First of all we would like to commend the US government for initiating a dialogue aimed at trying to enhance the global fight against piracy. This is a fight that is critical to maintaining US competitiveness, and one that we risk losing unless we can work creatively with our trading partners to ensure that norms and enforcement practices are relevant and appropriate with respect to the challenges confronting modern society.

The record industry, together with all of the copyright industries, faces a piracy challenge of tremendous dimension and diversity. “Piracy” no longer has a single face. If we are to be successful in maintaining the integrity of copyright in the digital age, we must be prepared to successfully attack both physical and online infringement. We have provided a number of proposals for consideration in adapting best practices in the fight against piracy. These are not developed in a vacuum, but rather reflect our experiences in working with law enforcement authorities around the world in attempting to address piracy. We believe that it is essential to begin this process by carefully defining the nature of the challenges that are faced. We offer the following observations.

To begin with, enforcement authorities must recognize that the emergence of commercial scale CD-R piracy has localized pirate production, thus forcing a change in anti-piracy strategies away from uniquely trying to control production and towards simultaneously addressing of consumption as well (i.e. the offer for sale of pirate products in the marketplace). This should take place alongside the adoption of optical disc regulations (requiring the use of SID codes) in territories producing large quantities of pirate discs, or where the production capacity vastly exceeds legitimate needs. Policy makers and law enforcement authorities must also recognize that internet-based infringement, even when done without a profit motive, takes place on a commercial scale and has the same impact on copyright owners as for-profit piracy. It is essential—and required by TRIPS, to criminalize such conduct, even though the individual actor may not be acting with any profit incentive, or possess what one would ordinarily think of as "criminal intent."

We offer a number of fundamental observations. States should:

1- ensure that criminal penalties are adequate in law and implemented in practice to serve as a deterrent in light of the fact that any fine, no matter what size, can be absorbed as a cost of doing business;
2- amend criminal laws to make copyright offenses cognizable under organized crime and criminal conspiracy provisions, thus giving governments better investigative tools and resources in order to fight organized piracy;
3- criminalize the provision of raw materials in furtherance of piracy;
4- ensure that law enforcement officials have ex officio authority to seize any infringing materials, and that they are directed to seize, without complaint from the copyright owner, any materials that are offered for sale. (this is

necessary in light of the practical inability to control piracy by focusing exclusively on the suppression of illegal production--efforts need to be diversified and include market control).
5- secure ratification and implementation of the WIPO Treaties to ensure that adequate rights are established;
6- ensure that ISP's are required by law to engage in reasonable business practices with respect to the detection and removal of infringing files, preventing access to their networks on the part of known infringers; terminating the accounts of repeat or serious infringers; and employing available technological tools that would prevent infringement provided that use of such tools would not pose an unreasonable financial burden and would not impair the operation of the network;
7- ensure that persons or companies whose actions effectively “induce” the infringement of others are liable for copyright infringement, in line with the US Supreme Court decision in ***Grokster***
8- amend criminal laws so that they relate to the present internet "piracy" problem by applying criminal penalties to acts undertaken WITHOUT any commercial purpose when they are done on a commercial scale, like making materials available through the internet as was done in the US via the Net Act; and
9-increase the ability of law enforcement agencies from different countries to cooperate with each other in multi-territorial cases, including by securing broad adherence to the Cybercrime Convention

Enforcement Best Practices

A. Legal Obligations

Parties shall:

1. Make deterrence against piracy and counterfeiting a priority legal matter.

2. Provide criminal sanctions for any act of copyright infringement that takes place on a commercial scale, including in the online environment, regardless of whether such acts are undertaken with a financial incentive.

3. Make it a criminal offense to import or export, manufacture, sell or otherwise distribute a device or system, or a component of a device or a system, knowing or having reason to know that the device or system is primarily used or designed to circumvent technological protection measures used in conjunction with materials protected by intellectual property rights.

4. Provide monetary fines and sentences of imprisonment for the importation, exportation, distribution, sale or other manner of making available of counterfeit or pirated goods sufficient to deter future infringements, consistent with a policy of removing the infringer's monetary incentive .

5. provide for the availability of civil and injunctive relief against landlords that fail to reasonably exercise their ability to control the infringing conduct of their tenants.

6. In territories with high rates of production of pirated optical discs, provide for a system of licensing prior to the manufacture or export of optical discs, as well as the import or export of manufacturing equipment, and manufacturing materials, including optical grade polycarbonate, "stampers" and "masters."

B. Investigatory Provisions

Parties shall:

1. provide law enforcement authorities ex officio powers to investigate criminal infringements of intellectual property rights and initiate criminal actions on their own initiative.

2. permit law enforcement authorities, both at the border and internally, to seize clearly infringing copyright and trademark materials and to seize and/or place under seal equipment or materials suspected of being used to produce such infringing copies without the need for a complaint from the right holder, and without regard to whether protected materials have been recorded or otherwise registered with border authorities.

3. allow law enforcement officials to communicate and share information with right holders with respect to material evidence

of infringement of intellectual property that officials have in their possession.

4. ensure that courts have the authority to issue ex parte search orders.

5. provide that orders by judicial authorities need not individually identify the items subject to seizure, so long as they fall within general categories specified in the order.

C. Border Control

Parties shall:

1. Provide that goods that have been determined to be pirated or counterfeit by competent authorities at the border shall be destroyed, except in exceptional cases.

2. In no event authorize their border authorities, except in exceptional circumstances (such as to facilitate a controlled delivery or other law enforcement operation), to permit the exportation or transshipment of counterfeit or pirated goods.

3. Provide that competent authorities have the authority to initiate border measures ex officio, with respect to imported, exported, or in-transit merchandise suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods, without the need for a formal complaint from a private party or right holder, and regardless of whether the relevant right that is being infringed is recorded with Customs otherwise registered.

4. In civil judicial proceedings concerning the enforcement of intellectual property rights, provide that judicial authorities have the authority to order a party to desist from an infringement, in order, inter alia, to prevent, immediately after they clear customs, the entry into the channels of commerce in the jurisdiction of those authorities of imported goods that involve the infringement of an intellectual property right, or to prevent their exportation.

D. Seizure of Materials

Parties shall:

1. Provide that judicial authorities have the authority to order the seizure of suspected counterfeit, pirated or other infringing goods, any related materials and implements including that used in the commission of the offense, any assets traceable to the infringing activity, and any documentary evidence relevant to the offense.

2. Provide that orders by judicial authorities need not individually identify the items subject to seizure, especially when the seizure involves a large amount of infringing items, so long as they fall within general categories specified in the order.

3. Allow for ex parte freeze orders to give the territory's authorities and rights holder an opportunity to ensure that infringer's profits are confiscated and that monetary damages are recoverable.

E. Destruction of Materials Determined to be Pirated or Counterfeit

Parties shall:

1. Provide that goods that have been determined to be pirated by competent authorities shall be destroyed, except in exceptional circumstances.

2. Provide that courts shall confiscate and destroy the equipment used for the manufacture of pirated goods in order to ensure that infringing parties do not repeat their illegal activities,

3. Provide that goods determined to be infringing are subject to forfeiture and destruction regardless of whether any action for infringement is initiated, whether civil, administrative or criminal and without any compensation of any kind to the defendant, and

regardless of whether there has been any finding of liability on the part of any person.

F. Evidentiary Standards

Parties shall:

1. Provide that the person whose name is on the protected material is presumed to be the relevant right holder.

2. Provide that proof of ownership may be obtained by means of an affidavit, unless this issue is placed into question by material evidence to the contrary.

3. Provide that the presumption of ownership may be rebutted only if the defendant is able to provide concrete evidence to the contrary.[1]

4. As a deterrent to groundless defenses, award plaintiffs full costs and fees for overcoming frivolous challenges to titles.

G. Transparent Judicial Proceedings, Policies and Guidelines

[1] Absent proof to the contrary, the physical person or legal entity whose name is indicated as author, producer, performer or publisher of the work, performance or phonogram shall be presumed to be the lawful right holder.

Parties shall:

1. Provide clear, transparent, and predictable judicial proceedings, policies, and guidelines related to intellectual property enforcement.

2. Provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights be in writing and state any relevant findings of fact and reasoning or the legal basis on which the decision or rulings are based

3. Publicize information on their efforts and actions to provide effective enforcement of intellectual property rights in their civil, administrative, and criminal systems, including any statistical information that may be collected for such purpose.

4. Publish information related to respective intellectual property enforcement actions, including relevant statistical information.

H. Penalties

Parties shall:

1. Establish policies or guidelines that encourage judicial authorities to impose remedies at levels sufficient to deter future infringements and to adequately compensate right holders, particularly bearing in mind that many large scale infringements

are properly understood as criminal conspiracies and/or organized crime.

2. Establish statutory minimum and maximum penalties that are adequate to deter persons that engage or contemplate engaging in acts of piracy.

3. Provide, whenever law enforcement authorities' investigatory powers are dependent on the level of minimum/maximum penalties available for criminal infringements, that criminal penalties are set at a level that ensures that law enforcement authorities have adequate powers to investigate copyright infringements. For example, penalties should be set at a level that ensures that law enforcement officials have the authority to initiate investigations, search premises, seize goods, and arrest suspects of criminal activity.

4. Continuously monitor the level of fines imposed and where necessary issue sentencing guidelines to ensure that fines imposed by the judicial authorities remove all gains from the infringer and deter future infringements.

5. Provide that right holders are entitled to recover their costs of investigation and litigation against infringers of intellectual property rights.

6. Provide that courts have the authority to close commercial outlets and manufacturing plants that have been used to manufacture or distribute pirate or counterfeit products.

7. In criminal matters, provide that competent authorities keep an inventory of goods and other materials proposed to be destroyed, and have the authority temporarily to exempt such materials from the destruction order to facilitate the preservation of evidence upon notice by the right holder that it wishes to bring a civil or administrative case for damages.

I. Monitoring Activities

Parties shall:

1. With respect to A.1 above, provide adequate safeguards against the unauthorized manufacture of infringing optical discs, and provide that facilities producing such products comply with the standards established by the association of replicators (IRMA) in their Anti-Piracy Compliance Program.

2. Compel manufacturers of optical discs in their territory to maintain complete and accurate records to enable right holders and public authorities to trace the person or entity that ordered the infringing discs.

3. Require that OD replicators apply unique source identification codes to all optical discs, including master discs and stampers. Secure and unique identifiers enable the tracing of the source of a product and provide a deterrent against piracy.

Online Infringing Activities

Parties shall:

Provide exclusive rights under copyright to unambiguously cover internet use.

Establish appropriate rules regarding liability of service/content providers:

(a) establishing primary liability where a party is involved in direct infringement; and ensure the application of principles of secondary liability, including contributory liability and vicarious civil liability, as well as criminal liability for aiding and abetting if appropriate.

(b) establishing liability for actions which, taken as a whole, encourage infringement by third parties, in particular with respect to products, components and/or services whose predominant application is the facilitation of infringement.

