Setting Standards for Excellence

EVAN R. GADDIS
President and Chief Executive Officer

March 20, 2008

Mr. Stanford K. McCoy
Acting Assistant US Trade Representative for
Intellectual Property and Innovation
Office of the United States Trade Representative
600 17th Street, NW
Washington, D.C. 20508
ACTA@ustr.eop.gov

RE: Anti-Counterfeiting Trade Agreement (ACTA): Request for Public Comments, 73 Federal Register 8910 (February 15, 2008)

Dear Mr. McCoy:

The National Electrical Manufacturers Association (NEMA) is pleased to have the opportunity to submit the following comments on the proposed Anti-Counterfeiting Trade Agreement announced by Ambassador Schwab on October 23, 2007.

The National Electrical Manufacturers Association is the trade association of choice for the electrical manufacturing industry. Founded in 1926 and headquartered in Rosslyn, Virginia, its 430 member companies manufacture products used in the generation, transmission and distribution, control, and use of electricity. These products are used in utility, medical, industrial, commercial, institutional, and residential applications. Domestic production of electrical products sold worldwide exceeds $120 billion.

Counterfeiting in the electrical products industry has been a growing problem for over a decade now. The threat posed to the export and domestic markets served by NEMA member companies is just one dimension of the problem; the threat to the safety of persons and property is the other equally, if not more important dimension. Our industry's experience with counterfeit electrical products is that they are almost always substandard, posing a risk of harm to persons and property. The counterfeiters are very good at copying the external appearance of an electrical product and its packaging, but the internal design, materials or chemical composition, which is typically not seen by the purchaser or the installer, is very different from the genuine product. For example:

- Counterfeit power and extension cords are often found to conceal an inadequate gauge of copper wire, which will not carry the intended current and erupts into flames.

National Electrical Manufacturers Association
www.nema.org

1300 North 17th Street, Suite 1752
Rosslyn, VA 22209
703. 841.3210
Fax 703.841.3310
evan_gaddis@nema.org

- Counterfeit residential circuit breakers conceal the fact that they are either made with missing safety components or in some cases no components at all. See: http://www.voltimum.co.uk/news/9428/infopro.whatsnew.latest/Counterfeiting-Alert.html
- Counterfeit grounding rods are made with only 20% of the copper coating required by safety standards, causing them to degrade forty or fifty years earlier than normal, and putting property and persons at risk.
- Numerous other examples can be cited, and I invite you to visit NEMA's website at http://www.nema.org/gov/anti-counterfeiting/news.cfm

Counterfeiting in the electrical sector is a global problem. For NEMA members who manufacture and sell "NEMA type" electrical products for the electrical infrastructure of the Americas, most of the genuine products (almost all of which is copied in China and exported to the Americas) are made in the United States, Canada, Mexico and the Caribbean for this Hemisphere. For those NEMA members who also manufacture "IEC type" products for the electrical infrastructures of Europe, the Middle East, Africa, and parts of Asia, the genuine product may be exported from the United States or manufactured in local markets abroad before being faced with unfair competition from dangerous fakes in those export markets.

NEMA regards the ACTA initiative as an important announcement, because it intends to (a) increase international cooperation, (b) strengthen enforcement and make it more effective, and (c) strengthen IPR enforcement laws and measures. The efforts of both the private and public sectors to date have fallen short of stemming the growing threats to innovation and public safety above. While it is acknowledged that there has been some growing interest and activity in cooperative IP law enforcement among nations in recent years, much more needs to be done, requiring focused attention and increased resources. Our existing institutional arrangements and agreements, such as the World Trade Organization and the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, have contributed to better IPR legislation around the world and minimum enforcement measures, but they have not promoted, and we believe it is unlikely that they will promote, stronger IP law enforcement and deterrent regimes in the near future. The ACTA initiative must therefore endeavor to work toward solving this deficiency by leading the fight against counterfeiting and piracy *well beyond* what these other institutions and bilateral or multilateral negotiations can likely be expected to achieve in the near future.

1. The role of our various Free Trade Agreements (FTAs) has been to clarify and improve upon the international norms of the TRIPS Agreement, which establishes only minimum enforcement standards. Our ambition with ACTA must be to meet, and where necessary, exceed those FTA provisions with this Agreement. NEMA thus encourages the United States to resist compromising our own national standards for enforcement in ACTA. For example, with the group of countries that have agreed to negotiate the ACTA agreement, the intellectual property provisions of the Oman Free Trade Agreement should not be compromised in the areas of copyright, trademarks and enforcement (including border measures). Here are just a few of the provisions of the Oman FTA (and some other FTAs) that are extremely important to the electrical industry, and which at a minimum must be part of ACTA:

   A. application of the trademark laws to certification marks;
   B. protection of famous or well-known marks;

C. a rebuttable presumption that a registered trademark is valid;
D. a presumption of confusion for identical marks for identical goods;
E. rights-holder's ability to elect statutory or pre-established damages in a counterfeiting case;
F. non-discretionary authority of the judiciary to order the seizure and destruction of infringing goods, materials, and implements relevant to infringement, as well as to order the seizure of documentary evidence; furthermore, the decision to not destroy infringing goods must belong only to the rights-holder;
G. that competent authorities have power to initiate border measures *ex officio*, with respect to not only imported, but exported goods and in-transit merchandise in free trade zones, with respect to infringing goods and activities, and those border measures include the right to inspect all shipments, detention of suspicious shipments, and seizure and destruction of all infringing goods identified by rights holders; and
H. the other border measure provisions in the Oman FTA.

2. ACTA must include the provisions of the Stop Counterfeiting in Manufactured Goods Act, which became law here in the United States in March 2006, particularly that law's provisions relating to trafficking in packaging, labels, containers, tags, and the like bearing counterfeit marks. Our industry has seen shipments of packaging bearing counterfeit trademarks and goods (including goods bearing no marks) moving in international commerce separately from one another, only to be married in some warehouse near the destination market. Border officials and law enforcement need to be able to stop this trafficking, and criminal sanctions need to be applied here where the *mens rea* requirements are met.

3. ACTA must include in the treaty meaningful and effective criminal sanctions that promote effective deterrence. We note recent criminal sentences here in the United States for trafficking in counterfeit electrical products have been in the 7 to 8 year range. ACTA must include provisions that if a counterfeit product causes injury to person or property, enhanced criminal sanctions including higher fines and jail time shall be imposed. ACTA must recognize counterfeiting and piracy as serious global crime.

4. ACTA must include provisions that provide for establishing law enforcement and border protection coordination and information-sharing networks among each of the parties to ACTA with respect to individuals and entities involved in the financing, production, trafficking and sale of counterfeit and pirated goods, and a mutual commitment to prosecute intellectual property crimes in accordance with the provisions of the treaty. ACTA will suffer if there is variability in enforcement among its treaty participants, if that variation cannot be explained by the extent to which counterfeiting and piracy varies among the nations.

5. ACTA must include a provision that each party will designate a high-level executive branch officer to serve as principal intellectual property law enforcement coordinator to ensure that the protection of intellectual property laws is recognized as a national priority, to oversee effective coordination among all government agencies responsible

for IP policy and enforcement, to allocate financial and personnel resources, and to implement public education and awareness about the impact and harms of counterfeiting and piracy on the public.

6. ACTA should include provisions for the development of sentencing guidelines to be used by prosecutors and the judiciary in connection with the prosecution and punishment of IPR crimes.

7. ACTA should also include provisions that prohibit procedures and practices that have been employed in some countries to make border measure, civil, and criminal enforcement more difficult than it should be. On this latter point, NEMA refers USTR to the Report of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15) on the US-Colombia Trade Promotion Agreement 21-24 (September 20, 2006).

8. ACTA should address the growing problem of the sale or offers for sale of counterfeits on the Internet. NEMA members have documented how foreign websites are introducing those who sell illegal counterfeit product to prospective customers here in the United States and throughout the Americas.

Thank you for your consideration of these remarks. NEMA stands ready to work with the negotiators to establish a strong, effective, and deterrent international enforcement network that will reflect true leadership in addressing IP crimes.

Respectfully,

Evan R. Gaddis
President & CEO

March 21, 2008

By E-Mail
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508
Attention: Rachel Bae

Re: Anti-Counterfeiting Trade Agreement -- PhRMA Response to Request for Written Comments 73 Fed. Reg. 8910 (Feb. 15, 2008)

Dear Ms. Bae:

The Pharmaceutical Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Anti-Counterfeiting Trade Agreement ("ACTA") in response to the above-referenced Federal Register notice. As a representative of America's leading research-based pharmaceutical and biotechnology companies, PhRMA strongly supports the objectives of ACTA and urges USTR to develop a framework of commitments that will serve as a gold standard for pharmaceutical anti-counterfeiting enforcement efforts throughout the world.

I. Background on Pharmaceutical Counterfeiting

Counterfeit medical products are manufactured, marketed and sold with the deliberate intent to deceive purchasers as to the source or nature of the product. As such, they pose a very serious risk to the health and safety of consumers worldwide. In 2006, for example, the U.S. Food and Drug Administration alerted the American public to the existence and threat of fraudulent flu remedies. And over the past decade, thousands of deaths have resulted from counterfeit vaccines (Niger), cough medications (Haiti) and antimalarials (Cambodia), disproportionately afflicting the world's poorest and most vulnerable persons. These examples are merely the tip of the iceberg and represent the small percentage of cases actually known and reported.

Although the volume of counterfeit drugs in today's global market is difficult to quantify, the problem appears to be growing in magnitude, scope and sophistication. One report estimates that counterfeit drug sales will reach US$75 billion globally in 2010, an increase of more than 90% from 2005. [1] According to the WHO, the prevalence of counterfeit drugs ranges from 10 to

[1] See Centre for Medicines in the Public Interest, cited at http://www.who.int/mediacentre/factsheets/fs275/en/

30 percent in developing markets that lack adequate oversight and enforcement, to less than 1 percent in developed markets with rigorous drug safety controls. Nevertheless, even the most tightly regulated drug supply chains are not impervious to counterfeits. The United States and European Union have witnessed a significant increase in counterfeit drug imports in recent years. The U.S. FDA investigated 53 cases of drug counterfeiting in 2006 (up from 32 cases in 2005),[2] and the U.S. Immigration and Customs Enforcement has initiated close to 200 criminal investigations of counterfeit pharmaceutical smuggling since 2003. U.S. customs seizures of counterfeit pharmaceuticals surged in 2007 to over $11.1 million in illicit imports, an almost 500 percent increase over the previous year.[3] European customs reported seizures of 2.7 million articles of counterfeit medicines in 2006 alone, an increase of 384 percent from 2005.[4]

The Internet plays a large role in the increased domestic and international sales of counterfeit medicines.[5] According to U.S. Immigration and Customs Enforcement (ICE), the Internet has become the primary tool for criminal organizations to sell, and the primary mechanism for consumers to find, counterfeit medicines.[6] The WHO estimates that medicines purchased from rogue Internet sites that conceal their actual physical address are counterfeit in over 50 percent of cases.[7] Investigations by the U.S. FDA suggest an even greater risk of counterfeit drugs. For example, in 2005 the FDA found that 85 percent of Internet drugs from so-called "Canadian" websites actually came from 27 other countries, including India, Costa Rica and Vanuatu.[8] Recent research by the European Alliance for Access to Safe Medicines indicates that 93% of online pharmacies do not have a named, verifiable pharmacist to answer questions, and 95% are not licensed by a pharmacy board or listing.[9] The anonymous and unregulated nature of the Internet provides a fertile breeding ground for sellers of counterfeit and illegal medicines.

