

IPR Center Report

Volume 3: No. 1 • January 2010



Partners in Action

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The IPR Center stands as a focal point in the U.S. government's fight against counterfeiting and the flow of counterfeit goods into the commerce of the U.S. The center employs a true task force model to optimize the roles and enforcement efforts of member agencies, while enhancing government-industry partnerships to support ongoing IPR enforcement initiatives.

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IPR Center Coordinates International Internet Week of Action



ICE, CBP, FDA, DEA and USFIS special agents inspect packages of suspicious medical products.

By Richard Halverson,
U.S. Immigration and Customs Enforcement

In April 2009, the concept of a global operation to target illegal Internet pharmaceutical activity began to circulate amongst law enforcement and regulatory agencies worldwide. The response was overwhelmingly positive, with 25 countries participating in an International Internet Week of Action (IIWA) from November 15-20, 2009.

During this week, participating countries targeted the sale of counterfeit and illicit medicines that threaten the public's health and safety. The IIWA, code-named Operation Pangea II, resulted in numerous arrests and the seizure of thousands of potentially harmful medical products across five continents.

In the United States, the National Intellectual Property Rights Coordination Center (IPR Center) spearheaded the U.S. government's participation in Pangea II.

Led by ICE and FDA, special agents and officers from ICE, CBP, FDA, DEA and USFIS targeted over 8,500 suspect packages, resulting in 858 detentions. In addition to the interdictions, the FDA issued 22 warning

letters about illegal activity occurring on 138 independent Web sites. The suspect Web addresses have since been posted on the FDA Web site; to date, 136 of the sites have been permanently suspended.

Worldwide, more than 16,000 packages were inspected by customs and regulatory authorities, resulting in the seizure of more than 1,000 packages and the confiscation of nearly 167,000 illicit and counterfeit pills, including antibiotics, steroids, lifestyle drugs and diet pills.

"Counterfeit pharmaceuticals pose a significant threat to the public's health and safety and must be targeted by coordinated global law enforcement action," said John Morton, assistant secretary for ICE.

"Many U.S. consumers are being misled in the hopes of saving money by purchasing prescription drugs over the Internet from illegal pharmacies," said FDA Commissioner Margaret A. Hamburg, M.D. "Unfortunately, these drugs are often counterfeit, contaminated, unapproved products, or contain an inconsistent amount of the active ingredient. Taking these drugs can pose a danger to consumers." ■

AGOA IPR Session Highlights Importance of IP Protection for African Business

By Carrie LaCrosse, U.S. Department of State,
Office of Intellectual Property Enforcement

On August 5, 2009, during a standing room only session at the 2009 African Growth and Opportunity Act (AGOA) Trade Forum, panelists and participants discussed how African businesses have been harmed by the lack of intellectual property (IP) protection and high levels of counterfeit goods in African markets. The result has been job losses, a decrease in government revenue and even de-industrialization in parts of Africa.

During the event, held in Nairobi, Kenya, co-chairs Rick Wade, deputy chief of staff to U.S. Commerce Secretary Gary Locke, and Fernando dos Santos, director of Mozambique's Industrial Property Institute, both emphasized the importance of IP in Africa's economic development. The lack of adequate IP protection in many parts of Africa is hindering investment and development while also enabling the widespread sale of counterfeits, creating public health and safety concerns.

Dos Santos called on all partners to help African countries build capacity for the management and protection of IP rights. Wade noted that managing and protecting IP is a sign that a country is making an investment in its own technical, financial and human resources—all strong potential sources of economic growth.

Next, three panelists representing African business interests highlighted the direct impact of counterfeiting on African jobs, business and investment.

Sarah Walusimbi, from Nice Plastics Co. in Kampala, described the effect that the influx of poor quality, counterfeit "Nice" toothbrushes has had on the company's production. Sales of the Nice Classic brand currently stand at less than 50 percent of the pre-2004 figures due to the presence of vast quantities of counterfeit versions in the East African region. As a result, the company's production jobs have been cut in half.

Manchester Trade's Tony Carroll discussed the dramatic decline of the West African traditional textile



industry, which has seen jobs drop from 250,000 to less than 40,000 in the last few decades; at the same time, vast amounts of trademark-infringing counterfeit textiles have entered regional markets.

James Lennox, head of the Southern African Federation Against Copyright Theft (SAFACT), noted both the good and bad in the realm of copyright protection—while counterfeiting and piracy continue to be a huge concern, the creative industries are still an area of great economic potential in Africa, particularly in film, music and TV. Lennox emphasized that in order to more fully develop, the African creative industries must become more business-like and better organized. ■

Vice President Biden Hosts IP Roundtable

By Heather O'Malley, U.S. Immigration and
Customs Enforcement

On December 15, 2009, Vice President Joe Biden hosted a roundtable discussion spotlighting the current administration's commitment to protecting intellectual property rights.

Biden was joined by high ranking government officials, including DHS Secretary Janet Napolitano, ICE Assistant Secretary John Morton, Commerce Secretary Gary Locke, FBI Director Robert Mueller and Victoria Espinel, the recently confirmed IP enforcement coordinator, or "copyright czar," for the U.S. government. This meeting was also attended by leaders from major media conglomerates, union representatives and legal experts.

The White House billed this meeting as the first of its kind. The major topic of discussion was the enforcement of intellectual property rights during a time of rapid technological growth and change.

The industry attendees emphasized the fact that piracy poses a grave danger to the health of their businesses, and thus, to the U.S. economy. Participants voiced their concerns that piracy can result in the loss of jobs and creativity, a consequence that has been raised by the IPR Center, and recently was echoed by ICE Assistance Secretary Morton at a press conference that highlighted the IPR Center's recent enforcement actions. ■

CBP Electronic Recordation of Trademarks and Copyrights Speeds Targeted Enforcement

By Charles Stewart, U.S. Customs and Border Protection

U.S. Customs and Border Protection (CBP) protects consumers worldwide from counterfeit and pirated goods through a Web-based recordation system called Intellectual Property Rights e-Recordation (IPRR).

