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COUNTERFEIT PHARMACEUTICALS: 
A WORLDWIDE PROBLEM

By Maria Nelson,** Michelle Vizurraga*** and 
David Chang****

I. INTRODUCTION
Pharmaceutical counterfeiting has grown in recent years to become a widespread, highly sophisticated worldwide enterprise. Capitalizing on advanced technologies to exploit the global economy, counterfeiters are no longer local players constrained to local markets. Pharmaceutical counterfeiting accounts for 5-7% of international trade, and is worth an estimated $512 billion in global sales each year.1 Counterfeit drugs have been reported to constitute over 10% of the world’s medicines, with percentages reaching as high as 60% in some developing countries.2 It is estimated that pharmaceutical counterfeiting will grow by an average of 13% annually through 2010, by which time it will generate $75 billion in revenue and represent 15% of the size of the legitimate industry.3 While the general crime of counterfeiting

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3. Peter Pitts, 21st Century Health Care Terrorism: The Perils of International Drug Counterfeiting, Center for Medicines in the Public Interest (Sept. 20, 2005), available at
is a problem of serious concern in many sectors, it presents challenges unique to the pharmaceutical industry.

The problems and dangers posed by pharmaceutical counterfeiting cannot be overstated. In addition to financial impacts counterfeiting has on pharmaceutical and health care companies, counterfeiting threatens the health and welfare of much of the world population. The pharmaceutical and healthcare industries, domestic agencies and foreign governments must work together closely in order to counteract the growth of this serious and potentially deadly crime.

A. The “Perfect Crime”

First and foremost, because counterfeit and authentic drugs are virtually indistinguishable by consumers, the crime is difficult to detect. Should a patient’s condition improve, no counterfeiting is ever suspected. On the other hand, if the patient’s condition deteriorates, the decline is often attributed to causes other than the pernicious medicine. And if the medicine is suspected, it is often the legitimate drug manufacturer who is blamed and whose goodwill and reputation are at risk.

For example, counterfeit drugs may be contaminated or contain inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients. As a result, patients may be at risk for serious adverse health consequences and will either never know—or not know until it is too late. One such example was when the drug PROCRIT, an injectable, sterile drug used by cancer and AIDS patients, was counterfeited by replacing the active ingredient with non-sterile tap water, which could have caused a severe infection of the bloodstream of these vulnerable patients (an infection that would not be traceable to the


5. Statement of Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning Food and Drug Administration, Hearing before the Subcommittee on Criminal Justice, Drug Policy and Human Resources Committee on Government Reform at the U.S. House of Representatives (November 1, 2005) available at http://www.fda.gov/ola/2005/counterfeit1101.html (testimony on the FDA’s efforts regarding counterfeit prescription drugs). In addition, in the summer of 2004 and again in the spring of 2005, OCI received Voluntary Suspect Counterfeit Drug notifications from the drug manufacturers of ZOCOR, CARISOPRODOL, LIPITOR, VIAGRA, and EVISTA. Counterfeit versions of these drugs were being sold to U.S. consumers from Mexican pharmacies along the U.S. border. Id. The analysis of all these drugs showed they either contained little or no active ingredients.
counterfeit drug until it was too late). Similarly, counterfeiters labeled Aspirin tablets as ZYPREXA, a drug for schizophrenia and bipolar disorder, which could have been particularly dangerous for patients who are Aspirin-sensitive or Aspirin-allergic, who have bleeding disorders, and to those patients who took the counterfeit drugs and no longer received appropriate treatment for their mental illness.

For this reason, pharmaceutical counterfeiting has been dubbed the “perfect crime.” Once the patient figures out (if ever) that he or she has taken a counterfeit drug, it is often too late. The first target is either the doctor or the legitimate pharmaceutical company (or both), who must then prove that it was not the diagnosis or the legitimate drug that caused the patient’s subsequent damage or illness. By the time a counterfeit drug is even suspected, the counterfeiters have disappeared or covered their tracks.