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[2] See http://www.fda.gov/oc/initiatives/counterfeit/hdmanadcs1113_files/800x600/slide3.html

[3] See http://www.cbp.gov/linkhandler/cgov/import/commercial_enforcement/ipr/seizure/trading/07_topirp_seizures.ctt/07_topirp_seizures.pdf

[4] See http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf

[5] Coincidence or Crisis, p. 18.

[6] U.S. Immigration and Customs Enforcement Fact Sheet (July 11, 2006). See http://www.ice.gov/pi/news/factsheets/counterfeit_pharms.htm

[7] IMPACT, Counterfeit Medicines: an Update on Estimates (Nov. 2006); http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf

[8] *See* FDA news dated Dec. 16, 2005 at http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html.

[9] European Alliance for Access to Safe Medicines, "The counterfeiting super-highway: An online pharmacy research and test purchase report" (March 14, 2008).

However, the counterfeit drug trade is not limited to Internet purchases or illicit channels of commerce. By exploiting parallel trade and weaknesses in drug distribution oversight, counterfeiters can penetrate all stages of the otherwise legitimate distribution chain.

As drug counterfeiting activities have expanded in volume and reach, so too have the types of pharmaceutical products impacted by counterfeiting. In the poorest markets, counterfeiters more often target anti-infectives, such as anti-malarial drugs, HIV therapies and vaccines. In developed countries, the range of counterfeit products is often broader- including cancer therapies, cardiovascular medicine, and "lifestyle" drugs because of the lure of high profits with little risk of detection and punishment. With that said, counterfeiters do not discriminate; they will prey on any patient in need of treatment, no matter their resources, age, illness or geographic location.

To help combat the spread of counterfeit drugs, PhRMA and its member companies are actively engaged in a broad range of domestic and international outreach and educational activities. In addition, our members utilize anti-counterfeiting technologies that help secure legitimate products and distribution channels and make it more difficult for counterfeiters to evade detection. However, while these technologies are helpful in resisting counterfeiting, they are by no means a silver bullet and cannot secure the safety of the global drug market. Anti-counterfeiting markers on packaging are most effective as deterrents when supported by interactive processes that interrogate the package or product and verify the trade as legitimate as soon after the transaction takes place as possible (i.e., electronic pedigree systems).

Private sector initiatives must be complemented by active government oversight and enforcement of each link in the drug supply chain, from the supply of bulk chemicals to the export of finished products. It is equally critical that governments expressly address and prioritize drug counterfeiting as a serious health and safety offense that warrants administrative and criminal liability, rigorous enforcement and tough, deterrent penalties. To succeed, the war against counterfeit drugs demands the same commitment of law enforcement resources, interagency coordination and multilateral cooperation that we bring to other global organized crime activities.

Despite the very serious dangers of counterfeit drugs, very few countries have enacted laws that expressly address pharmaceutical counterfeiting, *per se,* or the full range of upstream and downstream activities that contribute to the manufacture and supply of counterfeit medicines. Instead, drug counterfeiting activities are typically covered by a patchwork quilt of laws and regulations typically administered by different agencies and law enforcement authorities. The most significant of these are the drug safety laws that regulate the pharmaceutical supply chain and the trademark laws that guard against infringing uses of pharmaceutical brands.

However, neither trademark nor drug safety laws are an adequate substitute for measures specifically targeting drug counterfeiting offenses. The hallmark of a counterfeit medicine is deception as to identity or source, which often but not always entails the unauthorized use of another party's trademark or use of a trademark that is confusingly similar thereto. Moreover, while trademark laws provide a valuable weapon against drug counterfeiters, pharmaceutical

counterfeiting has significant public health ramifications far beyond issues of brand integrity. Even in countries with strong IP regimes, trademark laws are inherently incapable of protecting drug distribution channels against the full spectrum of activities that contribute to the proliferation of counterfeit medicines.

Similarly, drug safety laws are designed to regulate legitimate manufacturers and domestic supply channels, and thus are typically ill-equipped to combat the underground criminal organizations that manufacture and distribute counterfeit medicines throughout the world. These entities operate outside the framework of the health and safety regulatory environment. Moreover, the effectiveness of such laws is often undermined by non-deterrent penalties, inadequate enforcement and weak coordination among drug regulators, customs and criminal law enforcement authorities. Also problematic is the fact that many countries limit administrative and/or criminal remedies to "substandard", "adulterated" or "harmful" drugs. These limitations significantly slow, and in many cases prevent, effective enforcement against pharmaceutical counterfeiters and ignore the inherent dangers of any deceptively labeled medicine.

Finally, there is very little oversight of the upstream suppliers of bulk chemicals and downstream wholesalers and pharmacies that contribute to the manufacture and flow of counterfeit medicines, and virtually no attention paid to the cross-border activities of these entities, particularly with respect to Internet distribution channels. Existing laws and associated border measures are typically focused solely on domestic supply channels, ignoring altogether the fact that the majority of counterfeit medicines and bulk chemicals are destined for export markets.

ACTA provide an important opportunity for the U.S. Government to address each of these deficiencies and lay the foundation for stronger drug counterfeiting laws and remedies throughout the world. With that goal in mind, we urge USTR to ensure that ACTA expressly address pharmaceutical counterfeiting offenses and, in particular, incorporates each of the measures recommended below.

II. Recommendations to Strengthen Enforcement against Pharmaceutical Counterfeiting

A. Define Counterfeit Medical Products and Expressly Prohibit Related Counterfeiting Offenses

<u>Recommendation</u>: Require ACTA parties to (i) codify a definition of counterfeit medical products that encompasses any unauthorized pharmaceutical product or medical device that is deceptively misidentified as to the source or nature of the product, and (ii) prohibit all activities involving the manufacture, sale, distribution, import and export of counterfeit medical products.

Very few countries have codified a comprehensive definition of counterfeit medical products that encompasses any deceptively misidentified drug or medical device. Similarly, few

jurisdictions prohibit all activities involving the manufacture, sale, distribution, importation and exportation of counterfeit medical products.

Without an explicit, comprehensive definition of counterfeit medical products and pharmaceutical counterfeiting offenses, it is all but impossible to wage a coordinated attack against each link in the counterfeit supply chain, and very difficult to report and track drug counterfeiting activity. To provide adequate enforcement against drug counterfeiting activities, it is essential that ACTA members agree to establish a framework of laws and remedies that specifically targets drug counterfeiting offenses.

i. Definition of Counterfeit Medical Products

As a starting point, ACTA should require each member state to codify a definition of counterfeit medical products that encompasses any unauthorized pharmaceutical product or medical device that is deceptively misidentified as to the source or nature of the product. Both the WHO definition of "counterfeit medicines" and the U.S. definition of a "counterfeit drug" serve as potential models for ACTA.

The WHO defines a counterfeit medicine as "one which is *deliberately and fraudulently mislabeled with respect to identity and/or source*" (emphasis added).[10] The WHO further notes that "[c]ounterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."[11] This same approach is reflected in the U.S. Food, Drug, and Cosmetic Act ("FDCA"), which defines a "counterfeit drug" as:

> "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

Thus, under both the WHO and FDCA definitions, an unapproved drug need not be adulterated or substandard to qualify as a "counterfeit" medical product (though many, in fact, are). Instead, the key feature of a counterfeit medical product is deceptive misidentification of the product, no matter what form that deception may take. Counterfeiters are keenly aware of drugs under development and often seek exclusive "marketing" opportunities by offering fake formulations of such drugs prior to regulatory approval in one or more markets. Moreover, each of these definitions clearly excludes legitimate, authorized medical products that fail to comply with GMP or other quality standards. GMP violations by legitimate manufacturers are more

[10] *See* http://www.who.int/medicines/services/counterfeit/overview/en.
[11] Id.

appropriately dealt with under drug safety laws and should not be treated as counterfeiting offenses.

PhRMA recommends that ACTA adhere to these same definitional standards, i.e., the definition of a counterfeit medical product should include any deceptively, misidentified pharmaceutical or medical device, without the need to prove physical or qualitative differences, and the definition should exclude authorized products that fail to meet regulatory drug safety standards.

ii. Explicit Prohibitions against Pharmaceutical Counterfeiting Offenses

As noted above, the fact that few countries recognize pharmaceutical counterfeiting as a specific administrative offense or crime, separate from trademark or drug regulatory violations, is one of the chief obstacles to effective enforcement against drug counterfeiting activities. To rectify this deficiency, ACTA should require each member to prohibit expressly all activities involving the manufacture, sale, distribution, importation and exportation of counterfeit medical products.

Here again, both WHO guidelines and the U.S. FDCA provide a potential model for ACTA. In particular, under model legislative principles recently adopted by the WHO International Medical Products Anti-counterfeiting Task Force ("IMPACT"), member states are encouraged to recognize the following pharmaceutical counterfeiting offenses, regardless of the monetary value or volume involved[12]:

- manufacture a counterfeit product,
- own, possess or control counterfeit medical products in transit, trans-shipment, free trade zones, bonded-warehouses and other situations of international commerce,
- introduce into the distribution chain any counterfeit medical product by any means, including but not limited to, selling, delivering, distributing, importing, exporting, donating, storing or otherwise supplying others with a counterfeit medical product;
- own, possess or control counterfeit medical products that are likely to enter the distribution chain;
- design, produce, print, sell, deliver, distribute, import, export, donate or otherwise supply others with any packaging material or labels, intended for a counterfeit medical product;
- manufacture, transport, or distribute any equipment, materials, components (including genuine articles) or documentation used in the production of, or to accompany the distribution of, counterfeit medical products with the knowledge or being reckless to the fact that they be used for such purposes;
- provide services such as on-line services, electronic-sale platforms, electronic payments, or transportation when providers have reasonable grounds to believe or notice has been

[12] See WHO IMPACT website at http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf

given to them by the appropriate authorities of such services being exploited by persons engaged in any of the offences described above; and

- conspire to commit, attempt to commit, aid, abet, counsel, facilitate, or incite any of the offences set forth in these provisions.