The IPRR system allows U.S. right holders to electronically record their federally registered trademarks and copyrights with CBP and facilitates IPR seizures by making trademark and copyright information readily available to CBP personnel. CBP uses this recordation information to actively monitor shipments and prevent the importation or exportation of infringing goods.

Recording a trademark or copyright via CBP's electronic recordation system benefits both the right holder and CBP by:

1. Eliminating paper applications and the need for supporting documents (including registration certificates);
2. Allowing right holders to upload images of the federally protected right (trademark or copyright);
3. Reducing lag time from filing of the application to enforcement by field personnel;
4. Allowing for online payment by credit card or by submission of a check or money order after the filing of the application.

As soon as a trademark or copyright is registered with the U.S. Patent & Trademark Office or U.S. Copyright Office, respectively, the right holder may record the right with CBP. An

applicant records their right with CBP by:

1. Filing online and paying by credit card;
2. Filing online and mailing a check or money order; or
3. Submitting a hard copy of the application with accompanying check by mail.

The fee for recording a copyright with CBP is \$190, and for a trademark it is \$190 per International Class of goods. The information a right holder must include in its recordation application is located by querying the following regulations: 19 CFR §§ 133.1, 133.2 for trademarks, and 19 CFR §§ 133.31, 133.32 for copyrights.

IPRR is available at <https://apps.cbp.gov/e-recordations/>. Trademarks and copyrights that are recorded with CBP may be viewed by the public in the Intellectual Property Rights Search (IPRS) database at <http://iprs.cbp.gov/>.

Once a recordation is accepted by CBP, the Los Angeles National Targeting and Analysis Group (NTAG) plays a critical role in the national enforcement of the trademark or copyright. The Los Angeles NTAG is staffed by international trade specialists (ITS) who are assigned as industry officers to specialize in those industries with the highest risk for IPR infringement. Each ITS will conduct outreach within his or her

industry to familiarize IPR holders on how to work with CBP to protect IPR at the border and enhance the working relationship with right holders and CBP personnel.

In addition, ITS conduct both computer-based risk model and national officer driven targeting based on industry research and analysis and industry allegations.

ITS are available to assist CBP and ICE personnel and IPR holders, attorneys, importers and other members of the trade community. The IPR Help Desk can be reached at 562-980-3119 ext. 252 or by e-mail at iprhelphdesk@dhs.gov.

CBP has also established an online procedure called "eAllegations" which allows individuals to quickly and easily report illegal import and export activity. By completing and submitting the form, you can help CBP prevent international trade violations and ensure trade compliance. The eAllegation system is accessible online at <https://apps.cbp.gov/eallegations/>. ■



CBP Recordation Web site

Pfizer-SFDA Partnership May Close “Bulk Chemical” Loophole, Save Lives

By Rubie Mages, Pfizer

In 1998, the Chinese Ministry of Chemicals was dismissed, resulting in the deregulation of many Chinese companies that manufacture active pharmaceutical ingredients (API). This lack of state regulation allows chemical manufacturing companies to distribute products directly to parties engaged in pharmaceutical counterfeiting. Under a recent agreement between the China Center for Pharmaceutical International Exchange (CCPIE) and Pfizer, China’s State Food and Drug Administration (SFDA) will work with Pfizer to both research the problems caused by lax regulation and propose legislation for their resolution.

Counterfeit medicines pose a serious global threat to patient health and safety. Counterfeiting of drugs used for medical purposes is a growing problem, as counterfeits continue to breach even the most regulated, legitimate supply chains. Unsuspecting patients who place orders with online pharmacies, particularly those sites that conceal their location or the source of the medicines they dispense, often receive fake medicines. Underlying the proliferation of fake pharmaceuticals is the availability and use of unregulated bulk chemicals. Easy access to API has increased to the point that it is now “a significant contributing factor” in the growth of counterfeit medicines. (2009 Special 301 Report, U.S. Trade Representative, April 30, 2009).

Under the agreement, Pfizer Global Security will provide training to SFDA officers. Both parties believe that the training will increase



CCPIE and Pfizer Signing Ceremony

awareness to the threat counterfeit medicines pose to patients within China and permit the SFDA and industry to work together to more effectively combat the problem.

Although the manufacture and trade of API by unregulated chemical companies exposes all patients to serious health risks, the SFDA currently does not have the authority to conduct enforcement actions. It is anticipated that the research conducted under this agreement will result in CCPIE and the SFDA’s enforcement department proposing legislation that would empower such actions.

The agreement, signed by Zhao Yajun, director of CCPIE, and Ahmet Esen, Pfizer China Country Manager, is another milestone in the partnership between private sector entities such as Pfizer, the pharmaceutical industry and the SFDA. It echoes the theme of the November 2008 Joint China Commission on Commerce and Trade Anti-Counterfeiting Workshop, and optimizes the cooperation between private industry and SFDA to combat counterfeit medicines, ultimately protecting

both supply chain integrity and patient health and safety.

Director General Wang Lifeng, Market Supervision Department of SFDA, and Director Zhao of CCPIE, gave remarks recognizing the importance of this agreement as a starting point for enhancing the existing Pfizer-SFDA strategic partnership and serving as an industry-wide model. ■

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Let’s Hear from You

The IPR Center staff welcomes all of our law enforcement and business partners to submit articles to the quarterly *IPR Center Report*. Our editorial board will consider any article presented in an electronic format to IPRCenter@dhs.gov.

In the subject line, please write **IPR Center Report**.