1. Technology and Market Forces

Developments in modern technology and global market practices have fostered greater opportunities for pharmaceutical counterfeiting. For instance, when legitimate drugs circulate with different types of packaging (due to repackaging of parallel-traded goods, foreign imports, or generic copies), consumers may not be able to detect counterfeits from authentic drugs. Counterfeit drugs may also be mixed with shipments of legitimate drugs, making detection virtually impossible. Free-trade zones add to the problem because a large portion of counterfeit drugs are routed through free-trade zones where governmental control is often lax or absent.

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6. Id.
7. Id. Similarly, foreign versions of LIPITOR and CELEBREX were smuggled into the United States from South America and resold after being re-packaged to conceal the true origin of the drugs. Id. Counterfeit LIPITOR also was manufactured in South America and then smuggled into the United States where it was co-mingled with the genuine foreign LIPITOR and sold in the United States. These are but a few examples of the severity of the global problem with counterfeit drugs. In addition, participants conspired to buy, sell and traffic almost $8 million worth of stolen Glaxo Smith Kline and Roche drugs, using fake pedigrees to launder the drugs and thereby concealing that they were stolen.
Short or erratic drug supplies combined with high prices cause consumers to look for cheaper alternatives which in turn creates a market for counterfeiters. These problems are typically more prevalent in developing countries where drug regulation is ineffective, smuggling of drugs is rampant, manufacturing is clandestine, sanctions are absent or very weak, or there is widespread corruption.\footnote{See WHO, General Information on Counterfeit Medicines, supra note 2.}

The Internet provides some of the best opportunities for criminals to exploit the global market for counterfeit drugs.\footnote{MacInnis, Fake Drugs, Including Tamiflu, Thrive on Internet, Reuters (February 21, 2006). As recent as February 21, 2006, global sales of counterfeit TAMIFLU, the bird flu drug, have been sold over the Internet, according to the United Nations. Id.} It is difficult to identify anonymous Internet sites and track down counterfeit product. Although many counterfeit Internet pharmacies have been shut down, many still remain.

2. Developing Countries

Counterfeit medicines remain more prevalent in developing countries.\footnote{See WHO, General Information on Counterfeit Medicines, supra note 2.} While no country is immune from the problem of drug counterfeiting, developing countries pose special problems in the fight against counterfeiters. Certain countries may lack the political will and commitment to fight counterfeiting, or underestimate the gravity of intellectual property offenses.\footnote{Union des Fabricants, Organized Crime and Counterfeiting, supra note 2, at 5.} These countries may, for instance, lack appropriate legislation against intellectual property theft or lack the desire or wherewithal to enforce the rights of financially sound pharmaceutical companies. Unlike developed countries, few developing countries have enacted special national legislation on counterfeit drugs.\footnote{See WHO, General Information on Counterfeit Medicines, supra note 2. See also 21 U.S.C. § 331(i)(3) (2000);.}

Weak or corrupt enforcement also increases the rate of counterfeiting and makes it difficult to find, arrest, prosecute and convict criminals.\footnote{See WHO, General Information on Counterfeit Medicines, supra note 2.} Lack of export controls makes it easier for counterfeiters to distribute their products.\footnote{Id. at 26.} Moreover, local protectionism often creates problems in enforcement. For instance, in certain low-income or poverty stricken areas that depend upon counterfeiting for revenue, local governments may be reluctant to crack down on criminals.\footnote{Id. In China, Russia and Africa, high-volume and expensive drugs are the main targets of counterfeiters, with the largest number of reports related to antibiotics, antiprotozoals, hormones and steroids.} For these reasons, trademark owners
may be left with no effective remedy for intellectual property theft, even when the theft runs tandem with other questionable or illegal activities, such as over-production by licensed factories, distribution and shipment fraud, gray market goods, bribery, criminal conspiracy, money laundering, and industrial espionage.\textsuperscript{19}

### 3. Consequences of Counterfeiting

Consumers of counterfeit drugs pay a hefty price in terms of risk to their health and lives. Counterfeiting severely harms pharmaceutical companies as well as society as a whole. As counterfeiters profit from the goodwill associated with a legitimate drug’s image and reputation, they simultaneously damage the very goodwill that accords high prices and high demand. The more successful a branded drug, the more value it has to counterfeiters.