In a more concise manner, the FDCA recognizes the following drug counterfeiting offenses:

- Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug; and [13]

- The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.[14]

In each case, the goal of the WHO guidelines and U.S. law is to capture the full range of domestic and cross-border activities that contribute to the national and international proliferation of counterfeit medical products. ACTA should reflect an equally comprehensive approach to pharmaceutical counterfeiting offenses.

B. Provide Strong Administrative and Criminal Penalties for Pharmaceutical Counterfeiting Offenses

<u>Recommendation</u>: Provide effective administrative and criminal remedies and tough, deterrent penalties for all offenses involving counterfeit medical products, without the need to prove threatened or actual harm or meet other burdensome evidentiary requirements.

Pharmaceutical anti-counterfeiting enforcement efforts are hindered by weak and sometimes nonexistent administrative and criminal remedies, inadequate penalties and burdensome evidentiary requirements. To provide a solid foundation of enforcement tools, it is imperative that ACTA require each member state to provide both criminal and administrative remedies for drug counterfeiting offenses, without the need to prove threatened or actual harm, accompanied by tough, deterrent penalties. In addition, such laws must provide administrative and criminal law enforcement officials with the full range of enforcement tools needed to investigate and defeat sophisticated counterfeiting operations. It should be noted that the enforcement involvement of the legitimate brand owner or IP right holder is constrained by the fact that they do not have legal or regulatory control over the disposition of counterfeit goods.

[13] FDCA § 301(i)(2).

[14] FDCA § 301(i)(3).

Therefore, immediate and decisive response by enforcement authorities is the best means of protecting the consumer.

In that regard, we strongly support USTR's stated goal to build within ACTA the types of IP enforcement provisions found in the U.S. Free Trade Agreements ("FTAs"), and we urge that comparable enforcement measures apply to offenses involving counterfeit medical products.

C. Provide Effective Border Enforcement against the Importation and Exportation of Counterfeit Medical Products

<u>Recommendation</u>: Provide customs officials with explicit authority to stop the importation, exportation and transshipment of counterfeit medical products.

Customs officials are a critical line of defense against cross-border trade in counterfeit medical products, and yet all too often lack explicit authority to seize inbound and outbound shipments of counterfeit pharmaceuticals and medical devices. Here again, PhRMA recommends that ACTA include the strong border enforcement measures found in the U.S. FTAs and extend all such measures to the importation and exportation of counterfeit medical products. Furthermore, PhRMA recommends that where health and safety are at stake, appropriate authority should be vested in customs and border protection agencies to intervene or intercept medical products that are being moved through a country through a free trade zone or transshipment area to a destination where such product would be illegal. Appropriate mechanisms should be put in place to share information on a timely manner between rights holders, marketing license holders, health regulatory agencies, and customs agencies to address these types of shipments. Border enforcement authority should extend to free trade zones, which are often used to make, market or re-label counterfeit drugs, and to counterfeit imports and components destined for transshipment. Of course, this increase in authority implies that customs personnel are equipped with the knowledge to spot counterfeits as goods are inspected. PhRMA members routinely work with customs agents to provide the training and product information needed for them to properly distinguish genuine from fake medical products. In some instances, illegal product is sent back to the original sender only to be resent into the destination country by the suspect party. If the shipment of a product across a border is illegal, customs authorities should have adequate authority, resources and facilities to destroy such product in a timely manner.

Moreover, without effective controls against diversion, parallel trade in pharmaceuticals becomes a potential pathway for the introduction of counterfeit medical products. ACTA members should also be required to prohibit the distribution of medical products diverted from legitimate distribution channels and such distribution of diverted products should be treated as a counterfeiting offense.

D. Strengthen Enforcement against Each Link in the Drug Counterfeiting Channel

Recommendation: Ensure that criminal and administrative remedies extend to all upstream and downstream links in the drug counterfeiting channel, including the supply of unauthorized bulk chemicals and the distribution of finished counterfeit products.

Effective anti-counterfeiting enforcement depends critically upon law enforcement's ability to block so-called chokepoints in the counterfeiting manufacture and distribution channel, from the upstream supply of raw materials to the downstream distribution of finished products. In the case of counterfeit medical products, this holistic approach to enforcement necessitates effective enforcement tools and remedies to stop the unauthorized manufacture and supply (both domestic and international) of the bulk chemicals used to produce counterfeit medical products, as well as measures to prevent the unauthorized wholesale and retail distribution of counterfeit products.

To address the supply of bulk chemicals and other materials used to produce and market counterfeit medical products, ACTA should require members to recognize as an administrative and criminal offense the manufacture, transport, distribution, importation and exportation of any equipment, materials, components or documentation used in the production or distribution of counterfeit medical products, consistent with the WHO guidelines specified above. Similarly, ACTA should expressly prohibit all acts involving the wholesale or retail distribution of counterfeit medical products, whether through traditional brick and mortar operations or Internet pharmacies or other online outlets.

E. Establish liability for Internet Service Providers and Other Operators that Facilitate Trade in Counterfeit Medical Products

Recommendation: Expressly prohibit online activities that directly or indirectly facilitate trade in counterfeit medical products and provide legal incentives for ISPs and online intermediaries to cooperate with legitimate manufacturers in combating counterfeiting activities.

Much of the explosive growth in sales of counterfeit medical products can be attributed to Internet pharmacies, spammers and other online distribution and marketing activities. Thus, in order for ACTA to achieve its stated goals, it must expressly address the full range of online activities that facilitate marketing and distribution of counterfeit medical products.

It may be appropriate to require some form of registration or licensure for Internet pharmacies and to require them to meet minimum requirements that protect against counterfeits, using standards in place for brick-and-mortar pharmacies.

Because of the anonymous and unregulated nature of the Internet, enforcement efforts are very difficult and often resemble the carnival game "whack a mole". Efforts must be targeted

toward intermediaries that facilitate online commerce. Search engines should be required to remove from search results (natural and sponsored) websites pages advertising counterfeit medicines. Payment service providers (credit card companies) should be required to stop processing financial transactions for illegal online pharmacies. ISPs hosting illegal pharmacy sites should be required to disable Internet access to those sites.

We note that Korea recently implemented a system for taking down websites selling counterfeits, and recommend examination of that system for possible adaptation and use in other countries to combat online counterfeit medicines. Legitimate online pharmacies should be easily identifiable by prospective purchasers by maintaining their official registration through a third party database. In addition, Internet pharmacies should be required to verify that all orders are initiated by a licensed prescriber not associated with the site.

Beyond penalizing Internet pharmacies and other online operators that knowingly and directly engage in drug counterfeiting offenses, ACTA members should provide legal incentives for Internet service providers to cooperate with legitimate manufacturers in deterring the unauthorized distribution and marketing of counterfeit medical products. Such measures, which would be analogous to U.S. FTA provisions on online piracy and could include immunity from liability for claims arising from such cooperation, would significantly enhance the ability of legitimate drug manufacturers to combat deceptive online practices that facilitate the counterfeit drug trade.

F. Promote Cooperation Among Law Enforcement Officials, Educate Consumers, and Create Tracking and Reporting Mechanisms

<u>Recommendations</u>: Develop international programs to (i) facilitate cooperation among law enforcement officials tasked with drug counterfeiting enforcement; (ii) educate all stakeholders about the inherent dangers of counterfeit medicines; and (iii) develop harmonized, international mechanisms to report and track drug counterfeiting activity and enforcement actions worldwide.

The United States is at the forefront of global efforts to promote training of, and cooperation among, law enforcement officials responsible for IP enforcement efforts. However, international programs of this type typically have not focused on, or included all agencies tasked with, drug counterfeiting enforcement. To address the clear need for greater expertise and multinational coordination among officials tasked with enforcement against pharmaceutical counterfeiting offenses, ACTA should require international law enforcement programs that specifically address the unique aspects of the drug counterfeiting trade and bring together all responsible officials, including IP and criminal law enforcement officers, drug regulatory authorities, customs agents and legitimate manufacturers. Similarly, ACTA members should include among their outreach efforts programs designed to educate all public and private stakeholders, particularly consumers and healthcare providers, on the inherent dangers of counterfeit medical products.

Finally, to better understand the scope, source and impact of drug counterfeiting activities and assess the effectiveness of ACTA-related enforcement efforts, it is imperative that ACTA members develop harmonized systems for tracking and reporting incidences of counterfeit medical products, resulting investigations and prosecutions, and the ultimate administrative or judicial resolution of such cases.

* * *

In conclusion, PhRMA commends USTR for its leadership in developing a framework of strong, harmonized enforcement tools and remedies to combat the global proliferation of counterfeit medical products. PhRMA and its member companies look forward to working with U.S. Government officials as the ACTA negotiations proceed, and stand ready to provide any additional information that might be useful to support the negotiators.

Before the
OFFICE OF THE UNITED STATE TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

In the matter of:	)
	)
Anti-Counterfeiting Trade Agreement	)
	)
(ACTA):	)

COMMENTS OF PUBLIC KNOWLEDGE

Rashmi Rangnath
Sherwin Siy
Michael Weinberg, *Law Clerk*

Public Knowledge
1875 Connecticut Ave., NW
Suite 650
Washington, D.C. 20009
(202) 518-0020

Dated: March 21, 2008

COMMENTS OF PUBLIC KNOWLEDGE

Public Knowledge submits these comments in response to the request for written submissions published in the Federal Register of February 15, 2008.[1] Public Knowledge is a Washington D.C. based non-profit organization dedicated to promoting innovation and citizens' rights in the emerging digital culture.

Introduction

In pursuing the worthy goals of protecting consumers, enforcing copyrights, and combating counterfeiting, the USTR should ensure that the proposed Anti-Counterfeiting Trade Agreement (ACTA) is narrowly tailored against bad actors. An overbroad set of enforcement laws and mechanisms would detrimentally affect legitimate users of copyrighted works, as well as technological innovators whose new creations might not be adequately accounted for in current law.

We appreciate the opportunity to comment on ACTA at this preliminary stage of the proceedings, and would hope that the process moving forward will be an open one, allowing interested parties and the general public the ability to comment on the agreement when its actual draft text is available. At present, the lack of anything more than a sparse outline prevents a more detailed discussion of the many complex issues that can and will be encompassed by such an agreement.

These comments therefore will address several broad themes discussed in the USTR's Fact Sheet, as well as more specific proposals that, while not mentioned in the Fact Sheet, have been recently discussed in the context of copyright and trademark enforcement.

Ensuring Targeted Enforcement

An extremely wide and disparate range of activities can be encompassed by the terms "counterfeiting and piracy." While each represents a type of offense related to intellectual property, the particular risks to the public created by each are distinct, and therefore the enforcement response should be tailored to the type of infringement as well as to the severity of the threat to the public.

