of pharmaceutical R&D costs.

## V. CONCLUSION

Very little is really known about the scope and nature of counterfeit drugs. Congress should obtain real facts before it criminalizes behavior which may be socially valuable. We need data on counterfeiting which is free from industry control and bias. Our primary focus should be protecting our pharmaceutical supply chain from criminal counterfeiters that serve no positive social value. This problem also presents an opportunity to re-evaluate the foundations of the pharmaceutical IP systems to see if a better world is possible.

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[http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines\\_papers.html](http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html); James Love, Remarks at Colombia Univ.: A New Trade Framework For Global Healthcare R&D (Dec. 4, 2003), *available at* [http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines\\_papers.html](http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html). A recent treatment of these subjects was done by Peter Drahos. Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights*, AUSTRIAN J. OF DEV. STUDIES (forthcoming 2006) *available at* <http://cgkd.anu.edu.au/menus/workingpapers.php>.

<sup>108</sup> WORLD HEALTH ORG., GLOBAL FRAMEWORK ON ESSENTIAL HEALTH RESEARCH AND DEVELOPMENT, EXECUTIVE BD. RES. 13 (Jan. 27, 2006) *available at* [http://www.who.int/gb/ebwha/pdf\\_files/EB117/B117\\_R13-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB117/B117_R13-en.pdf) (last visited Oct. 1, 2006).

<sup>109</sup> *Id.*