The counterfeit drug trade also stifles investment and innovation, and retards economic growth. Counterfeiters pay no taxes or import/export duties, do not comply with basic manufacturing standards for health and safety, and are not concerned with product quality and performance.\textsuperscript{20} Countries affected by drug counterfeiting suffer from decreased tax revenues and deterred investments.

### II. A GLOBAL SURVEY OF COUNTERFEITING PROBLEMS AND SOLUTIONS

The most comprehensive international multilateral agreement on intellectual property is the “Trade-Related Aspects of Intellectual Property Rights” Agreement, or TRIPS.\textsuperscript{21} By signing the TRIPS Agreement, all member-countries agreed to rewrite their national laws to conform to internationally agreed standards for protecting patents, trademarks, copyrights, industrial designs, and other intellectual property.


\textsuperscript{20} USTR, Special 301 Report, Executive Summary, \textit{supra} note 10.

\textsuperscript{21} World Trade Organization, \textit{Overview: the TRIPS Agreement} (last visited Feb. 22, 2006), \textit{available at} http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm. The TRIPS Agreement was formulated at the December 1993 Uruguay Round of the General Agreement on Trade and Tariffs (GATT) at the World Trade Organization and came into effect on January 1, 1995. The TRIPS Agreement also extended protection to such technological areas as pharmaceutical products and computer software, which were previously unprotected in many countries. The Trademark Law Treaty is an international treaty that harmonizes and simplifies the requirements and procedures for filing, registering, and renewing trademarks, and gives service marks the same legal status as trademarks and was adopted at the 1994 World Intellectual Property Organization Diplomatic Conference in Geneva. The treaty has entered into force, but has not yet been ratified by the United States Senate.
and trade secrets. However, despite TRIPS, there remain worldwide discrepancies in intellectual property laws and enforcement.\textsuperscript{22}

All countries were required to be in substantial compliance with TRIPS by 2006. Ensuring that the developing countries are in compliance with the TRIPS Agreement has been one of the biggest priorities for the World Trade Organization (WTO) and GATT-Member countries.\textsuperscript{23} Predictably, variations in each country’s laws and regulatory schemes have created problems for IP protection and enforcement, even in TRIPS-compliant countries. In addition to the TRIPS Agreement, there are almost 300 different worldwide trade agreements, with close to forty of those involving intellectual property.\textsuperscript{24}

Compounding the problem is the fact that there remains no universally accepted definition of counterfeit drugs.\textsuperscript{25} The World Health Organization defines the term counterfeit medicine as “one which is deliberately and fraudulently mislabeled with respect to identity and/or source.”\textsuperscript{26} United States law defines counterfeit drugs as those whose identity is knowingly and intentionally mislabeled to suggest that it is the authentic approved product.\textsuperscript{27} This can include products without an active ingredient, with an insufficient quantity of the active ingredient, with a wrong active

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\textsuperscript{23} USTR, Special 301 Report, Executive Summary, supra note 10. Developing countries were required to fully implement TRIPS as of January 1, 1996, but were given a transition period for many obligations until January 1, 2000. Every year, the U.S. Government provides extensive technical assistance and training on the implementation of the TRIPS Agreement to a large number of its trading partners. This assistance is provided by a number of U.S. Governmental agencies, including the USPTO, the U.S. Copyright Office, the Department of State, the U.S. Agency for International Development, U.S. Customs and Border Protection, the Department of Justice, and the Department of Commerce. The assistance is provided on a country-by-country basis as well as in group seminars, including those co-sponsored by the World Intellectual Property Organization and the WTO. In addition, U.S. industry is also actively involved in providing specific enforcement-oriented training in key markets.


\textsuperscript{26} Id. “Counterfeiting 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.” Id.