For instance, the public harm posed by counterfeit pharmaceuticals or tainted food products is clear and considerable. On the other hand, counterfeit designer clothing or pirated music and movies, while representing non-trivial losses to rightsholders, do not threaten the public health and safety in the same way. It is critical for any policymaking in this realm to draw these distinctions between different violations, and recognize the relative priority that enforcement authorities with finite resources will logically give them.

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[1] Anti-Counterfeiting Trade Agreement (ACTA): Request for Public Comments, 72 Fed. Reg. 8910 (Feb. 15, 2008).

Even within the smaller scope of copyright alone, myriad fact patterns and situations can all be classified under the terms of "infringement" or "piracy." An industrial optical disc manufacturer, a single P2P downloader, and a student burning a mix CD can all be liable for copyright infringement, and classified as "pirates," even though each of their activities stems from a different motivation and can be addressed with differing levels and methods of enforcement.

Aside from the general themes outlined in the USTR Fact Sheet, several specific proposals for copyright enforcement have been much-discussed in the press and in international enforcement circles of late.[2] Public Knowledge urges the USTR to resist attempts to enshrine such technology-specific enforcement mechanisms in the requirements of a multilateral agreement. Enforcement efforts in affected countries must account for a wide variety of variables, including the state of national intellectual property laws, the cultural and economic needs of individual and institutional users, and the resources available to local law enforcement.

For instance, in countries lacking a robust and flexible regime of limitations and exceptions, many legitimate uses remain unlawful, but are permitted through non-enforcement. Requiring specific enforcement practices in such a situation, before legitimate uses can be recognized and codified into local limitations and exceptions, will frustrate the balance of intellectual property required to ensure creativity and innovation.

We discuss some of these specific proposals below.

Technological Mandates for Internet Service Providers

One of the legal measures being considered under ACTA is the creation of a legal framework to deal with piracy via the Internet. In doing so, the framers of ACTA should exercise caution in the scope of the agreement, given that binding multilateral agreements such as the so-called WIPO Internet Treaties[3] already create a system of requirements for governing intellectual property and secondary liability on the Internet. The United States' implementation of the WIPO Internet Treaties already accounts for Internet Service Provider (ISP) liability via the safe harbor provisions of the Digital Millennium Copyright Act (DMCA).[4] Furthermore, the diplomatic conference adopting the WIPO Internet Treaties adopted an "agreed statement" noting that ISPs should not be held liable

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[2] Tim Wu, *Has AT&T Lost its Mind? a Baffling Proposal to Filter the Internet*, SLATE, Jan. 16, 2008, http://www.slate.com/id/2182152; Brad Stone, *AT&T and Other I.S.P.s May Be Getting Ready to Filter*, BITS, N.Y. TIMES BLOGS, Jan. 8, 2008, http://bits.blogs.nytimes.com/2008/01/08/att-and-other-isps-may-be-getting-ready-to-filter/; Bobbie Johnson, *Pirates face crackdown over movie downloads*, THE GUARDIAN, Nov. 24, 2007, at International 30, *available at* http://www.guardian.co.uk/technology/2007/nov/24/crime.france; Danny O'Brien, *Three Strikes, Three Countries: France, Japan, and Sweden*, EFF DEEPLINKS BLOG, Mar. 18, 2008, http://www.eff.org/deeplinks/2008/03/three-strikes-three-countries.

[3] Specifically, the WIPO Copyright Treaty, Dec. 20, 1996, 36 I.L.M. 65 (1997) (*hereinafter* "WCT"); WIPO Performances and Phonograms Treaty, Dec. 20, 1996, 36 I.L.M. 76 (1997).

[4] 17 U.S.C. § 512; U.S. Senate Executive Report 105-25 (105th Cong., 2d Sess.).

when acting as a mere conduit for communication.[5]

Therefore, in assessing the legal framework of preventing Internet piracy, ACTA should not oblige countries to impose further requirements on ISPs that would compromise consumer privacy, create new responsibilities to monitor content, and impose unfair penalties on consumers. In particular, ISPs should not be required to reveal the identities of their customers accused of copyright infringement without adequate procedural safeguards. Nor should ISPs be required to enact experimental measures such as filtering content for copyright infringement, automatically terminating access, or blacklisting accused infringers from the Internet.

Disclosure of user identity

In order to safeguard the essential values of privacy and trusted communication on the Internet, ISPs must have strong legal grounds before disclosing the identities of their users. There is a significant history in the United States of false or groundless claims intended to reveal a user's personal information.[6] Any provisions regarding disclosure should contain adequate procedural safeguards to protect privacy and prevent harassment. Rightsholder requests for information about the identity of customers should be subject to judicial scrutiny. The targeted ISP should be required to notify its customer of the request, and the customer in turn should have the opportunity to object to the request. Such safeguards are necessary to prevent the unwarranted erosion of Internet users' privacy and anonymity and to promote the free exchange of information.[7]

Network filtering

ACTA should not oblige member countries to require ISPs to filter their networks in order to prevent copyright infringement. Such a filtering mandate could seriously invade users' privacy, would be unworkably burdensome and expensive for ISPs, and would have an adverse impact on lawful uses of copyrighted content. In addition, such measures would be ineffective in preventing piracy.

Implementing a filtering technology based on content inspection would require ISPs to inspect every bit of information passing over their networks, giving rise to serious privacy concerns. Apart from the question of legality, ISPs required to institute content inspection would have to fundamentally reconfigure their networks. This would not only increase the costs of operation, it would slow traffic dramatically. In an era of increasing demand for the critical services provided by the Internet, it is unfair and unjustified for all consumers to pay more for poorer service in order to protect private rights against the occasional infringer.

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[5] *See* WIPO Copyright Treaty, Agreed statements concerning Article 8, Dec. 20 1996, 36 I.L.M. 65 (1997).
[6] *See*, *e.g.*, Shaun B Spencer, *CyberSLAPP Suits and John Doe Subpoenas: Balancing Anonymity and Accountability in Cyberspace*, 19 J. MARSHALL J. COMPUTER & INFO. L. 493 (2001).
[7] *See* Brief of Amici in Support of Verizon's Opposition to RIAA's Motion to Enforce, Recording Industry Association of America, Inc. v. Verizon Internet Services Inc., Civ.No. 1:02MS00323 (D.C. August 30, 2002).

In addition, all filtering technologies are by design unable to distinguish between infringements and lawful uses. While network filters may be able to recognize copyrighted content, they would be unable to distinguish the context in which the work was being used. Copyrighted content may be lawfully transmitted over a network for the purpose of fair use or other lawful uses. Meanwhile, determined infringers could circumvent network filters by encrypting content. Thus filters would on the one hand prevent lawful uses and on the other be ineffective against piracy.[8]

Termination of Internet access

Recently, proposals have been put forward in some nations mandating ISPs to terminate customer access to the Internet in response to alleged infringement. While abuse of an account may subject a customer to termination, the critical importance of an Internet connection requires that any such action be procedurally sound, allowing the accusation of infringement to be contested by the customer and reviewed judicially.

Some proposals go further, requiring ISPs to penalize infringement by the "blacklisting" of infringing users, permanently terminating their Internet access. Such a measure would be a completely disproportionate response to alleged infringement. It would ignore the fact that Internet is not merely a conduit through which consumers access copyrighted content, but also a vital means of communication for millions who otherwise would be unable to speak to a global audience, or to participate in a global exchange of ideas. Internet access therefore is a vital outlet for citizens to both provide and receive civic and political information.

Given the myriad ways in which the Internet is of crucial importance to individuals, terminating access should not be a penalty for individuals merely because they are liable for infringement via the Internet. While it is entirely appropriate that infringers compensate copyright holders for their losses, depriving users of a forum for speech and expression is a uniquely disproportionate penalty divorced from any relationship to the losses suffered by the copyright holder or the unjust enrichment of the infringer.

It should also be noted that proposals like network filtering and access termination are still in their infancy. Absent any evidence of their comparative efficacy or efficiency in the countries in which they have been proposed, mandating such systems multilaterally would be at best premature, and at worst require a uniformly poor and onerous solution to be implemented worldwide.

Additional protections for technological protection measures

In addressing the intersection of copyright infringement and evolving information technologies, ACTA should not contain any provisions relating to Technological

[8] For additional explication of these arguments, see Reply Comments of Public Knowledge, *et al.*, on Broadband Industry Practices, FCC 07-52, July 16, 2007, *available at* http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6519558072.

Protection Measures (TPMs) and remedies against circumvention. Any TPM provision in ACTA would, at a minimum, be duplicative. The WCT already obliges member countries to provide adequate legal protection measures and effective legal remedies against the circumvention of TPMs used by copyright owners[9]. As a signatory to the WCT, the United States has already passed domestic legislation to give effect to these provisions. Any ACTA provision requiring such measures would thus be redundant, and could potentially conflict with existing agreements.

Furthermore, any ACTA-required protection for TPMs would reinforce a system that, at least in the United States, has failed to adequately account for a range of lawful uses. The DMCA, which implements the WCT,[10] imposes a blanket ban against circumvention of technological protection measures with extremely narrow exceptions that do not account for fair use and other lawful uses.[11] It also prohibits trafficking in devices that would permit such legitimate circumvention[12]. As a result, a person who desires to circumvent a TPM for a lawful use is prevented from doing so. Additionally, the law has been used in ways Congress never intended: in attempts to prevent free expression and security research, as an anticompetitive measure, and as a method of frustrating fair use.[13] The range of problems associated with TPMs has even been recognized by large segments of the various content industries, who are in growing numbers removing copy restrictions from digital media such as e-books[14] and digital music.[15]

Discretion in assessing penalties for copyright infringement

The USTR Fact Sheet notes the importance of "strengthening enforcement measures." This, we assume, would include increasing minimum penalties for infringement.