3. Provide remedies and injunctive relief against any entity that:

(a) creates or otherwise maintains directories of infringing materials;

(b) provides "deeplinks" to infringing files;

(c) commits any act, practice or service that has little or no purpose or effect other than to facilitate infringement, or that intentionally induces others to infringe (specifically allowing proof of "intent" by reference to objective standards--i.e. a reasonable person would surmise such an intent);

4. Require internet service providers and other intermediaries to employ readily available measures to inhibit infringement in instances where both legitimate and illegitimate uses were facilitated by their services, including filtering out infringing materials, provided that such measures are not unduly burdensome and do not materially affect the cost or efficiency of delivering legitimate services;

5. Require internet service providers or other intermediaries to restrict or terminate access to their systems with respect to repeat infringers.

6. Establish liability against internet service providers who, upon receiving notices of infringement from content provides via e-mail, or by telephone in cases of pre-release materials or in other exigent circumstances, fail to remove the infringing content, or access to such content, in an expeditious manner, and in no case more than 24 hours;

or

Provide that, in the absence of proof to the contrary, an internet service provider shall be considered as knowing that the content it stores is infringing or illegal, and thus subject to liability for copyright infringement, after receiving notification from the right holder or its representative, normally in writing, including by

email or by telephone in the case of pre-release materials or in other exigent circumstances.

Establish, adequately fund and provide training for a computer crimes investigatory unit.

Provide injunctive relief against intermediaries whose services are used for infringing activities regardless of whether damages are available.

Establish policies against the use of government networks and computers, as well as those networks and computers of companies that have government contracts, to prevent the use of such computers and networks for the transmission of infringing materials, including a ban on the installation of p2p applications except, and to the extent to which, some particular government use requires such installation.

Consideration to be given to the following: possible rules on data retention, the right to information giving right holders access to data held by ISPs in the preparation and course of proceedings including in civil proceedings, and availability of complete and accurate WHOIS data.

Organizational Issues

Parties shall:

1. establish anti-piracy units, including at a minimum Police and Customs officers. Such units will gather intelligence on IP crime in order to facilitate policy formulation and generate criminal investigations. Units would be expected to prepare annual reports on the criminal environment in the key IP sectors. This would document key facts on manufacturing sources and distribution networks, including any international links/exports. Reference would be made, inter alia, to key personalities, organized crime groups, and links to terror networks.

2. establish single point of contact for law enforcement officials from other countries, as well as for affected right holders.

PRINCIPLES FOR THE ANTI-COUNTERFEITING TRADE AGREEMENT

In response to the February 15, 2008 request for comments published in the *Federal Register*, the undersigned entities submit the following principles that should guide the U.S. delegation in negotiating the Anti-Counterfeiting Trade Agreement (ACTA).

- ACTA should focus on the facilitation of legal action against those entities and individuals that intentionally engage in counterfeiting and intellectual property infringement on a commercial scale for commercial purposes. ACTA should not target innocent intermediaries such as shippers, payments systems, search engines, online marketplaces, and Internet access providers that are used by those counterfeiters and infringers. Nor should ACTA target activities that fall within exceptions to exclusive intellectual property rights.

- While the elimination of counterfeiting and commercial infringement certainly is a very important objective, ACTA must ensure that the pursuit of counterfeit and infringing products does not unduly burden legitimate commerce, impede innovation, undermine consumer privacy, or restrict the free flow of information.

- ACTA should concentrate on measures relating to *enforcement* of intellectual property rights, not on substantive issues of intellectual property such as the scope of protection, limitations and exceptions, and secondary liability.

- ACTA should not serve as a vehicle for changing U.S. domestic law relating to intellectual property enforcement.

- ACTA should be technologically neutral and not create disparate burdens or obligations depending on whether a counterfeit product is sold online or offline. Similarly, ACTA should not encourage the imposition of technology mandates, such as the mandatory filtering of Internet traffic.

The Fact Sheet on ACTA distributed by the Office of the U.S. Trade Representative references provisions that may appear in ACTA. The following comments address some of those proposed provisions.

- **Public/private advisory groups**. Any advisory groups formed pursuant to ACTA must represent the broad spectrum of interests, including rightsholders, intermediaries, and consumers.

- **Consumer Public Awareness.** Public education campaigns must present a balanced and accurate view of intellectual property. Consumers should learn not only about exclusive rights, but also exceptions and limitations to those rights. If consumers are presented with simplistic and draconian perspectives, they will

reject them. ACTA should not mandate a specific role for governments in consumer awareness campaigns, but allow each government flexibility.

- **Internet distribution and information technology**. As noted above, ACTA should be technologically neutral. While the Internet does pose some unique challenges in terms of identifying, locating, and apprehending perpetrators, it is also far more transparent than other means of distribution and preserves far more evidence that can be used in enforcement proceedings. Furthermore, the harm caused by the distribution of counterfeit and infringing products through the Internet is qualitatively the same as the harm caused by other forms of distribution. Accordingly, special penalties that target the Internet are inappropriate.

Center for Democracy & Technology
Computer & Communications Industry Association
Consumer Electronics Association
EDUCAUSE
Library Copyright Alliance
NetCoalition
Visa Inc.

Office of the United States Trade Representative
ACTA@ustr.eop.gov
Attn Rachel Bae

Subject: (ACTA): Request for Comments: Federal Register: February 15, 2008 (Volume 73, Number 32)

British American Tobacco Group Comments

The British American Tobacco Group is grateful for the opportunity to submit some perspectives on the international ACTA negotiations to the U.S. Government.

Introduction

The illicit trade in cigarettes – counterfeiting and smuggling – is a serious problem. By our reckoning, it accounts for 6% of the world's global tobacco market, deprives governments of up to $20 billion in tax revenue annually, and costs our business upwards of $700 million per year. Illicit trade is a global problem that undermines increases in excise taxes and government regulation of our products.

British American Tobacco is absolutely committed to stamping out illicit trade. Internally, we have linked up our trademark protection, brand enforcement, supply chain protection and legal and regulatory efforts. Externally, we are working with customs and border officials in many of our key markets to help build capacity and better understand ways to address the problem. We have worked assiduously to ensure that our own house is in order by only supplying volumes of product that reflect the market profile and implementing systems that can assure us, and our government stakeholders, that we know where our product is going, how it is getting there, who is selling it and all the points in between. We share intelligence and information with governments around the world on a daily basis and we collaborate with authorities to seize illegitimate product while destroying all our used equipment to make it harder for illegal operators to set up shop.

ACTA

We applaud the efforts of the U.S. Government in negotiating the ACTA. We believe that ACTA will be a valuable tool to address the growing world market in counterfeit cigarettes. We would strongly advocate tobacco and tobacco products being prioritized in the course of the negotiations when specific areas of concern are being addressed. In terms of the elements of the potential agreement of particular interest to British American Tobacco, we would note that:

- A comprehensive agreement covering all products most susceptible to counterfeiting will make the agreement most credible and useful.

- The issue of enforcement is key and should be reiterated throughout the negotiations. Many countries have rules and laws that are simply not properly enforced. Many countries have no ordered or systemic mechanisms in place to

add teeth to anti-counterfeiting commitments. Both of these factors have to be addressed if the agreement is to genuinely improve the situation.

- Key vulnerabilities in the global trading system should be addressed to avoid creating safe havens for counterfeiters. We believe particular attention should be paid to Free Trade Zones. In 2002 there were approximately 3,000 Free Trade Zones spanning 116 countries. The growth since has been quite alarming both in numbers and in size. We view many of these zones as 'hotspots' that operate as gateways to counterfeit product and reduce the capacity for supply-chain control. An agreement that does not seek to address enforcement measures in Free Trade Zones will be weaker as a consequence.

- Capacity building of enforcement officials will need to be addressed in the negotiations. This is an area where companies who are already invested in capacity building in key markets may be of assistance. British American Tobacco is committed to capacity building in many of our markets and has good partnership agreements that may add value to the ACTA agenda.

- It is important that ACTA seek to create new IP protection and enforcement provisions that exceed already existing agreements. In addition, it will be important for negotiators to recognize and create synergies with other parallel processes that are seeking to improve the enforcement climate, such as the negotiation of the Framework Convention on Tobacco Control Protocol on Illicit Trade in Tobacco Products.

- It is important to ensure that all ACTA parties keep in mind commercial realities and real-world considerations in the course of the negotiations. For this reason, we see great value in maintaining ongoing private sector consultation. It is also why British American Tobacco very much appreciates the opportunity to provide comments for these negotiations.

In addition to the above remarks, British American Tobacco would like to endorse the comments submitted by the Business Action to Stop Counterfeiting and Piracy (BASCAP) and International Trademark Association (INTA), two organizations in which we actively participate.

Again, I'd like to reiterate our gratitude in being able to provide our views on this process and please let me take the opportunity to emphasize once more that British American Tobacco remains committed, internally and externally, to doing everything possible to reduce and eliminate illicit trade.

With kind regards,

Pat Heneghan
Global Head of Anti-Illicit Trade
British American Tobacco

BSA®
BUSINESS SOFTWARE ALLIANCE

Robert W. Holleyman, II
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March 20, 2008

Mr. Stanford K. McCoy
Acting Assistant USTR for Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

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

Dear Mr. McCoy:

This letter responds to the Request for Public Comments appearing in the Federal Register on February 15, 2008. The request invites submissions from the public concerning specific matters that should be the focus of an anti-counterfeiting trade agreement that USTR seeks to negotiate with US trading partners.

The Business Software Alliance (BSA)* strongly supports USTR's efforts to address counterfeiting and piracy through a plurilateral trade agreement that strengthens international cooperation, enforcement practices, and participants' legal frameworks.

Piracy in the Software Sector and its Economic Impact

BSA companies, and the software industry as a whole, lose billions of dollars to software piracy each year. In 2006 35% of PC software placed in service was illegally copied. In many countries the piracy rate exceeded 75%, reaching highs of 90% or more in some markets. The resulting losses total more than $39 billion worldwide. These losses have an impact on local economies around the world that go well beyond the direct impact to software producers. A recent IDC study estimates that reducing software piracy by 10 points over four years could stimulate the entire IT sector and produce 600,000 new jobs, $24 billion in increased tax revenues and $141 billion in new economic growth.

Software Industry Efforts to Reduce Piracy

BSA and its individual members devote significant financial and human resources to preventing piracy worldwide. Our efforts are multi-faceted.

First, we are engaged in extensive educational efforts, designed to increase public understanding of the value of intellectual property and to improve overall awareness of copyright laws, on a global basis.

Second, we work closely with national and international bodies to encourage adoption of laws that strengthen copyright protection and promote an environment in which the software industry can continue to innovate.

Finally, where appropriate, BSA undertakes enforcement actions against those involved in the unlawful use, distribution or sale of its members' software. On the Internet, for example, BSA conducts a far-reaching "notice and takedown" program. BSA also engages in civil litigation against corporate end-users who are using our members' products without authorization. We work closely with local, national and international law enforcement bodies to protect the intellectual property rights of our members.

Software Industry Expectations for ACTA

In response to the request for "specific matters that should be the focus of such and agreement," there are a number of elements that we propose for inclusion in ACTA. These elements would have a direct, beneficial impact on industry efforts to reduce piracy of business software.