\textsuperscript{27} Statement of Randall W. Lutter, Ph.D., supra note 5; see also 15 U.S.C. § 1114, et. seq. (2000). Counterfeiting is statutory trademark infringement under U.S. law.
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ingredient, or with packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer. Differing definitions lead to problems in determining whether a particular drug is “counterfeit” in a particular country. This interferes with communication and information exchange between countries. However, there are generally three varieties of counterfeit drugs—complete fakes, tampered fakes, and re-labeled fakes.28

The remainder of this article provides a survey of the effects of pharmaceutical counterfeiting in major portions of the world. Each region faces unique challenges to overcoming counterfeiting. With respect to the United States in particular, this article will discuss measures taken by both the public and private sectors to prevent distribution of counterfeits within the United States, as well as measures to block imports of counterfeits into the United States from foreign countries.

A. The United States

1. Federal Agencies and Initiatives

The United States has one of the strongest systems for intellectual property protection in the world. As such, it has a number of weapons to use in the war on counterfeit drugs. One such weapon is the office of the U.S. Trade Representative (USTR), which intercedes directly in countries where piracy is especially prevalent or where governments are exceptionally tolerant of piracy.29 Among the USTR’s most effective tool is the annual “Special 301” review mandated by the U.S. Congress in the 1988 Trade Act.30


29. See Office of the U.S. Trade Representative home page, http://www.ustr.gov (last visited Feb. 22, 2006). In effecting its goal, the USTR consults closely with the United States Congress on its priorities and strategies and uses domestic trade law, regional initiatives in Europe, Asia (APEC), Latin America (FTAA) and Africa, as well as, existing institutions, notably the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).

30. Id. Another bilateral tool is preferential tariff benefit treatment, such as the Generalized System of Preferences, the Caribbean Basin Initiative and Andean Trade Preferences Act. These programs provide tariff-free treatment to certain products of beneficiary countries, subject to certain conditions, including adequate and effective protection of intellectual property rights. The threat of loss of these benefits has proven to be an effective point of leverage with some of the United States’ trading partners. Other bilateral tools include the inclusion of IPR provisions in the USTR’s science and technology agreements and Bilateral Investment Treaties. But perhaps the most important of the remaining tools is the USTR’s ability to offer technical assistance to help other countries draft good intellectual property laws. The U.S. Patent and Trademark Office and the Copyright Office have been critical in this regard. The USTR also works with the FBI, Department of Justice and Customs Services to provide as much assistance in enforcement as possible within resource limitations.
Special 301 confers on the USTR the power to identify foreign countries that deny adequate and effective protection of intellectual property rights or that deny fair and equitable market access for U.S. persons that rely on intellectual property protection.31 Countries with the most onerous or egregious laws or practices, or whose actions have the greatest adverse impact on U.S. companies and products are designated “Priority Foreign Countries.” Countries that have more particular problems with respect to IP protection, enforcement, or market access are identified on a “Priority Watch List” or a “Watch List.” Finally, countries may be subject to special monitoring (called “Section 306” monitoring) to determine compliance with bilateral intellectual property agreements. Countries can face trade sanctions for failure to comply with intellectual property enforcement and protection obligations under TRIPS.32

In 2006, there were thirteen countries on the Priority Watch List, 34 countries on the Watch List, and three countries subject to Section 306 monitoring.33 Annual publication of the Special 301 Report warns a country of U.S. concerns and also warns companies based in the United States, or other developed countries that intend to do business abroad, that their intellectual property rights are not likely to be satisfactorily protected.34


32. USTR, Special 301 Report, Executive Summary, supra note 10. Despite progress by some countries, the 2006 Special 301 Report found that the manufacture and distribution of counterfeit pharmaceuticals continues to be a serious problem and calls for actions to combat global piracy and counterfeiting, particularly with respect to requiring stronger and more effective border enforcement, as well as seizure and destruction of equipment used to make counterfeit goods.