An obligation to increase penalties in U.S. law would create further imbalances in an already imbalanced copyright remedies regime. Currently, civil damages for

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[9] WIPO Copyright Treaty, Article 11, Dec. 20 1996, 36 I.L.M. 65 (1997).
[10] The DMCA, in fact, goes beyond the requirements of the WCT. Pamela Samuelson, *Intellectual Property and the Digital Economy: Why the Anti-Circumvention Regulations Need to be Revised*, 14 BERKELEY TECH. L.J. 519, 521 (1999).
[11] *See* 17 U.S.C. § 1201(a).
[12] 17 U.S.C § 1201(b).
[13] ELECTRONIC FRONTIER FOUNDATION, UNINTENDED CONSEQUENCES: SEVEN YEARS UNDER THE DMCA, (Apr. 2006), http://www.eff.org/wp/unintended-consequences-seven-years-under-dmca.
[14] Rachael Deal, *Random Audio's DRM Decision Renews Debate*, PUBLISHERS WEEKLY, Mar. 3, 2008, *available at* http://www.publishersweekly.com/article/CA6536974.html?industryid=47152; Richard Wray, *Penguin audiobooks to be free of copyright protection*, THE GUARDIAN, Mar. 4, 2008, at Financial 24, *available at* http://www.guardian.co.uk/technology/2008/mar/04/digitalmusic.booksnews.
[15] *See, e.g.*, Erik Schonfeld, *Amazon Completes DRM-Free Roster With Sony-BMG*, TECHCRUNCH, Jan. 10, 2008, http://www.techcrunch.com/2008/01/10/amazon-completes-drm-free-roster-with-sony-bmg/; Catherine Holahan, *Sony BMG Plans to Drop DRM*, BUSINESSWEEK, Jan. 4, 2008, *available at* http://www.businessweek.com/technology/content/jan2008/tc2008013_398775.htm; Nate Anderson, *Three down, one to go: Warner Music Group drops DRM*, ARS TECHNICA, Dec. 27, 2007, http://arstechnica.com/news.ars/post/20071227-3down-1-to-go-warner-music-group-drops-drm.html.

copyright infringement in the U.S. are tilted heavily in favor of copyright owners. For example, a district court ordered a Minnesota woman to pay statutory damages of $222,000 for sharing 24 songs on a peer-to-peer network.[16] Similarly, a piece by Utah law professor John Tehranian highlights the disproportionate nature of damages.[17] Cataloguing the ordinary activities of a hypothetical person—forwarding emails, passing out news articles, reciting a poem—Tehranian finds that these mundane acts of a single day can expose this imaginary person to $12.45 million in damages, all without a single act of P2P file sharing or other commonly recognized "bad acts."

Increasing penalties also creates problems in evolving areas of copyright law. For instance, a number of copyright questions remain unsettled in the United States regarding the nature of incidental copies, the distinction between digital distributions and digital performances, and many other issues. Other nations involved in ACTA may likewise have unsettled areas of law that will be affected by these measures. As the balances between users, rightsholders, and the public are calibrated in each jurisdiction, each country should be free to decide the measure of remedy for violation of law based on its social structure and legal culture.

Therefore, any provisions that contemplate increasing or instituting new criminal penalties such as increased fines, prison terms or forfeiture of property for copyright infringement should be mindful of the differences between large-scale commercial pirates and individual infringers. The provisions should also allow for maximum legislative flexibility in accounting for these differences as well as the evolution of technology.

Conclusion

We anticipate that a number of submissions will indicate areas of counterfeiting and piracy that might benefit from a multilateral enforcement agreement. In lieu of repeating the benefits of enforcement against violations of intellectual property rights, Public Knowledge submits the above comments in the interest of ensuring that measures taken to protect intellectual property do not also prejudice the rights of consumers or the creativity of technological innovators.

[16] *See* Jeff Leeds, *Labels Win Suit Against Song Sharer*, N.Y. TIMES, October 5, 2007, *available at* http://www.nytimes.com/2007/10/05/business/media/05music.html.
[17] John Tehranian, *Infringement Nation: Copyright Reform and the Law/Norm Gap*, 2007 UTAH L.REV. 537 (2007).

Resolving dysfunctional pharmaceutical arbitrage and counterfeit drugs through the proposed Pharmaceutical R&D Treaty

Kevin Outterson*

Abstract: One obstacle to the widespread rollout of compulsory licensure or greatly expanded access to essential pharmaceuticals is the fear that drugs intended for the poor will be diverted into high income markets, undermining pharmaceutical profits and ultimately, pharmaceutical R&D. In fact, this form of dysfunctional pharmaceutical arbitrage is rarely observed. A much greater threat to both pharmaceutical profits and public health is the production and sale of counterfeit drugs. The proposed R&D Treaty would eliminate the threat of dysfunctional arbitrage and dramatically reduce incentives to counterfeit.

I. Dysfunctional Pharmaceutical Arbitrage of AIDS Drugs

A. Dysfunctional Arbitrage is Rarely Observed

International pharmaceutical arbitrage (or parallel trade) seems to pose a plausible risk to pharmaceutical companies and essential access programs for high-cost drugs. The consumer retail price of a kilogram of the active ingredients in Combivir[1] is about $20,000 in the U.S., but sells for as little as $612 in Hyderabad and sub-Saharan Africa.[2] This price differential is equal to about twenty-five times the average per capita income in the lowest income countries. Neo-classical economic theory predicts that entrepreneurs[3] will divert these drugs from the poor and export them to wealthy countries where they will fetch higher prices. Domestic arbitrage occurs within the U.S. at much lower thresholds. Much smaller price differentials have instigated significant arbitrage within the US market,[4] a billion dollar trade flow from Canada to the US,[5] and a multi-

* Associate Professor of Law, West Virginia University. Kevin.Outterson@mail.wvu.edu.

[1] Combivir is GlaxoSmithKline's best selling ARV drug, and the company holds a forty-five percent global market share in HIV/AIDS drugs. *See* Gautam Naik, *Glaxo's HIV Drugs Come Under Pressure: Competition, Calls for Price Cuts Weakens Company's Dominance of Maturing Market*, WALL ST. J., Sept. 22, 2003, at B3; GLAXOSMITHKLINE PLC, 2003 ANNUAL REPORT, Form 20-F, at 63 (total of all HIV sales), *available at* http://www.sec.gov/edgar/searchedgar/companysearch.html.

[2] The active ingredients in Combivir total 450 mg per tablet. A kilogram of active ingredients will create approximately 2222 tablets. The retail price of 2222 tablets of Combivir in the U.S. retail market exceeds $20,000. See http://www.drugstore.com (visited July 9, 2004).

[3] Or smugglers, depending upon your perspective.

[4] Jackie Judd, Senior Fellow with the Kaiser Family Foundation Speaks with Gilbert M. Gaul and Mary Pat Flaherty, Washington Post Staff Writers on a Five-Day Special Report Called "Pharmaceutical Roulette," that Focuses on Prescription Drug Safety Issues in the United States, (Kaiser Family Foundation transcript, Oct. 24, 2003), http://www.kff.org (describing significant arbitrage diversion within the U.S. market taking advantage of relatively modest price differentials).

[5] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §VII (pending, 2004).

billion euro parallel trade in Europe.[6] Since the great majority of the world's AIDS patients are in poorer countries, if only a small percentage was diverted, significant volumes of ARVs could flow into high income country markets.[7]

Further, criminal organizations might be attracted to the profits to be found in dysfunctional pharmaceutical arbitrage. The pricing ratios operating in the illegal cocaine market are broadly similar to ARV pricing ratios. The U.S. wholesale price of a kilogram of cocaine ranges from $13,000 to $25,000,[8] comparable to the U.S. retail value of a kilogram of the active ingredients in Combivir.[9] The U.S. retail price of a gram of cocaine is about $100.[10] The retail price of cocaine in Columbia is between three dollars and five dollars per gram,[11] yielding a ratio of about 25:1.[12] Since ARV arbitrage offers potentially higher profits than cocaine trafficking, one might expect criminal enterprises to enter the ARV business, especially since the risk of apprehension and punishment are so severe for cocaine trafficking, but relatively modest for prescription drug counterfeiting.[13]

Given these facts, it would be striking if dysfunctional ARV arbitrage did not occur. And yet reality appears to depart from the neo-classical economic model, for there is quite limited evidence of dysfunctional arbitrage. It is notable that generic drugs have been produced in India for decades without apparently infiltrating or undermining Western markets.[14] As of April 2002, both the European Commission and the

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[6] PETER WEST & JAMES MAHON, BENEFITS TO PAYERS AND PATIENTS FROM PARALLEL TRADE (York Health Economics Consortium Working Paper, May 2003); *see also* PANOS KANAVOS ET AL., THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE: A STAKEHOLDER ANALYSIS 15-16 (Special Research Paper, London School of Economics and Political Science, Jan. 2004) *available at* http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/documents/otherpaperseries.htm.

[7] The United States is a likely target market. The EU may not be as vulnerable to diversion because most of its citizens are covered by a third party prescription drug benefit, and may not as price sensitive. *See, e.g.*, DG TRADE, EUROPEAN UNION, TIERED PRICING FOR MEDICINES EXPORTED TO DEVELOPING COUNTRIES, MEASURES TO PREVENT THEIR RE-IMPORTATION INTO THE EC MARKET AND TARIFFS IN DEVELOPING COUNTRIES (EU Working Document, Apr. 22, 2002), at §3.3. This conclusion might be true for ultimate consumers, but European intermediaries such as parallel traders could seek arbitrage earnings from this trade. The available evidence suggests that European parallel traders are closely scrutinized and do not knowingly participate in illegal diversions. *See, e.g.*, Glaxo Group Ltd v. Dowelhurst Ltd, [2004] E.T.M.R. 39 (July 31, 2003) *available at* 2003 WL 21729286.

[8] U.S. Drug Enforcement Administration, Drug Trafficking in the United States, Sept. 2001, *available at* http://www.usdoj.gov/dea/pubs/intel/01020/index.html (visited July 7, 2004) (2000 data). Retail prices per gram are significantly higher, particularly for smaller quantities.

[9] *See supra* note 2.

[10] OFFICE OF NATIONAL DRUG CONTROL POLICY, TRENDS IN COCAINE PRICES (1981-2000) (price per gram for purchase of 1 to 10 grams). The UK price for a gram in similar lots is around £ 50. Independent Drug Monitoring Unit Ltd., UK Drug Prices 2002, http://www.idmu.co.uk/prices02.htm.

[11] From a hopelessly anecdotal source, a travel journal of an American using drugs in Columbia. David Ashley, Cocaine in Columbia, http://www.erowid.org/experiences/exp.php?ID=1796 (last visited—the website, not Columbia—July 9, 2004).

[12] The numerator is $100 per gram and the denominator is $4 per gram.

[13] Alliance Against Counterfeiting & Piracy, Proving the Connection: Links Between Intellectual Property Theft and Organised Crime 7-8 (circa 2002) *available at* www.a-cg.com (visited Oct. 7, 2004).

[14] One would expect some significant reported court cases over the past 20 years on illegal imports of Indian and other unlicensed generics if the problem was widespread. Andrew Farlow of Oxford finds little

pharmaceutical companies acknowledged that pharmaceutical arbitrage from poor countries into high income countries was "still largely theoretical."[15] Only six months later, GlaxoSmithKline, the patent holder for several important AIDS drugs, brought the sensational charge that 36000 packages of HIV/AIDS medicines worth approximately US$18 million were found to have been diverted from West Africa to the EU.[16] GlaxoSmithKline sued several participants in the transactions, including a legal parallel trader in pharmaceuticals, Dowelhurst Ltd, for trademark infringement.[17]

The Dowelhurst case unearthed several remarkable facts which undercut the public relations spin that Glaxo had put on the case. First, 99% of the packages handled by Dowelhurst were not part of Glaxo's charitable access initiative for Africa, but were ordinary commercial sales to Africa, at prices approximating EU prices.[18] The Deputy Judge expressed keen displeasure upon finally understanding this point, as he had been led to believe that all of the packages were destined for charitable access programs.[19] Second, 99% of the packages had been sold within Europe, to addresses in France, and probably never made the trip to Africa.[20] The alleged diversions occurred in Europe, not in Africa. I say alleged diversions, because the case clearly says that the resale of the drugs was not proscribed by contract.[21] Third, by placing the packages into commerce within Europe, Glaxo exhausted its IP rights within Europe.[22] Finally, Glaxo sold the packages without any attempt to label them as ineligible for sale or re-importation into the EU. They were packaged in French, with EMEA license codes and nothing was done to indicate they were destined for a charitable access program.[23] Legal European parallel traders were led to believe the drugs had been lawfully placed into European commerce. Indeed, the defendant suggested that Glaxo did so deliberately in order to generate the

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evidence of diversion, Andrew Farlow, Costs of Monopoly Pricing Under Patent Protection, Presentation at Columbia University, Dec. 4, 2003, slide 19.