- ***Government software legalization:*** Parties to the agreement should take appropriate action (through legislation or administrative or executive decrees) to ensure that government agencies do not use infringing computer software and only use software as authorized in the relevant license agreement. These measures should regulate both the acquisition and management of software for government use. The US government and the governments of many of our trading partners have already adopted such measures. Legalizing public sector software use provides a valuable example to private businesses, as well as reducing piracy rates directly.

- ***Statutory damages:*** Parties should establish and maintain a range of pre-established (statutory) damages that are available in civil infringement cases at the election of the right holder. These damages should be in an amount sufficient to deter future infringements and to compensate fully the right holder for the harm caused by the infringement.

- ***Prohibition on illicit product packaging and labels:*** ACTA parties should strengthen anti-counterfeiting enforcement rules by prohibiting trafficking in illicit product packaging and labels (e.g., stolen or misapplied labels or packaging elements that indicate product authenticity). These materials, once taken out of the legitimate supply chain, are destined inevitably for use in connection with pirate products in order to deceive consumers and law enforcement. Nonetheless, some

countries laws against counterfeiting do not cover these materials unambiguously.

- ***Clarification of the meaning of "copyright piracy on a commercial scale":*** Article 61 of the TRIPS Agreement requires parties to "provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting copyright piracy on a commercial scale." The US and a number of other trading partners have interpreted "copyright piracy on a commercial scale" to include end-user software piracy when committed willfully by a business entity. ACTA provides an opportunity for like-minded trading partners to confirm this interpretation among themselves.

- ***IP address collection:*** In a number of European countries one of the biggest impediments to efforts by right holders to enforce their IP rights on the Internet is the overbroad interpretation of privacy laws by some European authorities that has arguably made it illegal for right holders effectively to investigate open and notorious piracy. These authorities consider Internet Protocol (IP) addresses to be personal data that cannot be collected or used without the permission of the individual with whom the data are associated. This interpretation not only impedes online enforcement, it also stymies efforts by the software industry to provide security products that protect consumers from computer viruses, phishing, spyware and malware, and other harmful activities. We urge the US government to raise these concerns – particularly with our European trading partners – within the framework of the ACTA negotiations.

- ***Resources for law enforcement:*** Another key impediment to effective enforcement of IP rights around the world is inadequate resources for authorities tasked with IP law enforcement. The agreement should make clear that, notwithstanding Article 41.5 of the TRIPS Agreement, decisions by governments concerning the allocation of enforcement resources will not excuse that country from complying with its obligation to provide adequate and effective protection and enforcement of IP rights.

Tech Industry Concerns about Mandated Use of Technologies

As a right holder organization, BSA supports truly voluntary, industry-led cooperation between right holders and ISPs as a means of combating online infringement. There are complex technical and policy issues that must be addressed for such a voluntary system to function effectively and fairly.

However, BSA opposes the imposition of regulatory requirements on ISPs and technology providers aimed at detecting, intercepting or preventing

online copyright infringements. The regulatory process simply cannot keep pace with technological change. Moreover, technology develops most effectively in response to market forces. Government mandates would stifle innovation and retard progress. Consequently, BSA would oppose the inclusion of any such requirements within the ACTA framework.

Of course, technology plays a role in protecting intellectual property rights. Content owners must take responsibility to ensure that their works are not easily subject to theft, rather than rely wholly on others to protect their intellectual property. Accordingly, BSA's members have invested hundreds of millions of dollars and thousands of engineering hours in developing technologies to protect content and intellectual property. Our companies have worked diligently, voluntarily and cooperatively with content providers and consumer electronics companies to create systems that will foster the legitimate distribution of digital content. Experience clearly demonstrates, however, that there is no silver bullet technological solution that will solve the problem of piracy.

* * * * *

Thank you for the opportunity to provide the views of our industry on this important initiative. We look forward to working with the Administration as this effort moves forward.

Sincerely,

Robert W. Holleyman, II
President and CEO

** The Business Software Alliance (www.bsa.org) is the foremost organization dedicated to promoting a safe and legal digital world. BSA is the voice of the world's commercial software industry and its hardware partners before governments and in the international marketplace. Its members represent one of the fastest growing industries in the world. BSA programs foster technology innovation through education and policy initiatives that promote copyright protection, cyber security, trade and e-commerce. BSA members include Adobe, Apple, Autodesk, Avid, Bentley Systems, Borland, CA, Cadence Design Systems, Cisco Systems, CNC Software/Mastercam, Corel, Dell, EMC, HP, IBM, Intel, McAfee, Microsoft, Monotype Imaging, PTC, Quark, Quest Software, SAP, Siemens PLM Software, SolidWorks, Sybase, Symantec, Synopsys, and The MathWorks.*

Submission of the Cable and Satellite Broadcasting Association of Asia (CASBAA)
to the Office of the U.S. Trade Representative
March 20, 2008

Negotiation of an Anti-Counterfeiting Trade Agreement

The Cable and Satellite Broadcasting Association of Asia (CASBAA) is a trade association with activities in 15 Asian countries and regions, dedicated to the promotion of multi-channel pay-television via cable, satellite, broadband and wireless video networks. Founded in 1991, CASBAA represents some 125 member companies, which serve more than 3 billion people. US-owned member organizations include AETN International, Bloomberg Television, Boeing Space Systems, Comcast International Media, CNBC Asia, Discovery Networks Asia, ESPN Star Sports, HBO Asia, Intelsat, Microsoft, Morgan Stanley, the Motion Picture Association, Motorola, MTV Networks Asia Pacific, National Geographic Channel, NBC Universal, Playboy Entertainment, Paul, Weiss, Rifkind, PricewaterhouseCoopers, Qualcomm, Cisco, Sony Pictures Television International, STAR Group (NewsCorp), Time Warner, Turner International Asia Pacific, Voom HD Networks, and Walt Disney Television International.

CASBAA appreciates USTR's request for input on the matters to be covered by an Anti-Counterfeiting Trade Agreement (ACTA). The Request for Public Comment notes that an ACTA should address "today's challenges" in the field of intellectual property protection; we would urge that as far as possible, the new agreement should be forward-looking, addressing not only the patterns of infringement that are epidemic today, but also those emerging threats that – with the propagation of new technologies and increases in broadband network capacity – are likely to create common forms of international infringement tomorrow.

This is particularly true insofar as our industry is concerned: the rapid spread of broadband internet capacity in many countries has produced a situation where widespread piracy of video content – previously deterred or delayed by a lack of bandwidth – is becoming more easy and therefore more common. Many of these patterns of infringement are becoming increasingly international, with computer servers, index sites, and upload locations present in one country being used to feed piracy in many other countries. Forms of content, such as broadcasts of sporting events which – because of their immediacy and high time-value – have in the past not been widely pirated (on optical media, for example), are now increasingly susceptible to real-time piracy.

Given the many and growing international linkages in these patterns of piracy, we believe it is essential that effective action to address the problem be taken on an international scale. National legislation and national efforts must be supplemented by international cooperation. In this respect, we warmly welcome the initiative to negotiate an ACTA, as we believe such an agreement will set a benchmark for international cooperation that will become a reference, not only for the states and trading entities which are parties to the agreement, but also for the entire international community.

We believe, therefore, that an ACTA can and should be an extremely high-quality agreement. The negotiating parties should not accept a "lowest common denominator" approach that restricts the ACTA to provisions already in place in other broad international trade agreements. Rather, they should seek to include new provisions to cover areas of emerging importance in international infringement. A search for expeditious results is laudable; but we urge the negotiating parties not to allow the quest for speed to mitigate in favor of a weaker agreement. The overriding goal should be achievement of an agreement that sets the highest possible international standards for cooperation in this area.

CASBAA suggests three areas of particular relevance to the international pay-TV industry, for attention in the ACTA:

1) Signal Piracy: The ACTA should recognize that infringement of copyrights through interception and unauthorized commercial use of international satellite transmissions is a serious and growing problem in many parts of the world. As a technical matter, it is not possible to narrowly restrict satellite transmissions to the territory of individual countries. However, misuse of the signals can and should be addressed. Parties to the treaty should agree upon effective action to prevent all commercial misuse of such signals.

Common commercial infringements in today's world include:

-- Unauthorized interception, decryption and retransmission of encrypted broadcast signals to multiple customers of commercial cable networks or other broadcasters.

-- Unauthorized interception, decryption and retransmission of encrypted broadcast signals to multiple dwelling units by apartment building managers, as part of their building management business.

-- Unauthorized interception, decryption and public exhibition of encrypted broadcast signals, in public commercial venues such as restaurants, bars, hotels, and members' clubs.

-- Unauthorized distribution and use of broadcast signals (whether encrypted or unencrypted) to increase traffic to and through online websites.

-- Other unauthorized distribution and use of broadcast signals (whether encrypted or unencrypted), such as via pirated DVDs.

(It should be stressed that even where broadcast streams are delivered on an unencrypted basis, this does not imply authorization for retransmission of this content, or otherwise detract from the intellectual property and other legitimate rights of the content owner and/or licensee. Any use of unencrypted content also requires the consent of the content owner and/or licensee, and unauthorized use can significantly damage the brands and business models of broadcasting organizations.)

In all of these areas, the ACTA should embody international agreement that the damage to the interests of rights holders and broadcasters should be the principal criterion for setting penalties.

In addition to these commercially-based infringements, we believe that the ACTA should also address the problem of individual use of circumvention devices to view unauthorized broadcast programming. End-user piracy of this type should be made a criminal offense, so that governments cut off the financial flows that support the circumvention industry, and to send an unambiguous message to individuals about what is right and what is wrong.

We would suggest the following additional specific means of attacking these problems, for inclusion in the ACTA:

-- Agreement that, where publicly-licensed infringing organizations are misusing broadcast signals, governments will act *suo moto* to suspend those licenses. (These might include cable operating licenses, telecom licenses, public spectrum licenses, or business operating licenses.) Final judicial determination of copyright violations should *not* be required to invoke license suspension; regulatory authorities should be empowered to act under their own administrative procedures. Licenses of repeat offenders should be totally revoked without hope of renewal.

-- Application of strong criminal penalties to commercially-motivated retransmission of unauthorized broadcast signals to more than a minimum number of premises (say, 5 homes).

-- In civil law, enactment of statutory damages of sufficient size to have a meaningful deterrent effect which will also take into account the difficulty in assessing the damage to copyright holders and broadcasting organizations from public exhibition or retransmission of a single broadcast signal.

2) <u>Unauthorized online distribution of video programming:</u> Increasingly, online piracy includes not only individual works of video programming but entire streams of broadcast programming. We would urge the negotiating parties to ensure that ACTA's treatment of online piracy take account of the fact that, apart from the ownership of the individual works in question, ongoing piracy of broadcast streams does incalculable damage to the

brands and business models of broadcasting organizations. ACTA's provisions should include measures to suppress piracy both by host servers and by P-2-P networks.

ACTA parties should also agree to apply adequate and effective penalties against those who profit from unauthorized downloading, as well as those who induce the online infringement of others. This category includes websites offering directory and search services for online content, as well as websites in one country which market infringing content which is actually hosted on servers in another jurisdiction.