33. The thirteen countries were: Argentina, Belize, Brazil, China, Egypt, India, Indonesia, Israel, Lebanon, Russia, Turkey, Ukraine and Venezuela. Meanwhile, 34 trading partners were placed on the Watch List, meriting bilateral agreements to address the underlying intellectual property problems: Bahamas, Belarus, Bolivia, Bulgaria, Canada, Chile, Columbia, Costa Rica, Croatia, Dominican Republic, Ecuador, European Union, Guatemala, Hungary, Italy, Jamaica, Kuwait, Latvia, Lithuania, Malaysia, Mexico, Pakistan, Peru, Philippines, Poland, the Republic of Korea, Romania, Saudi Arabia, Taiwan, Tajikistan, Thailand, Turkmenistan, Uzbekistan and Vietnam. Finally, three countries—China, Paraguay, and Ukraine—were subject to Section 306 monitoring. See USTR, Special 301 Report, Executive Summary, supra note 10.

34. Id. The USTR obtains information on its global trading partners through an interagency “Trade Policy Staff Committee” that advises the USTR on the implementation of Special 301 and that obtains information from the private sector, U.S. embassies, various governmental agencies, and the National Trade Estimates. One important clarification under “Special 301” is that during the 1994 Uruguay Round Agreements Act, this portion of the Trade Act was amended to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement. This was an important amendment because the variance in each country’s intellectual property laws was clear at that time and the members at the Uruguay Round recognized the need for additional enforcement for certain countries.
Similarly, the “Strategy Targeting Organized Piracy” (or “STOP!”) Initiative, announced in October 2004, brings together the federal government, the private sector, and other like-minded countries to take concerted action in cracking down on piracy and counterfeiting. As part of STOP!, the USTR has advocated the international adoption of best practices guidelines incorporating enhanced enforcement disciplines drawn from the intellectual property chapters of recent free trade agreements. The USTR also has introduced multilateral initiatives to improve the global intellectual property environment that will aid in disrupting the operations of pirates and counterfeitters.

The United States Food and Drug Administration’s Office of Criminal Investigations (FDA-OCI) investigates counterfeiting involving drugs, medical devices, foods, blood and biological products. The FDA-OCI also has an online reporting system if a company or consumer finds an FDA-regulated product to be counterfeit. Over the past year, the FDA-OCI worked with manufacturers, wholesalers, pharmacies, consumer groups, technology specialists, standard-setting bodies, state and federal agencies, international governmental entities, and others to specifically advance protection against counterfeit drugs. In 2004, the FDA-OCI initiated fifty-eight counterfeit drug cases, a

Ukraine is still subject to $75 million in trade sanctions due to its failure to have adequate intellectual property protection and enforcement and for its rampant counterfeiting problem.


36. USTR, Special 301 Report, Executive Summary, supra note 10.

37. FDA, supra note 8. On May 10, 2005, the FDA warned consumers about counterfeit pharmaceuticals purchased in Mexican border towns—LIPITOR, VIAGRA and generic “Evista.” Counterfeit LIPITOR and VIAGRA were purchased at the Mexican border towns of Juarez, Los Algodones, Nogales and Tijuana. The bottles were labeled in English and were a copy of the original product. On July 29, 2005, the FDA warned U.K. residents of fake LIPITOR sold in the United Kingdom. FDA, FDA Alerts U.S. Residents to Recall of Counterfeit “Lipitor” Sold in the United Kingdom (July 29, 2005), available at http://www.fda.gov/bbs/topics/NEWS/2005/NEW01216.html

38. FDA, supra note 8.

39. For instance, in July 2003, the FDA-OCI formed a Counterfeit Drug Task Force that worked extensively with the non-governmental entities identified above in an effort to “create a comprehensive system of modern protections against counterfeit drugs.” Id. Through a series of meetings with manufacturers, wholesalers, retailers, professional and trade associations, standard-setting organizations, and consumer groups, visits to manufacturing facilities, wholesale distribution centers, retailers, radio-frequency identification (RFID) laboratories and pilot facilities, attendance at stakeholder task force meetings and industry RFID feasibility study meetings, meetings with academic and industry experts, and sponsorship of a public meeting and a technological forum, the Task Force received extensive comments from these organizations. See id. at Appendix B: Expanded Description of Comments Received.
significant increase from the thirty cases initiated in 2003.\textsuperscript{40} Fortunately, most of the counterfeit drugs at issue did not reach consumers because the FDA-OCI focused its resources and developed proactive investigations that enabled it to identify components of counterfeit products and to intercept finished counterfeit drug products before they entered domestic distribution.\textsuperscript{41}