[15] DG Trade, *supra* note 7, at §3.3.

[16] A sample of media reports from three continents in October 2002 include: Gautam Naik, *Profiteers Divert to Europe AIDS Drugs Meant for Africa*, Asian Wall St. J., Oct. 7, 2002, at A9; Sarah Boseley & Rory Carroll, *Profiteers Resell Africa's Cheap Aids Drugs*, The Guardian, Oct. 4, 2002, at P1; *HIV Drugs For Africa Diverted to Europe; Probe Targets Wholesalers*, Wash. Post, Oct. 3, 2002, at A10. *See also* Graham Dukes, Interim Report of Task Force 5 WORKING GROUP ON ACCESS TO ESSENTIAL MEDICINES 32 (UN Millennium Project, Feb. 1, 2004), at 50, n.1.

[17] Glaxo Group Ltd v. Dowelhurst Ltd, [2004] E.T.M.R. 39 (July 31, 2003) *available at* 2003 WL 21729286.

[18] *Id.* at ¶36.

[19] *Id.* at ¶46. The Deputy Judge imposed over 90% of the litigation costs on Glaxo, in part because he felt misled. Glaxo Group Limited v. Dowelhurst Limited, [2003] E.W.H.C. 3060 (High Court, Ch. Div. 2003) *available at* 2003 WL 23014797, at ¶¶ 10, 17.

[20] Glaxo Group Ltd v. Dowelhurst Ltd, [2004] E.T.M.R. 39 (July 31, 2003) *available at* 2003 WL 21729286, at ¶¶ 66-76. Only 1% of the packages had actually been sold to a buyer in Africa, namely the packages involved in the access program.

[21] *Id.* at ¶ 39.

[22] *Id.* at ¶¶ 66-76. On appeal, the Court of Appeal upheld the Deputy Judge's rulings on summary judgment, permitting the trial to proceed on the question of compliance with EU rules for pharmaceutical parallel trade. Glaxo Group Limited v. Dowelhurst Limited, [2004] E.W.C.A. Civ. 290 (Court of Appeal, Civ. Div., 2004) *available at* 2004 WL 412961. Specifically, the Court of Appeals upheld the exhaustion rule on 100% of the packages rather than just 99%. *Id.* at ¶¶ 30-40.

[23] Glaxo Group Ltd v. Dowelhurst Ltd, [2004] E.T.M.R. 39 (July 31, 2003) *available at* 2003 WL 21729286, at ¶¶ 46-50.

resulting publicity.[24] Within three weeks of the Glaxo diversion story, the European Commission announced plans to issue a regulation to curb such diversions.[25] The 2003 Council Regulation promptly required many modifications to packages and pills destined for essential access programs.[26]

The only other major media report of diversion of essential access drugs was in Forbes in April 2004, noting diversions in Indonesia, Chile and Lebanon.[27] This story parroted PhRMA's spin on the 2002 Glaxo case in Europe, but failed to mention any of the facts from the Dowelhurst case discussed above. The source of the report in Indonesia was a survey in Jakarta by a respected local health group, which found many donated drugs being either sold on the black market in Jakarta or available in the public health clinics for a price in excess of the statutory maximum.[28] This is a simple case of local corruption, and there is no evidence that the drugs are leaving the immediate market. This situation might be regrettable, but it is not dysfunctional arbitrage; it does not replace commercial markets in the high income countries. Similar local diversions occur in the United States.[29] The reports from Chile and Lebanon are sourced exclusively from local affiliates of PhRMA. Neither report was substantiated; nor do they suggest dysfunctional arbitrage as opposed to local movement of drugs within low or medium income countries. In sum, empirical evidence to date does not indicate a sizable arbitrage market in ARVs from low income markets into the high income countries.

B. Effective Measures to Hinder Dysfunctional Arbitrage

Possible reasons for the dearth of empirical evidence of dysfunctional pharmaceutical arbitrage include moral and legal sanctions within high income market countries. The impact of these norms is significant in pharmaceutical arbitrage markets. When pharmaceutical arbitrage is unmistakably legal, it flourishes, even at low differential pricing ratios. For example, the EU follows the "community exhaustion" rule, permitting parallel trade in patented and trademarked products within the European Economic Area. Differential pricing ratios of less than 2:1 have been sufficient to create a multi-billion euro legal arbitrage market within the EU,[30] subject to complex rules on repackaging and trademark infringement devised by the European Commission and the

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[24] *Id.* at ¶¶51-53.

[25] *EU/WTO – Plan to Curb Illicit Medicines Trade*, Eur. Rep. Oct. 26, 2002 (no page number available) *available at* 2002 WL 13768322.

[26] At present, the EU Council Regulation only applies to "tiered price" pharmaceutical exports to 76 listed developing and least-developed countries and to "HIV/AIDS, malaria, tuberculosis and related opportunistic diseases," (a limitation which should be amended following Cancun). The EU defines a "tiered price" pharmaceutical as being offered to the poor for either direct manufacturing cost plus no more than 15% or at less than 25% of the OECD weighted average ex-factory price. Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/6) art. 3(a).

[27] Richard C. Morais, *"Pssst … Wanna Buy Some Augmentin?"* Forbes 2000, April 12, 2004 *available at* http://forbes.com/forbes/2004/0412/112_print.html.

[28] *Id.*

[29] Judd, *supra* note 4.

[30] WEST & MAHON, *supra* note 6; KANAVOS ET AL., *supra* note 6, at 15-16.

European Court of Justice.[31] As described above, illegal pharmaceutical arbitrage is rarely observed in the EU.[32]

Canada provides a contrasting example. Pharmaceutical arbitrage from Canada to the U.S. operated for years under legal ambiguity. Proponents occupied the moral high ground of enhanced consumer access. The pricing differential is less than 2:1, but the arbitrage market now is in the range of $600 million to $1.1 billion a year.[33]

So the first imperative is to prevent any legal or moral uncertainty concerning dysfunctional arbitrage. At a minimum, diversion to high income country markets of drugs intended for the poor should be clearly illegal. The EU, for example, promptly moved in this direction following media reports of the Glaxo diversion.[34] The US should follow suit.

The second task is to modify the product to resist substitutability. The pharmaceutical manufacturing process could be altered to create multiple versions of any prescription drug, distinguished by radically different colors, shapes, names, sizes and packaging. Markets must be segmented into commercial and charitable markets, and never the twain shall meet. The Cancun General Council Decision addresses this issue: exporting countries must clearly identify the products through labeling or marking and through special coloring or shaping.[35] The EU Council Regulation follows this tact.[36] GlaxoSmithKline and others are complying, altering both the packaging and the color of the product.[37] These steps will eliminate the flow of improperly diverted essential access medicines through legal distribution channels such as parallel traders and distribution companies.

Third, consumers in high income markets can be persuaded to resist substitution. Advertising could be directed to commercial market consumers, warning them never to take the red pills with labels in Swahili. This should not be an implicit safety warning: "those pills may not be safe," since Africans will be told exactly the opposite: "the red pills are safe and effective."[38] Advertising should describe diversion as a moral and legal issue: high income patients who take pills intended for impoverished Africans are

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[31] For a recent discussion, *see* Boehringer Ingelheim KG v. Swingward Ltd, [2004] E.T.M.R. 65 (Mar. 5, 2004) *available at* 2004 WL 343819, at ¶¶ 3-17.

[32] *See supra* Section I.A.

[33] Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §VII (pending, 2004). The higher range estimate comes from IMS.

[34] *See* Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/6) art. 3(a).

[35] World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 ¶11 (Decision of the General Council of 30 August 2003), at ¶ 2(b).

[36] Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/5) ¶10. While the Council Regulation addresses importation in luggage for personal use, similar to the U.S. personal importation rule, it does not address (but probably covers) internet sales. *Id.* at ¶13, art. 10. Seized product may be used for humanitarian purposes. *Id.* at ¶14.

[37] GLAXOSMITHKLINE PLC, 2003 ANNUAL REPORT, Form 20-F, at 29.

[38] Vertical product differentiation based on quality is common in some products (regular v. premium gasoline), but is probably untenable in pharmaceuticals.

stealing from the poor.[39] Under the EU Council Regulation, all covered pharmaceuticals exported from the EU will bear a special logo identifying the product as destined for the poor.[40] In addition, domestic law within the high income countries should criminalize the practice.

The final front for anti-diversion measures are the borders of the high income countries. Pharmaceutical arbitrage may become dysfunctional only when diversion occurs from low or middle income markets to high income markets. Trade among or between low and middle income markets is not dysfunctional.[41] Thus, the key moment to control dysfunctional arbitrage is at the border of high income countries, not at the border of the exporting country. These protections can be put into place immediately by high income countries, and do not depend upon reaching a multilateral agreement at the WTO. Furthermore, the high income countries possess the resources and infrastructure to make interdiction a reality. Indeed, the absence of observed dysfunctional arbitrage may well be a result of the border controls over the entry of drugs that many high income countries enjoy.

C. High Income Markets Should Bear the Burden of Anti-Diversion Measures

The most striking aspect of these anti-diversion measures is that the responsibility for all of them logically rests upon the manufacturers and high income markets. All four measures do not require expenditure by low or medium income countries. Nevertheless, when PhRMA companies finally agreed to significant differential pricing of ARVs in low income countries, they insisted on strong anti-diversion protections and burden-sharing by the recipient countries.[42] The Cancun General Council Decision requires importing countries to implement reasonable measures to prevent diversion and re-exportation. "Reasonable" measures must be "within their means" and "proportionate to their administrative capacities and the risk of trade diversion."[43] Under Cancun, developing and least developed countries inappropriately bear these costs even if global patent rents are supra-optimal.[44]

Minor diversions at the clinic or patient level should not be an international enforcement focus. Given the difficulty in setting up a source collection system, it is unlikely that small batches or individual blister packs without packaging will filter back

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[39] If the arbitraged drugs were voluntarily sold rather than stolen, then the moral claim weakens.