3) International traffic in circumvention devices and services: A key support for international signal piracy, on both a commercial and individual level, is widespread trafficking in circumvention devices and services. ACTA parties should agree to apply adequate and effective border measures to interdict the supply of circumvention devices. Specifically, where an equipment supplier in one country has a record of trading in devices which function to circumvent pay-TV access controls or encryption, then future shipments of goods from that supplier should be subject to intensive inspection to ensure that those goods are not susceptible to use as circumvention devices.

ACTA parties should also agree to enact legislation to suppress the international supply of circumvention services, e.g. by the internet. (One real-world example concerns so-called "card sharing" of smart card encryption information: circumvention syndicates set up computer servers in one country which supply decryption data on a real-time basis which, when connected via the Internet to pre-equipped set top boxes, permit the mass unauthorized and unremunerated reception of pay-TV content. In some countries it is currently impossible to take legal action against such servers.)

General provisions:

A) We support creation of an effective peer review mechanism to allow ACTA parties to assess each others' policies and practices. Functioning international examples of such peer review mechanisms exist for several matters under the purview of the OECD and CSCE. An ACTA peer review mechanism should incorporate provisions for input from rights holders and other stake holders, so that the peers can examine the real-world impact of IP policies.

B) We also support creation of public-private cooperation in various forms to address the piracy problems. The pervasiveness and technical complexity of the intellectual property problems afflicting our industry mean that neither public administrations nor private operators have sufficient resources to address them individually; apart from specific infringement cases, public-private cooperation is essential to keeping an adequate level of enforcement awareness in an environment of constant technical change and development.

(Ends)

TO: The Office of the United States Trade Representative (USTR)

via ACTA@ustr.eop.gov

Colorcon, Inc. Response to Anti-Counterfeiting Trade Agreement (ACTA)

Request for Public Comments

Regarding International Cooperation, Enforcement Practices and Legal Framework Provisions

March 14, 2008

Submitted by:

Frederick R. Kettinger
General Manager
Brand Enhancement Services

This response regarding the request for public comments for ACTA (Anti-Counterfeiting Trade Agreement) international cooperation, enforcement and legal framework practices to contribute to the effective enforcement of Intellectual Property Rights (IPRs) and strengthening the relevant IPR enforcement measures is provided by Colorcon, Inc. with specific interest in protecting the public safety against counterfeit pharmaceuticals.

Specific comments requested and addressed below include:

- ACTA International Cooperation
- ACTA Enforcement Practices
- ACTA Legal Framework

Our comments are as follows:

ACTA International Cooperation

Pharmaceutical counterfeiting is a global problem affecting the health and lives of people around the world. Counterfeit drugs present a global financial burden as well as a health and safety burden, currently projected to approach $75 billion (U.S. Dollars) in lost pharmaceutical sales revenues by 2010. All peoples of the world and all pharmaceutical companies are affected by the threatening acceleration of counterfeit drugs both as a health and safety issue as well as an economic impact on the cost of drugs. Currently it is estimated that on the global level, 10% of all drugs are counterfeits.

This global problem can only be resolved through international cooperation. Intellectual Property Rights with specific focus on Trademark Protection needs to be embraced by all countries worldwide as trading partners. Trademark law is well established throughout the world through the Paris Convention, the Madrid Agreement and Madrid Protocol for International trademarks, various regional trademark systems such as the European Community Trademark system, etc. The International Trademark Association (INTA) has served to harmonize international trademark law throughout the world, thereby establishing a legal platform upon which countries can cooperate in managing and controlling the legal flow of product brands and the prevention of counterfeit trade. In the United States, this same platform enables pharmaceutical companies to leverage the power of IPR protection through Trademark Registration in conjunction with Customs Border Protection Recordation of the Registered Trademark. It is this platform that would serve to harmonize ACTA International Cooperation to resist the growing counterfeit pharmaceutical exportation and importation threat to public safety.

ACTA Enforcement Practices

Effective anti-counterfeit drug enforcement practices require cooperation between the pharmaceutical industry and IPR Enforcement by the governments of the world.

Branded and generic pharmaceutical products flow across country borders. Pharmaceutical supply chain security is a global issue. Counterfeit breach of global supply chains through repackaging and counterfeit introduction requires strengthening of IPR Enforcement worldwide to protect the public at the package level as well as the dosage level.

Pharmaceutical companies, both brand innovators as well as generic manufacturers, apply their Trade name, trademark or brand to the drug package and often the product dosage. Additionally, pharmaceutical product innovators are trending to design unique dosages to enable trademarking of the actual dosage design including the color, shape, size and imprint logo of the dosage (much like the trademark for the unique shape of the Coca Cola® bottle). For example, the Viagra® (sildenafil citrate) tablet manufactured by Pfizer, Inc. is a globally registered trademark for the blue color and diamond shape of the tablet for erectile dysfunction. The tablets contain the name Pfizer to identify the manufacturer. Pfizer has utilized the registered trademark of the Viagra tablet to enable legal protection against counterfeit importation into the United States. In this regard, Enforcement Practices utilize the registered trade name of the manufacturer and/or the registered trademark design of the dosage plus recordation of the registered trademark with Customs Border Protection (as in the United States and other countries), to enable Customs Border Protection (CBP) through existing IP law and enforcement systems, to identify and authenticate imported pharmaceuticals. Customs and Border Protection in the United States can serve as a model for international harmonization as it serves to protect against the importation of goods which infringe / violate Intellectual Property Rights (IPR) by devoting substantial resources toward identifying and seizing shipments of infringing articles. Global governmental conventions and alliances to coordinate the same approach to IPR protection are essential to preventing counterfeit pharmaceutical importation at the border.

Anti-counterfeiting enforcement technologies, to identify and authenticate pharmaceutical dosages versus counterfeit dosages, are being applied by pharmaceutical manufacturers to their products while meeting FDA and global regulatory and safety requirements for the ingestion of the product(s) by patients. Some of these systems are forensic requiring laboratory analysis, but the latest technology now provides for quick identification and authentication of pharmaceutical solid dosages in the field. The quick identification and authentication systems are covertly applied to the dosage form, and can provide Customs Border Protection with quick, economical and confident field determinations of a product's authenticity or counterfeit status. It is also anticipated that these systems will be interoperable with electronic Track and Trace anti-counterfeiting and e-Pedigree systems currently being developed in the United States and Europe. These systems can be applied to branded products as well as generic products with inspection guidance available to Customs Border Protection agents. Generic products present a special concern for import authentication, because generic products may be plain, white, round tablets that are easy for counterfeit replication. Generic products can easily be identified and authenticated by these on-dosage enforcement systems. These systems in conjunction with ACTA Border IP Enforcement can provide a critical security check point for import protection for the public from counterfeit drugs. The on-dosage anti-counterfeiting systems are critical to ensuring that the actual drug dosage is not counterfeit while in an authenticated package. It is the drug that is ingested by the patient, and it is therefore the drug, not the package, that absolutely must be authenticated.

ACTA Legal Framework

A model of the legal framework for global IP Protection and counterfeiting import prevention exists in the United States as a coordinated multi-agency enforcement team under the Immigration and Customs Enforcement (ICE) organization. The ICE organization can protect IP

from counterfeit importation through the protection of Trademarks that are registered in the United States Patent and Trademark Office and are Recorded with the Customs Border Protection (CBP). Registered Trademarks can be recorded with the CBP at: http://cbp.gov/xp/cgov/import/commercial_enforcement/ipr/ipr_enforcement/ipr_protect_infringe.xml
The recordation of the Registered Trademark allows for the CBP to prevent import Trademark infringement by "Counterfeits" and "Confusingly Similar" articles. The definitions for these terms are as follows:
"Counterfeit" – A spurious (false, non-genuine) trademark which is identical to, or substantially indistinguishable from, a federally registered U.S. trademark.
"Confusingly Similar" – A mark which is similar to the genuine trademark such that it is likely to cause confusion as to source or sponsorship.
The legal framework and Enforcement Systems described above, for registered and CBP-Recorded Trademarks, can provide the following protection:

- Aid in CBP detection of counterfeit pharmaceutical solid dosages
- Reduce potential for "confusingly similar" products
- Enable border control of violative imports (Exclude from entry, detain, and / or seize articles)
- Facilitate government criminal prosecution of violators (e.g. through inter-agency coordination with the FBI, Postal Inspection, Coast Guard, TSA, DOC, Federal State and Local Law Enforcement. Also, through International Customs Coordination as currently through Europe).
- Broadens penalties: Financial and incarceration

Intellectual Property Trademark Law with Customs Border Protection Laws and Enforcement, as coordinated in the U.S. by Immigration and Customs Enforcement to protect against counterfeit importation, can serve as a legal framework model for international coordination and application throughout the world.

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.
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I. INTRODUCTION

When I chose the title, *Counterfeit Drugs: The Good, the Bad and the Ugly*,[1] 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,[2] WHO fact sheets,[3] FDA press releases,[4] U.S.

[1] With apologies to Clint Eastwood and Sergio Leone (1967).

[2] Associated Press, *FDA: Al–Qaida Could Poison Medicines*, MSNBC, Aug. 12, 2004, *available at* http://msnbc.msn.com/id/5682351.

[3] 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].

[4] 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,[5] law review articles,[6] medical journals,[7] and international trade associations.[8]

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.[9] Drug companies are reluctant to release information that might harm the marketing efforts for their branded products.[10] 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.[11] 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.[12] Instead, I

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

[5] 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.

[6] *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).

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

[8] *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").

[9] 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.

[10] *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 GlaxonSmithKline refused to release information about potential counterfeits because of the negative effect it would have on business).

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

[12] *See* E-mail from Dr. Sebastian J. Mollo, Pharmaceutical Security Institute, to Kevin Outterson (on file with author).

was directed to the FDA, WHO and news reports.[13] 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.[14] Further, "[WHO] estimates that one in ten medicines sold worldwide is fake, with no medical effect whatsoever."[15] Yet another statistic is that "[i]n developing countries, up to 25% of the medicines used are counterfeit or substandard."[16] In fact, the WHO reports that "[s]ome estimates place the annual earnings from counterfeit medicines at over $32 billion globally."[17] 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."[18] But the WHO doesn't really defend this figure when pressed, and generally cites figures from the U.S. FDA.[19]

In the U.S., the FDA cites the WHO figures for global counterfeiting estimates.[20] 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."[21]

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[13] *Id.*

[14] 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 [hereinafter Nurses Raise the Alarm].

[15] Nurses Raise the Alarm, *supra* note 14.

[16] *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.

[17] Nurses Raise the Alarm, *supra* note 14.

[18] 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).

[19] *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%.").

[20] *See id.*

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

European officials also rely on the WHO estimates.[22] 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%."[23]

The pharmaceutical industry historically was reticent to discuss counterfeiting, for obvious reasons.[24] With the advent of consumer drug purchasing over the Internet, suddenly the industry was faced with cross–border arbitrage pressure.[25] 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.[26] 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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[22] 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).

[23] *Id.*

[24] *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).

[25] Kevin Outterson, *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].

[26] 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.[27] Less precise terms are used in press accounts[28] and by the U.S. and E.U. drug regulatory agencies.[29] In some cases, the terms *fake* or

[27] *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 [hereinafter COUNTERFEIT DRUG TASK FORCE INTERIM REPORT]. This definition conflates counterfeits with poorly manufactured or stored products.