[40] Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/7). The logo is found in Annex V of the regulation.

[41] Trade amongst individuals who could not afford pharmaceuticals at OECD prices is not dysfunctional since it does not reduce pharmaceutical patent rents. For a detailed explanation of this position, s*ee* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §V.D.2 (pending, 2004).

[42] Paul Blustein & Barton Gellman, *HIV Drug Prices Cut for Poorer Countries; Other Firms May Follow Merck's Lead*, WASH. POST, Mar. 8, 2001, at A1.

[43]World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 ¶11 (Decision of the General Council of 30 August 2003), at ¶ 4.

[44] If global patent rents are supra-optimal, these costs could be borne by the PhRMA companies without harming innovation. Placing the burden on countries with annual per capita health budgets of $100 or less is exceedingly unfair.

to high income country markets in significant quantities. Minor local diversions are likely to remain in the region, and may well be re-sold to other poor patients outside of the current distribution system.[45] This is not a best-case result, but certainly is not an enforcement priority. The priority should be on weaknesses in the supply chain where large batches could be diverted in a single transaction. The risk may be greatest while the product is still outside of the recipient country.[46]

Finally, some level of dysfunctional arbitrage may be tolerable from an innovation point of view. So long as commercial markets are not replaced, the practice will not harm innovation. Modest leakage from commercial markets may reduce patent rents, but will not harm innovation if patent rents are supra-optimal.[47]

II. Counterfeit Drugs

In the debates over essential medicines, care must be taken to distinguish arbitrage from counterfeiting. For example, a 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."[48] These drugs may be poorly produced, or too strong by U.S. standards, but they should not be called counterfeits.[49] In copyright and patent practice, a 'counterfeit' or 'pirated' copy is one that was manufactured by an unlicensed source, but it might well be as functional as the genuine article.[50] In pharmaceuticals, the term 'counterfeit' should be reserved for a drug which does not contain the proper active ingredient.[51] A safe and effective pill which is produced without a patent license should be called an 'unlicensed' product.

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[45] This appears to be the case in Jakarta. Richard C. Morais, *"Pssst … Wanna Buy Some Augmentin?"* Forbes 2000, April 12, 2004 *available at* http://forbes.com/forbes/2004/0412/112_print.html.

[46] Both conditions were present in the Glaxo case.

[47] A detailed discussion of pharmaceutical patent rent optimality may be found in Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §V (pending, 2004).

[48] Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead*, Wall St. J., Aug. 10, 2004, at D4. *See also* Mark McClellan, Testimony before the Senate Committee on Commerce, Science & Transportation, March 11, 2004 (discussing "unapproved, imported pharmaceuticals" and "unsafe and illegal drugs" with "ineffective, counterfeit" drugs) (McClellan was at the time the Commissioner of the Food and Drug Administration; he currently heads the Centers for Medicare and Medicaid Services).

[49] The trade association of European pharmaceutical research companies and the WHO use the broader definition. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, INTERNATIONAL EXHAUSTION OF TRADE MARK RIGHTS 5 (April 2001). My point is not to argue who's definition is 'right,' but to demonstrate the analysis which is possible when using a narrower definition.

[50] A counterfeit Gucci purse might nevertheless be a fully functional and stylish purse. A counterfeit music CD contains authentic, but unlicensed, recordings. Pharmaceuticals may contain sub-therapeutic doses of the active ingredients; be improperly packaged, labeled, or stored; or may contain improper contaminants. These drugs are substandard rather than being counterfeit.

[51] The FDA definition is broader, including drugs with improper dosages, sub-potent or super-potent ingredients, or contamination. U.S. Food & Drug Admin., FDA's Counterfeit Drug Task Force Interim Report 5 (Oct. 2003) *available at* http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html (visited Oct. 1, 2004). This improperly conflates counterfeits with poorly manufactured or stored product.

Empirical evidence suggests that virtually all of the internationally arbitraged drugs arriving in the US are not counterfeits by this definition.[52] These drugs might violate restrictions on parallel importation, FDA approval or labeling, or other laws, but they are not counterfeit. Most of the counterfeit drugs in the U.S. have domestic origins or domestic networks,[53] but the FDA still considers it a relatively rare practice,[54] which is nevertheless growing rapidly.[55] In 2000, the estimated value of EU pharmaceutical counterfeiting was Euro 1.554 billion. The UK-based Anti-Counterfeiting Group estimated in 2003 that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting.[56] If true, counterfeiting is a major threat not only to public health, but also to innovation, far outstripping the limited potential damage from dysfunctional pharmaceutical arbitrage.

Criminal enterprises are currently involved in pharmaceutical counterfeiting.[57] Counterfeiting opportunities may explain the absence of criminal ARV arbitrage. In the illegal, nonprescription drug market, counterfeiting is a difficult practice: If users do not get high, the product will not sell, particularly in sales between repeat players.[58] In prescription drugs, however, the opportunity for counterfeiting is much greater. Patients are often unable to know whether a counterfeit pill contains the correct active ingredients. It may take weeks or months to notice that therapy is failing, and the cause of failure may not be linked with the counterfeits. Counterfeits may be introduced into legitimate supply chains, diluting therapy but making the counterfeiting more difficult to observe and trace. These information characteristics enable the criminal seller of counterfeit prescription drugs to act as if the transactions were discrete, rather than repeating.

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[52] In the FDA seizures of imported drugs, no counterfeit drugs were found, FDA Press Release, Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004) (mentioning many categories of unapproved drugs but never indicating that any of them contained no active ingredient).

[53] Mary Pat Flaherty, *US Prescription Drug System Under Attack: Multibillion-Dollar Shadow Market is Growing Stronger*, Wash. Post, Oct. 19, 2003, at A1.

[54] FDA, Counterfeit Drug Task Force Interim Report 3 (Oct. 2003).

[55] The FDA estimates that pharmaceutical counterfeiting has increased four fold in the past few years. *See The Washington Post* series of articles on counterfeit drugs which ran in Fall 2003 by Mary Pat Flaherty and Gilbert M. Gaul. *See, e.g.*, Mary Pat Flaherty & Gilbert M. Gaul, *Anti-Counterfeit Steps 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. The Wall Street Journal has also covered the story. Anna Wilde Mathews and Heather Won Tesoriero, *Murky Channels: Bogus Medicines Put Spotlight On World of Drug Distributors*, WALL ST. J., Sept. 29, 2003, at A1.

[56] The Anti-Counterfeiting Group, Why You Should Care About Counterfeiting 14 (circa 2003) *available at* www.a-cg.com (visited Oct. 7, 2004).

[57] Alliance Against Counterfeiting & Piracy, Proving the Connection: Links Between Intellectual Property Theft and Organised Crime 2 (circa 2002) *available at* www.a-cg.com (visited Oct. 7, 2004) ("This document provides clear and unambiguous evidence of organised crime controlling, exploiting and benefiting from intellectual property fraud. It is on the increase.").

[58] The business plan of the Cali drug cartel probably includes a quality assurance mechanism. See the interesting (and merely conjectural) marketing plan for the Cali Cartel by Matthew Kwan, completed during his MBA studies at the Melbourne Business School, http://www.darkside.com/au/mba/cali.html (visited July 8, 2004).

While obtaining arbitraged ARVs might be possible, obtaining them in sufficient quantities would require a procurement team in the field (sub-Saharan Africa), with multiple diversions against an alerted supply chains, followed by repackaging and a reverse supply chain back to high income country markets. Counterfeits could be appropriately labeled and packaged, rather than having pills in the wrong color and packaging labeled for essential medicine programs. These characteristics enable counterfeits to be introduced into high income country supply chains directly, and much easier than diverted pills from Africa**.** Counterfeiting dispenses with many costs. The per pill cost to produce a placebo without active ingredients may be far cheaper than covert diversion and procurement, re-coloration, repackaging, and transportation. Finally, it us unlikely that anyone would bother to counterfeit a cheap generic drug. Expensive, patented drugs are the targets of counterfeiters; cheap generics are not.[59] A criminal is unlikely to counterfeit a pill and sell it as aspirin or Triomune, when it could be sold as Lipitor or Fuzeon. When low-cost unlicensed generics are widely available, the public health threat of counterfeits recedes.

Additional anti-counterfeit measures in high income countries should include a pedigree system of tracing drugs from the manufacturer to the consumer. A pedigree system (or the European system of parallel traders giving notice of intent to trade) would also hinder arbitrage by making product movement transparent to the manufacturer. Most importantly, routine market sampling for counterfeits must be introduced, and sources of counterfeit drugs aggressively traced by law enforcement.[60]

III. The Hubbard-Love R&D Treaty Resolves Both Issues

Free trade in goods and services is the default position for most international economists. In patented pharmaceuticals, free trade has been blocked largely on innovation grounds: parallel trade hinders pharmaceutical profits, and thus, pharmaceutical R&D. The Hubbard-Love R&D Treaty[61] proposes to take all R&D cost recovery out of the price system, and to fund R&D as a global public good. Doing so removes all of the innovation arguments restricting pharmaceutical trade.

Counterfeits, not dysfunctional arbitrage, are the more immanent danger to both public health and PhRMA innovation. Counterfeiting will remain an issue so long as the actual product has a high value relative to the cost of manufacturing a plausible placebo. Current ratios of marginal cost to sales price exceed 30:1, attracting criminal enterprises

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[59] The examples of counterfeits in most media and FDA reports are of expensive patented drugs such as Lipitor, Epogen, Zyprexa and Serostim. *See* Leila Abboud, Anna Wilde Mathews & Heather Won Tesoriero, *Fakes in the Medicine Chest; As Drug Counterfeiting Rises, FDA May Propose Changes in Sales, Distribution Network*, WALL ST. J., Sept. 22, 2003, at B1.

[60] Some steps towards an anti-counterfeiting policy are being taken by the FDA Task Force. FDA, Counterfeit Drug Task Force Interim Report 18-22 (Oct. 2003) *available at* http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html.

[61] *See, e.g.*, TIM HUBBARD, ALTERNATIVES TO THE PRICE SYSTEM (Presentation at Columbia University, Dec. 4, 2003) *available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html*; JAMES LOVE, A NEW TRADE FRAMEWORK FOR GLOBAL HEALTHCARE R&D (Presentation at Columbia University, Dec. 4, 2003) *available at http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html*

to the counterfeit drug market. By removing R&D costs from the retail pricing system, the R&D Treaty will greatly reduce counterfeiting pressure. If the ratio drops to 1:1, no incentive remains to counterfeit.

Public Comment on the Proposed "Anti-Counterfeiting Trade Agreement"
Submitted to the Office of the United States Trade Representative
March 21, 2008

If governed effectively, the trade in knowledge-based goods offers an historic opportunity to promote global prosperity. Medicines, information and communications technologies, and cultural resources (like books and music) all contain the promise of a better world where citizens, communities, and nations have access to the means of their own well-being. However, this promise brings immense responsibilities. The policy-makers and officials charged with overseeing the global trade of intellectual properties must balance competing claims in order to design effective governance systems. The recent actions of the Office of the United States Trade-Representative (USTR) reject balance, evidence, and democratic values in favor of elitism.