[28] *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].").

[29] *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/importeddrugs0714.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 (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 [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.[30]

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."[31] These drugs may be poorly produced, or too strong by U.S. standards, but they should not be lumped together with criminal counterfeits.[32] 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.[33] A prime example is prescription drugs purchased by U.S. citizens from

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

[30] *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.bmjjournals.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.

[31] 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.

[32] 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.

[33] *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.[34] The purchase is legal, but the FDA states that bringing these drugs back into the United States violates federal law.[35] 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.[36]

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

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

[34] 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).

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

[36] 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. (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.

[37] *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.).

[38] *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).

[39] *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.[40] This leads to the second distinction: this trade is not driven by criminals.[41] United States residents fill prescriptions in Canada because the products appear fungible with a transparent price differential.[42]

The primary negative effect of Canadian cross–border foot traffic is the lost pharmaceutical patent rents.[43] The patent–based pharmaceutical companies make a smaller profit when the prices are lower.[44] 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.[45] The dynamic effects may be positive if indeed current U.S. prices are supra–optimal.[46] Social welfare is improved if the market expands by selling therapeutically-equivalent drugs to lower–income populations with highly elastic demand curves.[47] Whether parallel trade is a net gain is

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

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

[42] *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).

[43] *See* Kevin Outterson, 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/KevinOutterson3january.pdf (indicating that patents allow drugs to be priced above the marginal cost of production).

[44] *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.").

[45] *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 Outterson, Associate Professor, West Virginia University College of Law), *available at* http://help.senate.gov/Hearings/2005_02_17/outterson.pdf (last visited Oct. 1, 2006).

[46] Pharmaceutical Arbitrage, *supra* note 25, at 197.

[47] *Id.* at 195; *see generally* Outterson, *supra* note 43 (explaining how charging higher prices to low–income populations often results in mortality for those unable to afford the drugs).

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

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.[51] US trade officials responded with quite intemperate language. A compromise was reached before the compulsory license was issued.[52] 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.[53] Many of these drugs were pre–qualified by the WHO.[54] Some have now even been approved by the FDA,[55] and yet they violate intellectual property (IP) law. These drugs provide affordable access to millions of people with AIDS.[56]

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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[48] Pharmaceutical Arbitrage, *supra* note 25, at 195–96, 206.

[49] 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 (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.

[50] *See* Outterson, *supra* note 43.

[51] Todd Benson, *Brazil to Copy AIDS Drug Made by Abbott*, N.Y. TIMES, June 25, 2005, at C12.

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

[53] *See* Kevin Outterson, *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.

[54] *See* Vanishing Public Domain, *supra* note 53, at 73; Hirschler, *supra* note 53.

[55] Hirschler, *supra* note 53.

[56] Vanishing Public Domain, *supra* note 53, at 73–74.

containing negligent or deliberate contaminants or poisons.[57]

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.[58] 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.[59] 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.[60]

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.[61] 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.[62] For limited English proficiency (LEP) populations, receiving a prescription with the proper U.S. FDA labels is practically useless.[63] For example, it

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

[58] *Id.*

[59] *See* William K. Hubbard, *supra* note 29.

[60] *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].

[61] *See id.*

[62] 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.*

[63] *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.[64]

Ugly drugs might also include products imported from legitimate Internet pharmacies.[65] 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.[66] Instead, most of the non–functional counterfeit drugs in the United States appear to have domestic origins or domestic networks.[67] The cause of this trade is simply the price differentials across borders.[68] The preferred solution of the FDA is to shut the trade down.[69] 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[70] and State–based

& 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").

64 *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).

65 *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).

66 *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).

67 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.

68 *See* Pharmaceutical Arbitrage, *supra* note 25, at 277–80.

69 *See* William K. Hubbard, *supra* note 29 .

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

importation plans, such as I-Save Rx,[71] 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.[72] Criminals follow the money. They typically counterfeit expensive patented drugs rather than generics.[73] The IP system creates the opportunity that counterfeiters exploit.[74]

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.[75] 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.[76] These drugs are sold at 60 times their marginal

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).

[71] *See* 29 Ill. Reg. 7108 (2005) (discussing the I–Save Rx program).

[72] *See* Vanishing Public Domain, *supra* note 53, at 91.

[73] *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).

[74] 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).

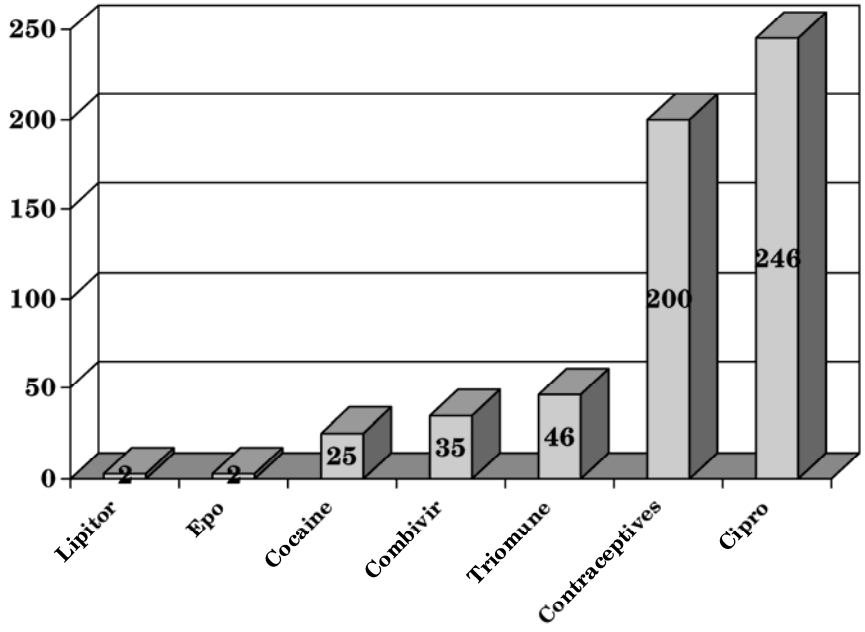
[75] Drugstore.com, Trizivir, http://www.drugstore.com/pharmacy/prices/drugprice.asp?ndc=00173069100&trx=1Z5006 (last visited Oct. 1, 2006) (listing the price of the antiviral anti–HIV medication Trizivir® based on a two pill per day dosage as $12,773.56).

[76] 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).[77] 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,[78] 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.[79] Others have found pricing ratios of 200:1 in global markets for vaccines and contraceptives.[80]

Table 1. Rx Pricing Ratios



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

[77] *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).

[78] 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).

[79] Pharmaceutical Arbitrage, *supra* note 25, at 254.

[80] 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.[81] The potential returns from parallel importation of some patented drugs are higher than cocaine by an order of magnitude.[82] Patented drugs are especially attractive if the markets are less crowded and law enforcement is less diligent.[83]

The story gets worse. These ratios are built by comparing safe and effective versions of a drug sold in different markets.[84] All of these pricing ratios assume that the criminal intends to deliver actual functional pharmaceuticals.[85] 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.[86] By the time it is noticed, it may be very difficult to re–trace the supply chain to the point where the counterfeit was introduced.[87] Some commentators reluctantly acknowledge that

msf.org/prod/publications.asp?scntid=20920021811218&contenttype=PARA& (last visited Oct. 1, 2006).

[81] *See* Pharmaceutical Arbitrage, *supra* note 25, at 262 (comparing the street price in producing countries and the street price in the US).

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

[83] Liang, *supra* note 57. Brian Liang and others have decried the poor law enforcement resources dedicated to pharmaceutical counterfeiting.

[84] *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).

[85] Liang, *supra* note 57.

[86] *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.

[87] *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."[88]

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.[89] Criminal enterprises may be increasingly involved in pharmaceutical counterfeiting.[90]

At this point the reader may complain that blaming the IP system for counterfeiting is akin to blaming the law for crime.[91] 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"[92] 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.'"[93] 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.[94] 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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[88] LEW KONTNIK, PHARMACEUTICAL COUNTERFEITING: PREVENTING THE PERFECT CRIME 1, *available at* http://www.fffenterprises.com/web_pages/anticounterfeiting.html, at 1 (last visited Oct. 1, 2006'.

[89] 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).

[90] *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).

[91] 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).

[92] *Romans* 4:15 (New International Version).

[93] *Id.* at 7:7.

[94] *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/INTRANETTRADE/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,[95] counterfeiting is nevertheless growing rapidly in the United States and in other high–income markets.[96] In 2000, the estimated value of EU pharmaceutical counterfeiting was more than 1.5 billion Euros.[97] In 2003, the United Kingdom–based Anti–Counterfeiting Group estimated that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting,[98] and recent estimates range even higher.[99] Given a pharmaceutical global market exceeding $500 billion, the total lost to counterfeiting may exceed $30 billion per year.[100] 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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[95] COUNTERFEIT DRUG TASK FORCE INTERIM REPORT, *supra* note 27.

[96] 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.

[97] Pharmaceutical Arbitrage, *supra* note 25, at 269–70.

[98] THE ANTI–COUNTERFEITING GROUP, WHY YOU SHOULD CARE ABOUT COUNTERFEITING 14 (2003), *available at* http://www.a-cg.com/guest_frames.html.

[99] *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).

[100] *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.

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.[101] 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."[102] 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.[103] The sum of the allegedly lost patent rents equals no more than $7.5 billion per year,[104] and is likely to be much smaller, as low as $355 million.[105] In any case, these numbers are much smaller than the pharmaceutical patent rents lost to counterfeiting.[106]

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.[107] Broadly similar

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[101] *See* innovation.org, Preserving Incentives for Innovation, http://www.innovation.org/index.cfm/InnovationToday/KeyIssues/Preserving_Incentives_for_Innovation (last visited Oct. 1, 2006).

[102] 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.

[103] Kevin Outterson, *supra* note 45 at 55–56.

[104] *Id.* at 58.

[105] *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).

[106] *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).

[107] *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.[108] Supporters generally seek to enhance financial access to patented pharmaceuticals by low and medium income populations.[109]

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.

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. 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.

[108] 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 (last visited Oct. 1, 2006).

[109] *Id.*

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July 8, 2008

Stanford K. McCoy
Acting Assistant USTR for Intellectual Property
Office of the U.S. Trade Representative
Washington, D.C.

Re: Anti-Counterfeiting Trade Agreement/ Request for comments

Dear Mr. McCoy:

Your February 15th Federal Register notice does not provide much detail concerning the differences between the proposed ACTA and existing TRIPs obligations. Nevertheless, there are some areas where an expansion of TRIPs would be helpful.

By way of example: Last month, I was a guest lecturer for CLDP (U.S. Department of Commerce) at a program in Ukraine for that country's IP enforcement authorities (Customs and National Police). The Ukrainians are clearly trying hard to comply with the conditions of their WTO accession, and have a rather comprehensive program which is generally TRIPs-compliant. I was surprised to discover, however, that the Ukrainian IP law does not distinguish counterfeiting and piracy from other forms of infringement. While there are criminal penalties for counterfeiting, there is no way for enforcement authorities to tell whether a dispute is a simple infringement claim or outright counterfeiting. The result has been to refer almost all cases to the judiciary as if they were civil infringements. This makes actual enforcement almost impossible for front-line authorities, and renders the criminal sanctions (or even seizures) very difficult.

I know that many countries' codes have similar problems. However tough penalties might be for counterfeiting and piracy, they become meaningless unless Customs and national police have the explicit authority to act against clear violations without serial referral to the courts to determine the distinctions between counterfeiting and infringement.

If nothing else, ACTA should address this problem, since other provisions of such agreements will be moot if counterfeits and pirated goods cannot be clearly identified as a matter of law.

I appreciate the opportunity to comment on this matter, and invite you contact me if you

have any questions or comments.

Very truly yours,

/s/

Donald E. deKieffer

DISTILLED
SPIRITS
COUNCIL
OF THE
UNITED
STATES

March 21, 2008

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

By email: ACTA@ustr.eop.gov

Re: Anti-Counterfeiting Trade Agreement -- Request for Public Comments

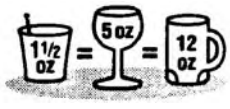
Dear Ms. Bae:

On behalf of the Distilled Spirits Council of the United States, Inc. (DISCUS or Council) and its member companies, I am pleased to submit these preliminary comments in response to USTR's request for comments (73 *Fed. Reg.* 8910 (Feb. 15, 2008)) concerning the specific matters that should be the focus of the proposed Anti-Counterfeiting Trade Agreement (ACTA). As you may be aware, the Distilled Spirits Council is a national trade association representing U.S. producers, marketers, importers and exporters of distilled spirits products. In 2007, U.S. imports of distilled spirits exceeded $5 billion in value (CIF); U.S. exports in 2007 were valued at more than $1 billion (FAS value). Measured by retail sales prices, the total value of the global distilled spirits market exceeded an estimated $288 billion in 2006.

The vast majority of globally-traded distilled spirits are high value, branded products with widespread consumer recognition. Counterfeiting is a serious problem in some overseas markets. As a consequence, DISCUS and its members wholeheartedly endorse USTR's proposal to negotiate the ACTA and we urge the United States and the other participants to commence formal negotiations as soon as possible. We also encourage USTR to solicit the broadest possible participation among key trading partners, including countries where counterfeiters operate. Indeed, multilateral negotiations such as the ACTA negotiations may provide an avenue for governments grappling with serious counterfeiting problems to participate in a constructive way toward identifying and remedying the problems they – and we – face.

At this early stage of the negotiations, we have identified four specific matters that we strongly urge be reflected in the ACTA. These are based broadly on the spirits industry's experiences in tackling counterfeiting problems in a number of countries. This list is not intended to be exhaustive, but merely to suggest a few general principles that we believe are central to anti-counterfeiting efforts in the distilled spirits sector. The points are:

- Inclusion of a provision making the counterfeiting of foods and beverages a criminal offense under public health or food safety laws, with mandatory jail terms for persons



convicted of manufacturing, distributing or retailing dangerous foods or beverages that threaten health or safety;

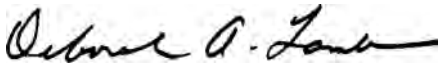
- Incorporation of a "zero tolerance" principle, *i.e.*, the elimination of thresholds for criminal penalties, where counterfeiting involves foods or beverages, since consumption of such products involves potentially serious risks to health and safety;

- Requirement for the establishment of clear and transparent standards for the imposition of criminal penalties, with escalating and substantially increased fines and penalties for repeat infringers. It has been the spirits industry's experience that many countries provide for minimum penalties for infringement of intellectual property rights, but these "minimums" become, in effect, the ceiling for penalties since authorities often do not impose fines or penalties that exceed the minimum penalty specified, except in the most egregious cases; and

- Designation in each participating country of a high-level officer or task force responsible for coordinating anti-counterfeiting initiatives across ministries and agencies, together with a commitment to provide the officer or task force with adequate resources, funding and authority to mount an effective anti-counterfeiting effort. The designated officer or task force would serve as a coordination point internally (ideally ensuring more efficient allocation of resources and improved information-sharing) and externally (to provide a single point of contact for companies/industries that are encountering problems with counterfeit goods).

These suggestions represent our initial thoughts concerning the specific matters that, in our view, should be reflected in the ACTA. We look forward to providing additional views as the negotiations proceed. We would be pleased to provide any additional information that USTR may find helpful.

Sincerely,



Deborah A. Lamb
Senior Vice President
International Issues and Trade

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

The Electronic Frontier Foundation (EFF) is pleased to submit the following comments to the Office of the United States Trade Representative (USTR) in response to the Request for Public Comments on a Proposed Anti-Counterfeiting Trade Agreement, published in the Federal Register of February 15, 2008 (Volume 73, Number 32, pages 8910-8911).

Executive Summary

Part III of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement), together with the 1996 WIPO Copyright Treaty and Performances and Phonograms Treaty, Model Provisions of the World Customs Union, and bilateral cooperation agreements, provide WTO Member States with a sophisticated array of remedies to enforce intellectual property rights both within, and across, WTO members' national borders. In addition, U.S. bilateral free trade agreements since 2002 have routinely required foreign trading partners to comply with a set of specific enforcement obligations beyond the internationally agreed standards embodied in the TRIPs Agreement.

EFF believes that no empirical evidence has been provided justifying the creation of a new TRIPs-plus plurilateral intellectual property enforcement treaty backed by the sanctions of international trade law. However, if the USTR decides to negotiate such a treaty, at a minimum it should (1) protect the fundamental privacy rights and freedom of expression of citizens of the U.S.A. and its trading partners, and (2) facilitate a global environment that fosters interoperability and is conducive to technology innovation.

Most importantly, any treaty on enforcement of intellectual property must balance the needs of all stakeholders. As treaty proponents have stated, a key part of effective enforcement is citizens' respect for copyright and other intellectual property laws. That is not just a matter of education in the narrow sense of telling consumers about the content of statutes. It is instead a matter of social value and fairness. In short, citizens will only respect a copyright system that is balanced, and serves the interests of all stakeholders. In the effort to curtail genuine commercial-level copyright infringement, the USTR must avoid harming other important public policy priorities, including in particular, citizens' privacy and expression rights, and technology innovation. If enforcement mechanisms are perceived to undermine the traditional balance embodied in the copyright system, it is inevitable that there will be less respect for, and correspondingly lower compliance with, copyright law.

Lack of Transparency

Unfortunately, the Request for Public Comments published in the Federal Register on February 15, 2008 contained very little information about the substance of the proposed trade agreement. EFF is aware of the existence of a "Discussion Paper" on the proposed

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substance of such an agreement, which is apparently circulating among content industry representatives, but is not aware of any substantive information about the agreement emanating from the Office of the USTR. In the absence of a specific text to comment upon, these comments focus on the appropriate scope of any proposed agreement, and three aspects of recent copyright enforcement activity that have raised significant public policy concerns, and which we anticipate could form part of the content of any proposed treaty.

1. Scope of Treaty

Part III of the TRIPs Agreement reflects the current level of international agreement about standards and methods for enforcement of intellectual property rights. We understand that the proposed agreement would cover the same scope – namely "counterfeit trademarked goods" and "pirated copyright goods" as those terms are used in Part III of TRIPs and defined in footnote 14 to the TRIPs Agreement:

> *(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;*
>
> *(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.*

Accordingly, we understand that the agreement would not apply to *all* copies of copyrighted works, but instead only to those copies (a) that would be an infringement of one of the exclusive rights granted to copyright holders by section 106 of the U.S. copyright statute, (b) that are made willfully, with the intent to commit copyright infringement, and (c) are made for the purpose of commercial gain. Thus, "counterfeit" goods do not include unauthorized but permitted uses of copyrighted works, such as uses that would be considered "fair use" under U.S. copyright law.

For the sake of clarity, we note that the internationally agreed definition of "counterfeit" works set out in the TRIPs agreement differs markedly from the broader definition used by particular entertainment industry groups calling for a new enforcement treaty, which would appear to encompass all unauthorized uses of works, including uses that are lawful

but not specifically authorized by rightsholders, such as non-infringing fair use under U.S. copyright law[1].

2. Internet Intermediary Liability

The U.S. Copyright statute contains four "safe harbors", limiting Internet intermediaries' liability for secondary copyright infringement for routine activities: acting as a conduit of Internet communications, caching of material, hosting of user created content, and provision of information location and search tools (17 U.S.C. §512). This regime has created a relatively stable environment for innovation and facilitated the development of robust hosting platforms, which have made possible a comprehensive and free worldwide encyclopedia (Wikipedia), a rich world of user created content (YouTube, MySpace), global economic enterprises (eBay, Amazon.com) and powerful search tools (Google, Yahoo!). There is no international harmonization of secondary copyright liability concepts and standards across countries. However, in recognition of the economic importance of the safe harbor regime to the U.S. telecommunications industry, this regime has been exported to the legal regimes of U.S. trading partners through the enforcement chapter of all bilateral and regional free trade agreements signed since 2002, as a specific implementation of Article 41 of the TRIPs Agreement.

The stable innovation environment resulting from harmonized limitation of liability regimes in the U.S., EU and elsewhere, is now under threat from various sources. Copyright owner industry groups have attempted to overturn the balance struck in the U.S. copyright safe harbor regime, in efforts to clamp down on perceived widespread online copyright infringement by Internet users. These efforts endanger fundamental privacy rights of Internet users and threaten the end-to-end principle that is central to the Internet's open architecture. Reflecting the decision in *Religious Technology Centre v. Netcom On-line Communication Services, Inc.*, 923 F. Supp. 1231 (N.D. Cal, 1995), the U.S. safe harbor regime specifically states that Internet Service Providers (ISPs) and Online Service Providers are not required to monitor, nor affirmatively search for evidence of potential infringement on their networks (17 USC §512(m)).

Major film and music copyright industry groups in Europe have recently advocated for a suite of proposals that seem to jeopardize this foundational principle. A memorandum produced by the International Federation of Phonographic Industries circulated to European Parliament staffers in November 2007 calls on the European Parliament to mandate that ISPs block communications using particular Internet protocols, install network-level filtering, and block access to websites that facilitate copyright infringement.[2] In December 2007, a proposed amendment to a European Parliamentary committee report would have required ISPs to filter their networks and monitor customer communications in order to find evidence of potential copyright infringement.

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[1] See International Federation of Phonographic Industries webpage entitled *"What is Piracy?"*, visited 19 March 2008:
<http://www.ifpi.org/content/section_views/what_is_piracy.html>

[2] <http://www.eff.org/files/filenode/effeurope/ifpi_filtering_memo.pdf>

If adopted, these proposals are likely to dramatically alter the current nature of the Internet. ISPs and Internet intermediaries will be obliged 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 they can be defeated by encrypting communications. Thus, mandatory network filtering is not likely to reduce online copyright infringement, but is likely to lead to file-sharing going "underground".