Since October of last year, the Office of the USTR has sought to promote an "Anti-Counterfeiting Trade Agreement" (ACTA). In public documents and statements, The office has claimed that ACTA will promote the sustainable development of the world economy and international cooperation by "fighting fakes." These claims lack any empirical grounding. As proposed, ACTA will neither encourage economic growth nor cooperation. Instead, ACTA will stifle democracy, development and innovation by creating an exclusive, ineffective agreement outside of the multilateral institutions that govern global trade. **As a result, ACTA threatens the interests of the United States and the world and it ought to be abandoned immediately.**

The Office of the USTR has not been forthcoming with substantive information about the details of ACTA. This lack of public information is both alarming and disgraceful in a democratic society. However, even the few existing arguments the USTR has made in favor of the agreement do not withstand rigorous scrutiny. For example, the USTR's ACTA "Fact Sheet" begins with the following statement:

> The proliferation of infringements of intellectual property rights ("IPR") particularly in the context of counterfeiting and piracy poses an ever-increasing threat to the sustainable development of the world economy.

This assertion - that counterfeiting and piracy threaten economic development - ignores current research on the nature of knowledge-based assets, IP-related trade, and innovation practices in the global economy. Numerous academic experts in the fields of economics, law, sociology, business, and political science have produced empirical analyses that undermine these claims. Furthermore, a growing consensus of legal and policy experts agree that the current system of strict IP-enforcement endorsed by the USTR does not serve the public interest. The fact that the USTR retains a myopic focus on devoting additional time and resources to strengthening enforcement reflects the office's inability to incorporate diverse perspectives into its policy-making process. Alternative models of IP regulation and management exist that can distribute

wealth, knowledge, and intangible assets more efficiently. *The USTR ignores these alternatives at the peril of the economic prosperity of the United States and the world as a whole.*

The "Fact Sheet" goes on to claim that international cooperation should play a crucial role in promoting economic development and safety through IP-related trade. Yet, the actions of the USTR on ACTA contradict this position. In the absence of widespread support for ACTA in public global governance forums such as WIPO and the WTO, the USTR has opted to pursue closed negotiations and consultations with wealthy states and industry lobby groups that stand to benefit from strict IPR regimes. In the process, the USTR has turned its back on transparent and accountable policy-making in public institutions. The USTR has also denied governments, civil society groups, academic experts, corporations, and citizens who disagree with the "strict IP enforcement" approach a seat at the bargaining table. Instead of truly cooperative and democratic dialogue, the USTR has demonstrated a preference for unilateralism, cronyism and corruption

In order for IP-related trade reform to produce sustainable economic growth and development, the USTR should puruse a more transparent and democratic approach. This means that the USTR must not create policy in a narrow-minded echo chamber, but through inclusive, deliberative process where all of the stakeholders have an equal ability to influence the outcome of the debate. The US government, other wealthy states, and a handful of large private firms can no longer afford to act as though they have a natural right to unilateral decision-making. More than ever, the possibility of global security, prosperity, and well-being depends upon the ability of the United States to embrace democratic due process in global governance. The knowledge-based economy will not produce public goods unless a broader public has a say in its control.

As a result, I recommend that the USTR take immediate action to ensure that the following three conditions for all future negotiations on IP governance and regulation are met:

(1) Abandon all efforts to pass ACTA and bring negotiations on future IP-related trade agreements into the global governance institutions where they belong. WIPO and the WTO remain far from democratic or public in many ways, but they would be a vast improvement over the fractious, power-politics embodied by ACTA today.

(2) Publicly recognize that strict enforcement of the existing, broken IP system does not advance the interest of the United States or the rest of the world. The USTR currently pursues a blinkered approach to IP policy. Part of the reason the gray-market in unlicensed reproductions of patented, copyrighted, and trademarked goods thrives around the world is that existing IP laws contradict legitimate social needs. By ignoring these issues the USTR does not make them go away. The United States and the world require a more forward-thinking policy and a public statement to this effect would be a positive first step towards meeting this need.

(3) Increase opportunities for substantive public participation in USTR policy-making and agenda-setting. Currently, the USTR values the interests of a small minority of the country's businesses at the expense of other firms and many millions of its citizens. The existing approach of closed-door meetings with industry lobby groups will not correct this problem. The USTR

should regularly hold open public fora, debates, and hearings on trade-related issues in locations around the country. All possible steps should be taken to ensure that diverse perspectives on US trade policy are represented in these settings and that the USTR takes these perspectives into account. The office must also make available more information on existing policies and proposals.

Thank you for to opportunity to submit a comment on this proposal. Please do not hesitate to contact me with any questions or concerns regarding my submission.

Yours sincerely,

Aaron Shaw

PhD Student
Department of Sociology
UC Berkeley

410 Barrows Hall #1980
Berkeley, CA 94720

adshaw@berkeley.edu

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

THOMAS J. DONOHUE
PRESIDENT AND
CHIEF EXECUTIVE OFFICER

1615 H STREET, N.W.
WASHINGTON, D.C. 20062-2000
202/463-5300 • 202/463-5327 FAX

March 21, 2008

The Honorable Susan Schwab
United States Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Schwab:

The U.S. Chamber of Commerce is pleased to submit the following comments in response to the United States Trade Representative's Federal Register Volume 73, Number 32.

Intellectual property (IP) protection is among a handful of issues that will determine America's economic growth and competitiveness in the 21st century. The ability to create, innovate, and generate the best artistic, technological, and knowledge-based IP is essential to global economic growth and the advancement of human progress. To that end, we are prepared to support an ambitious, comprehensive, and enforceable Anti-Counterfeiting Trade Agreement (ACTA).

We encourage the administration to collaborate with other ACTA partners to ensure a timely launch of negotiations. This agreement must establish a high standard and effective international framework for the protection and enforcement of IP. This may initially require negotiations with a small group of partners that are able and willing to reach the high standards required for an effective agreement.

Any new agreement must build on the enforcement text of Trade-Related Aspects of Intellectual Property Rights and recent U.S. Free Trade Agreements (FTAs) to produce a measurable improvement in the prevailing legal framework for the protection and enforcement of IP rights. Specific provisions of recent FTAs, especially those with Korea and Oman, should serve as templates for this agreement.

The agreement should include an effective and credible mechanism to monitor and provide incentives to encourage parties' compliance with obligations. As a binding dispute resolution mechanism is not contemplated, a system such as a peer review mechanism should be included. It must also include a meaningful level of deterrence.

The following list identifies measures we would consider essential for inclusion in a high-standard ACTA.

LEGAL FRAMEWORK:

Criminal Enforcement:

- Criminal penalties for IP crimes, including online infringements.
- Provisions mandating that physical and financial assets of violators may be seized.
- Provisions to make trademark counterfeiting an extraditable offense.
- Provisions requiring that penalties be sufficiently high to provide a deterrent and are "consistent with removing the monetary incentive of the infringer."
- Enhanced measures to allow rights holders and law enforcement agencies to identify and take action against proceeds of crimes.
- Enhanced legal framework relating to landlord liability.
- Provisions to clarify that the concept of counterfeiting or piracy "on a commercial scale" includes both infringing acts carried out for commercial advantage or private financial gain, and infringing acts of undertaken without a profit motive but which cause damage on a commercial scale.
- Measures to provide judicial authorities with the authority to order forfeiture of assets of violators traceable to the infringing activity.
- Commitment of all parties to criminalize unauthorized camcording of motion pictures in theaters.
- Broader search orders, without formal complaint by a rights holder, that facilitate seizures of all counterfeit and pirated material found at a raid site; the seizure of implements of the violators used in committing the offense; and the seizure of assets and documentary evidence without qualification.

Border Measures:

- Commitment by all parties to expand the powers of national customs authorities (ex-officio authority) to interdict shipments entering or exiting their jurisdiction, in transit or in free trade zones based on legally accepted and recognized terms of probable cause and acting on reliable information. Without prejudice to right holders' ability to initiate and terminate legal action against infringers, customs officials and prosecutors must have the authority to bring IP enforcement action without a formal complaint from rights holders.
- Measures to provide competent authorities with the authority to provide right holders with information, including identifying the consignee, exporter, importer, and consignor as well as the country of origin, quantity of goods seized, and description of goods.

Civil Enforcement:

- The agreement must establish global minimum standards in areas of adjudication of infringement cases, and include commitments to:
  - Ensure that civil damages must compensate the rights holder for damages suffered and deprive infringers of any profits from the infringement.
  - Establish a statutory (pre-established) damages option—at the election of the rights holder. Statutory damages must be "in amount sufficient to constitute a deterrent to further infringement."
  - Abolish rules against self-incrimination in civil IP cases.
  - Expansion of the authority of judicial authorities to cover infringing activity with regard to imports and exports of counterfeit and pirated material.
  - Require parties to authorize the seizure, forfeiture, and destruction (without exception) of counterfeit goods and the equipment used to produce them.

- Ensure that interpretation of data privacy rules appropriately balances the fundamental rights of privacy and property, including intellectual property, to ensure they do not create undue impediments to the enforcement of rights. In particular, ACTA should ensure that overly strict interpretations of national data privacy rules do not impede legitimate online enforcement efforts, including the graduated response mechanism, or leave right holders with the sole recourse of pressing criminal charges against online copyright infringers as the only avenue to enforce their rights.

Other:

- A universally acknowledged definition of "counterfeit goods" and "counterfeiting activities," that includes trafficking in illicit product packaging and labels (e.g., stolen or misapplied labels or packaging elements that indicate product authenticity) within the scope of "counterfeiting activities."
- Measures to ensure that government agencies do not infringe copyright and only use copies of works that have been lawfully licensed or acquired.
- Provisions tracking the language of recent U.S. FTAs to require each party to provide "legal incentives for service providers to cooperate with copyright owners."

INTERNATIONAL COOPERATION:

To effectively fight a problem that is truly global in scope, we must have cooperation across governments and law enforcement. We applaud the innovative provisions that are being considered to improve and strengthen coordination, especially the following:

- Measures to require keeping/publicizing of enforcement information.
- International cooperation among enforcement authorities including information-sharing.

- Commitment by all members to improve cooperation to carry out appropriate legal action against Internet sites that engage in the unauthorized reproduction, distribution, or transmission of copyright works.
- Provisions that mandate the sharing relevant information relating to counterfeit products and counterfeiting activities among relevant law enforcement agencies of participating governments.

The U.S. Chamber stands ready to provide whatever assistance you may think necessary to make progress on this important issue.

Sincerely,

Thomas J. Donohue