At the request of a major music industry rightsholder group[3], France and the United Kingdom have proposed draft legislation for a "graduated response" requiring ISPs to send a warning notice to alleged infringing subscribers, to suspend those customers' access on a second warning, and to terminate the Internet access of customers on the basis of a third rightsholder allegation of copyright infringement, independent of any judicial review. The French proposal also requires ISPs to create and exchange lists of "blacklisted" Internet users to whom Internet service cannot be provided.

In the digital age, as more of citizens' civic and cultural life takes place in online fora, excluding citizens from the ability to connect to, and communicate on the Internet, amounts to social exclusion from the knowledge economy. This is a disproportionate response to the harm in issue. As highlighted by the recent rejection of a similar termination proposal by Members of the Swedish Parliament, the penalty of exclusion from the Internet is far more severe than traditional copyright monetary sanctions, both for the individual involved, and also for society at large. It is likely to divide society into two communities – one, highly networked and able to take advantage of the educational, social and economic benefits that flow from access to the Internet, and a second, unable to access the Internet's rich informational resources nor utilize it for communications.

Imposing such an Internet access termination obligation via the proposed enforcement agreement, in order to meet the perceived needs of one group of rightsholder, is likely to create social division, and will certainly slow the momentum of technology innovation and impede the development of the Internet's global infrastructure.

Recommendation:

Any proposed agreement should respect countries' distinctive national legal regimes and not seek to impose secondary liability on ISPs and Internet intermediaries where none might otherwise exist under national law. The proposed agreement should incorporate remedies for rightsholders that are proportionate to the harm suffered from an incident of copyright infringement, and should not require Internet intermediaries to engage in

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[3] See 2008 IFPI DIGITAL MUSIC REPORT, *Introduction: Making ISP responsibility a reality in 2008*, and Section 5: *Time for Governments and ISPs to Take Responsibility*, available at: <http://www.ifpi.org/content/library/DMR2008.pdf>

mandatory termination of Internet access for their subscribers unless ordered to do so by a competent court, following a comprehensive judicial review.

3. Preserving Due Process and Copyright Enforcement

Article 47 of TRIPs allows, but does not require, WTO members to provide *judicial authorities* with the ability to order *infringers* to disclose the identity of third parties involved in an act of infringement, but only if this would not "be out of proportion to the seriousness of the infringement." EFF is disturbed by reports that major film and music copyright owner industry groups are seeking to include a *mandatory* obligation on ISPs to disclose to *rightsholders* information about the identity of alleged copyright-infringing file-sharers in the proposed agreement. An extra-judicial mandatory disclosure obligation raises very substantial privacy and due process concerns.

U.S. law does not currently provide an extra-judicial mechanism forcing disclosure of the identity of individuals allegedly engaged in file-sharing activity.[4] 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 20,000 lawsuits brought against individuals since 2003[5].

By comparison, the European Union introduced a mandatory disclosure obligation in the "right of information" enshrined in Article 8 of the 2004 Intellectual Property Enforcement Directive (2004/48/EC). National courts in the European Community have for some time been making determinations about requests for customer data made by European rightsholder organizations, taking into consideration EU Directive 2004/48/EC and the EU Information Society directive 2001/29/EC, the EU Electronic Commerce directive (2000/31/EC) and European personal data protection and privacy law (2002/58/EC).

However, following the European Court of Justice's decision in the *Productores de Música de España (Promusicae) v. Telefónica de España*[6] case where an ISP was not required to disclose customers' identity data, reports have surfaced that entertainment industry groups are seeking to incorporate a mandatory identity disclosure obligation in the proposed anti-counterfeiting trade agreement. From the public policy perspective, mandating divulgence of customer data from intermediaries without providing appropriate due process and judicial review threatens citizens' privacy and personal data protection rights and is ripe for misuse by unscrupulous parties.

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[4] 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., 3*51 F.3d 1229 (D.C. Cir. 2003).

[5] EFF Report, *RIAA v. The People: Four Years Later*, available at: <http://w2.eff.org/IP/P2P/riaa_at_four.pdf>

[6] European Court of Justice 2008/C 64/12, 29 January 2008, Case C-275/06 referred from Juzgado de lo Mercantil No 5 de Madrid, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:064:0009:0010:EN:PDF>

Recommendation

The proposed treaty needs to provide balanced solutions that recognize and respect the fundamental rights of all stakeholders in the information society. At a minimum, any disclosure obligation must incorporate adequate due process and be conditioned on a process of judicial review.

4. Criminal sanctions for IP infringement

There is widespread agreement that actual commercial enterprise-scale counterfeiting and piracy are unlawful and harmful to investment in research and development, technology innovation and consumer protection. This is embodied in Article 61 of TRIPs, which requires WTO Members to provide criminal sanctions for *willful* copyright piracy and trademark counterfeiting done on *a commercial scale.*

It was well understood at the time of negotiation of TRIPs that criminal sanctions would be reserved for only the most serious, and commercially motivated, cases of IP infringement. While there is agreement for measures addressing genuine enterprise level infringement done willfully and with commercial motivation, there is no public policy justification for changing the contours of current copyright law and penalizing *non commercial* activities of individuals and legitimate business practices.

The last 10 free trade agreements entered into by the United States have required trading partners to introduce criminal sanctions for a broader set of purposes than required by the TRIPs Agreement, including for acts that are not done with commercial motive or intent of financial gain, mirroring the language introduced into 17 USC §605 by the No Electronic Theft Act.

Criminal sanctions are intended to be a deterrent. While they are appropriate in the case of commercial-scale wilful infringement, applying criminal sanctions to non commercially motivated and unintentional infringement serves no public policy purpose. At the same time, it will harm consumers and the environment for technology innovation.

Recommendation:

Criminal sanctions should be reserved for actual commercial-level profit-motivated infringement. The terms “commercial-scale” and “wilful” should be defined narrowly, as originally intended, and should not be expanded to encompass non-commercially motivated infringement. If the real intent behind introducing expanded criminal sanctions is to address infringement on the Internet, this provision is not likely to accomplish that, but is likely to cause significant collateral harm to consumers.

Given the very significant numbers of individuals who regularly engage in file-sharing, it would be more effective to promote new business models focused on licensing of content exchanged on the Internet, rather than creating new legal rules that would criminalize millions of individuals. U.S. copyright law already contains criminal sanctions for certain

behavior. As the experience of the last five years, and over 20,000 lawsuits against individual filesharers in the United States has shown, legal sanctions have had little or no appreciable impact on the volume of file-sharing taking place on public and private networks across the globe. There is no reasonable basis for believing that adding criminal sanctions in the proposed trade agreement will change this situation. On the contrary, all indications are that filesharers will migrate to encrypted communication channels, evading detection and prosecution by current procedures.

At the same time, adopting legal rules that criminalize the behavior of such a significant proportion of the population, for what is widely perceived to be a market failure, is likely to lead to a lessening of respect for copyright law. The proposed trade agreement should avoid undermining the normative force of intellectual property law.

We would be pleased to provide further information on any of the above issues.

Thank you for your consideration.

Gwen Hinze
International Policy Director
Electronic Frontier Foundation
Email: gwen@eff.org

Via email: ACTA@ustr.eop.gov

March 21, 2008

Ms. Rachel Bae
Director for Intellectual Property & Innovation
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

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

Dear Ms. Bae:

The Entertainment Software Association (ESA) makes this submission in response to the Federal Register Notice (FRN) dated February 15, 2008, requesting comments on specific matters that should be the focus of the Anti-Counterfeiting Trade Agreement (ACTA) negotiations between the U.S. government and a number of its trading partners.

The ESA is the U.S. association exclusively dedicated to serving the business and public affairs needs of companies that publish entertainment software for game consoles, personal computers, and the Internet. ESA members collectively account for more than 90 percent of the $9.5 billion in entertainment software sold in the United States in 2007, and billions more in export sales of entertainment software.

The FRN requested that comments be addressed to three areas to be covered by ACTA: (1) international cooperation; (2) enforcement practices; and (3) legal framework. ESA's comments highlight aspects of international cooperation that our association and members find valuable and hope to be advanced by this agreement. We also identify certain elements that should be made part of the legal framework of ACTA participants as we deem each necessary to the continued provision of effective and adequate protection of intellectual property rights in our members' products.

Before proceeding to specifics in that regard, ESA and its members also address concerns over the general framework for ACTA. Undoubtedly, the negotiation of ACTA will require significant effort, and it is important to weigh that against the value of the reforms that can realistically be achieved. In recent years, the U.S. government has achieved great success in concluding free trade agreements that embody high standards of intellectual property rights protection. It is important that ACTA negotiations be pursued along the lines of the concluded free trade agreements, continuing the success that has

already been achieved in these agreements as well as benefits to be gained from their implementation and enforcement.

Recommendations

(1) International Cooperation

ACTA will offer USTR a valuable opportunity to promote cooperative IP enforcement in a more geographically comprehensive way than is currently the norm and practice. It should strengthen cross-border cooperation of law enforcement against various forms of IP crime, including the manufacture, sale and export of infringing product from outside the U.S., as well as online violations.

International piracy rings are a particular challenge. These groups have spread their tentacles into multiple countries and coordinate their efforts on a global scale. Combating this piracy requires a global strategy, one that equips law enforcement with the tools they need to pursue criminals across national borders. ACTA has the potential to make a genuine improvement in this area if negotiators succeed in developing a high-level standard for cross-border cooperation on investigation and enforcement of IP-related crimes.

We appreciate that international cooperation on criminal matters is a delicate issue, and that the establishment of any international standards must take into account the autonomy of local law enforcement. If some trading partners are unwilling to take on heightened cooperation commitments, that would be an unfortunate setback for ACTA. Such a result would greatly diminish the overall value of ACTA to right holders and call into question the usefulness of the proposed agreement to achieve meaningful improvements where they are needed the most.

(2) Improvements to Legal Framework

With respect to standards to be included in the legal framework of partner countries, the ESA wishes to highlight the critical importance of including specific obligations governing 1) the protection of technological protection measures, and 2) ISP responsibility in the online environment (modeled on the FTA provisions).

1. Technological Protection Measures ("TPMs") which prevent unauthorized access to, or use of copyright materials, are indispensable in today's global electronic marketplace to differentiate products to meet consumer demands, and to prevent unauthorized exploitation and transmission of valuable software. The entertainment software industry has long used TPMs and other forms of digital rights management (DRMs) to protect its products, and these measures have contributed to the phenomenal growth of the video game industry. However, no matter how sophisticated, creative and innovative the technological protections employed, none are entirely foolproof. Many can be circumvented through the application of specially developed software and hardware

applications which descramble, decrypt, bypass or deactivate TPMs without the authority of the copyright owner. Unfortunately, there remains a rich and growing demand for such devices and services precisely because of the role that they play in facilitating and enabling piracy. "Mod chips," for example, make possible the play of a wide variety of pirated videogames that are currently made available through pirate sites or P2P services on the Internet. "Game copiers" contain copyrighted code that is extracted from cartridge-based games enabling users to upload pirated games to the Internet and download pirated games on blank memory cartridge media for use in the game devices. Because of their uses in connection with piracy, manufacturers and vendors of these circumvention devices can command a premium, for both the devices and the provision of services to install such devices into video game hardware, though they themselves might not be involved in the production of infringing copies.

Given the harm done by entities engaged in the manufacture, distribution and sale of devices used to circumvent TPMs, it is imperative that the ACTA enforcement chapter contain provisions obliging partner countries to enact prohibitions specifically addressed to the act of circumvention and to trafficking in circumvention devices, as well as provide deterrent criminal and civil remedies against those engaged in the provision of services and tools that circumvent TPMs. Such provisions will also serve to flesh out the commitment to adequate and effective enforcement of anti-circumvention obligations that most major trading nations have taken on in acceding to the WIPO Internet Treaties.

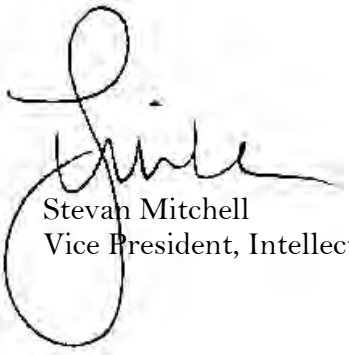
2. Internet service providers (ISPs) play a critical role in the online environment, and their assistance is vital in combating online piracy. Given the extent of online piracy, and the rise of digital distribution methods, it is critical that the ACTA enforcement chapter contain the elements necessary to providing an effective framework for enforcement against online piracy. ACTA partner countries should be obliged to provide incentives for ISPs to cooperate with right holders when informed of infringing activity occurring on their networks, to adopt measures to facilitate right holder action against online piracy (including mechanisms that will allow the disclosure of repeat infringer information to right holders as well as mechanisms that will facilitate the termination of repeat infringer accounts), and particularly in light of the growth of P2P piracy, adopt measures that would provide more effective enforcement against P2P services and other sites that facilitate unauthorized downloading. As technology evolves, it is possible that technical approaches to online piracy may yield useful results. IP legal regimes should be sufficiently flexible to encourage reasonable cooperation between ISPs and right holders in exploring streamlined mechanisms for curbing online piracy. With many copyright-based industries moving to online distribution methods, it is critical that they be able to deploy the necessary tools to protect their works, and they be able to count on meaningful cooperation from ISPs, since the latter benefit financially from, and play a key role in the delivery of, content online.

Conclusion

In sum, ESA calls for the negotiation of an agreement that significantly enhances the existing legal framework in certain prospective ACTA partners. ESA appreciates the

opportunity to provide comments at this initial stage of the negotiations, and welcomes additional opportunities for comment as the negotiations progress.

Sincerely,



Stevan Mitchell
Vice President, Intellectual Property Policy

Essential Action
P.O. Box 19405
Washington, D.C. 20036

March 21, 2008

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

Re: Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement

Dear Director Bae,

Essential Action submits the following comments to the Office of the United States Trade Representative (USTR) concerning a proposed Anti-Counterfeiting Trade Agreement (ACTA).

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. While we recognize that many other important issues are implicated by the proposed treaty, our comments focus particularly on concerns about the proposed ACTA in the context of the public health priority of ensuring access to safe and affordable medicines to patients around the world, regardless of income or wealth.

ACTA priorities

USTR's fact sheet and ACTA materials conflate patent, copyright and trademark infringement, "piracy" and counterfeiting. An agreement based on, or reflecting, such a conflation of distinct concepts is likely to be overly broad, proscribing behavior that cannot correctly be identified as counterfeiting and that is not necessarily detrimental to the public interest. For example, commercially interested parties sometimes cast compulsory licensing for medicines -- legal under national legislation and World Trade Organization rules -- as patent theft or "piracy," but no one can argue these practices bear any resemblance to counterfeiting. At the same time, an agreement focused on patent, copyright and trademark infringement is likely to overlook important options to control counterfeiting, including by requiring companies to disclose knowledge of counterfeit products.

A multilateral counterfeiting treaty should concern itself specifically and uniquely with the dangers and harms posed to the public by counterfeit goods. Paramount among these

concerns is the proliferation of unsafe and ineffective products. Sub-standard drugs, for example, threaten patient health worldwide. Notably, however, these dangers are not limited to counterfeit products: legitimate businesses, as well, commonly sell drugs with inappropriate amounts of the active ingredient, and a large percentage of brand-name drugs sold in the United States use raw materials manufactured in India, China and other countries in factories that are inadequately inspected by the Food and Drug Administration. The public interest in anti-counterfeiting, then, is not as a subset of patent, copyright and trademark enforcement, but rather a subset of state actions to ensure product safety and efficacy. At least as regards medicines, this suggests counterfeiting should be considered in a broader framework than the ACTA proposes.

Further, patents, trademarks and copyrights are private rights subject to private enforcement actions. While provided for in public laws, it is generally the responsibility of private parties to identify alleged violations of patents, copyrights and trademarks and bring suit. As proposed, ACTA would harness considerable public resources to strengthen the enforcement of these private rights. This use of public means for private ends is not only tangential to the legitimate public goals of protecting consumers from unsafe and ineffective products, it may also come at significant financial cost to taxpayers.

"Piracy"

ACTA's use of the term "piracy" also suggests an interest in capturing a much broader pattern of conduct than counterfeiting. Piracy as a term is not technically descriptive, but is instead broadly applicable and useful in the art of persuasion. Its inclusion in ACTA would open the agreement to abuse, and it should be eliminated. Conduct ACTA intends to regulate or discourage should be described in precise terms.

International cooperation: sharing of information and disclosure

USTR seeks input concerning the sharing of information between parties and cooperation of law enforcement agencies. Equally important is the sharing of counterfeiting information by legitimate private companies, which often have the first or most complete accounts of counterfeit products. Without private companies disclosing their knowledge, agencies will be handicapped in their law enforcement efforts.

For example, although pharmaceutical companies depend on law enforcement and public resources to locate counterfeits and maintain consumer confidence in their brands, companies do not always disclose what they know about counterfeits in the market. Reportedly, the Pharmaceutical Security Institute (PSI), formed by fourteen pharmaceutical companies in 2002, recorded 76 cases of counterfeiting in 2004. The FDA only knew of 58.[1] PSI's counterfeiting database is considered the world's best, yet

[1] "Counterfeit medicines – What are the problems?" Pharma-Brief Special, BUKO Pharma-Kampagne, a member of Health Action International (2007) at 5.

it "is not accessible to the WHO, health authorities or the public."[2] Industry groups seem to favor general public awareness of the counterfeiting problem, which may lead to public assistance in enforcement, but sometimes disfavor public knowledge of specific counterfeited products.

For example, in 1995, GlaxoSmithKline allegedly asked the Ghanaian government not to alert the public of the presence of fake halofantrine antimalarial syrup in the market, for the sake of the company's reputation.[3] In 2002 in Kansas City, BMS and Eli Lilly settled for $72 million with the families of deceased victims of counterfeit drugs, seemingly to avoid the precedent that drug companies could be held liable for failing to disseminate information about counterfeits.[4]

Governments should require companies to disclose any information they obtain about the existence of dangerous counterfeit products. If the public is to incur expenses combating counterfeiting, the public should at least have a right to the best information available so its enforcement activities are effective. We are concerned that proposals for mandatory disclosure requirements are absent from the available materials on the ACTA.

There are at least two existing proposals for statutory disclosure requirements. Cockburn *et al.* propose a model based on the United Kingdom Civil Aviation Authority's reporting requirements for suspected unapproved aircraft parts.[5] Companies would be required to report suspected counterfeits to regulatory agencies. The agency would then take responsibility for confirming the report and deciding whether and when to alert law enforcement and the public. Meanwhile, legislation introduced by Representative Steve Israel (2nd District of New York) proposed requiring drug companies to notify the FDA within two days of learning of a counterfeit threat.[6]

Enforcement practices: public/private advisory groups

USTR's ACTA fact sheet mentions provisions for advisory groups assisting in enforcement practices. It is important that any such advisory groups consist of balanced memberships representing not only industry, but also consumers, and, in the case of medicines, generics firms as well as brand-name companies. Overrepresentation of patent, copyright and trademark-dependent industries in anti-counterfeiting enforcement

[2] "The global threat of counterfeit drugs: why industry and governments must communicate the dangers." Robert Cockburn, Paul N. Newton, E. Kyerematen Agyarko, Dora Akunyili, Nicholas J. White, Public Library of Science (PLoS) Medicine, April 2005, Volume 2, Issue 4, at 305.

[3] BUKO, *supra*, and PLoS, *supra*. GlaxoSmithKline also was reluctant to share information about fake syrup with the authors of the PLoS article.

[4] PLoS, *supra*. There are, of course, counterexamples. "In 2002, Johnson and Johnson issued 200,000 letters to health care professionals in the US warning them of fake Procrit…within one week of being notified of a severe counterfeit problem." PLoS.

[5] PLoS, *supra* at 307.

[6] H.R. 2345, 109th Congress.

agencies could lead to enforcement priorities and expenses out of step with the public's interest in safe and effective products and a competitive marketplace.

Role of market forces

There is broad consensus that high prices of some legitimate products drive both supply and demand in markets for counterfeits. For example, according to the World Health Organization, "When the prices of medicines become excessively high and unaffordable, patients tend to look for cheaper sources. Such situation [sic] encourages counterfeiters to produce cheaper counterfeit drugs. … When price differences exist between identical products, patients and consumers go for the cheaper ones. This creates a greater incentive for counterfeiters to supply cheap counterfeit medicines." [7] Despite a relatively well-controlled drug supply, high prices make the United States an especially attractive target. "America has become the go-to market for counterfeiters because we pay the highest prices of anyone in the world," states Katherine Eban, author of "Dangerous Doses: How counterfeiters are contaminating America's drug supply."[8] Public Citizen commented to the FDA, "In our opinion, as the costs Americans pay for prescription drugs continue to skyrocket and as the disparity in these prices continues to grow in comparison to other countries the economic incentives for counterfeiting and selling substandard drugs increases proportionally. This incentive is now greater than ever before."[9]

Patent regimes, which often allow exclusive rights holders to set high prices without fear of competition, create incentives both to innovate and to counterfeit. The high cost of research and development is reflected in each consumer's purchase of a bottle of brand-name pills. By contrast, a prize system, in which medicines could be sold at marginal cost, with innovators compensated through prizes rather than marketing monopolies, would create incentives only to innovate. Counterfeiters would be forced to compete with low-price legitimate sales reflecting only the low overhead and manufacturing costs of each pill. Incentives to trade in fakes would dwindle. There are other possible measures to reduce prices, and which would also reduce incentives to counterfeit.

A treaty focused on counterfeiting should not fail to address the role of the high prices for medicines in promoting counterfeiting. We recommend that this matter be discussed in the context of any treaty negotiation, and that any resulting treaty include provisions for a study and review of the interconnections between high price and counterfeiting, and possible measures to contain prices.

Sincerely,

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[7] "What encourages counterfeiting of drugs?" World Health Organization Counterfeits FAQ, available at: http://www.who.int/medicines/services/counterfeit/faqs/16/en/index.html.

[8] Harcourt (2005).

[9] "Comments on the Final Rule implementing the Prescription Drug Marketing Act of 1987/PDUFA," Comments of Public Citizen's Health Research Group, October 27, 2000.

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