In addition, the United States has implemented specific border protections against importation of counterfeit drugs. The offices of U.S. Customs and Border Protection (CBP) assists in stopping drug imports at U.S. borders.\textsuperscript{42} Recordation of a federally registered trademark or copyright with the U.S. Customs Service significantly aids border enforcement by assisting CBP officials in identifying infringing goods. United States law requires that owners of trademarks or copyrights record their rights before CBP officials can seize pirated or counterfeit goods at the U.S. border.\textsuperscript{43}

Similarly, the U.S. International Trade Commission (USITC) has the power to conduct a so-called “Section 337” investigation when a company or individual files a claim regarding drug counterfeiting.\textsuperscript{44} The primary remedy available in Section 337 investigations is an exclusion order that directs Customs to stop infringing imports from entering the United States. The USITC also may issue cease and desist orders against named importers and other persons engaged in unfair acts that violate Section 337. Expedited relief in the form of temporary exclusion orders and temporary cease and desist orders are available in certain exceptional circumstances.\textsuperscript{45}


\textsuperscript{41} Id.

\textsuperscript{42} Michigan District Export Counsel, Reporting IPR Crimes Domestically (Aug. 8, 2005), available at http://www.exportmichigan.com/ibp_ipr_protection_in_the_us.htm. In order for the CBP to be able to stop infringing imports, a company must have secured a federal trademark registration from the USPTO, or a copyright from the U.S. Copyright Office, and have recorded their registration with the U.S. CBP.

\textsuperscript{43} See 19 C.F.R. § 133.1 et seq., Customs Duties; Bureau of Customs and Border Protection, Dep’t of Homeland Security; Dep’t of the Treasury; Trademarks, Trade Names, and Copyrights. 19 C.F.R. § 133.22, Restrictions on importation of articles bearing copying or simulating trademarks, subsection (b), for instance, allows for denial of entry of any “articles of foreign or domestic manufacture imported into the United States bearing a mark or name copying or simulating a recorded mark or name” (emphasis added). Note, however, that “gray goods” are subject to taxation exceptions permitting importation in some cases.

\textsuperscript{44} U.S. ITC, Trade Remedy Investigations, cited supra.

\textsuperscript{45} See 19 U.S.C. § 1337. Section 337 investigations, which are conducted pursuant to 19 U.S.C. § 1337 and the Administrative Procedure Act, include trial proceedings before administrative law judges and review by the Commission.
The U.S. government’s multi-layered system for combating counterfeiters has led to positive results in counterfeit prevention. The following are some examples:

- In February 2006, a Florida man was convicted of a multimillion dollar conspiracy to sell counterfeit pharmaceuticals, including the popular cholesterol-fighting drug LIPITOR, and was found guilty of federal charges of conspiracy to sell counterfeit, misbranded, and illegally imported drugs and to impede, impair, obstruct, and defeat the lawful governmental functions of the FDA and the U.S. Customs Service. The man faces up to five years in prison and a $250,000 fine for his part in the $13 million conspiracy.

- In October of 2005, two individuals involved in drug diversion and counterfeiting were sentenced to prison—one individual was sentenced to 30 months in jail for counterfeiting ZYPREXA and RISPERDAL prescription labels and selling them to various individuals and the other was sentenced to 24 months in jail for the illegal wholesale

Other federal law enforcement agencies fighting drug counterfeiting include the U.S. Department of Justice, the Federal Bureau of Investigations (FBI), the Central Intelligence Agency (CIA), and the Immigration and Customs Enforcement agency. See United States Immigration and Customs Office, National IPR Coordination Center Complaint Referral Form (last visited Feb. 22, 2006), available at http://www.ice.gov/graphics/cornerstone/ipr/IPRForm.htm; Reporting IPR Crimes Domestically, Michigan District Export Counsel (last visited Feb. 22, 2006), available at http://www.exportmichigan.com/ibp_ipr_protection_in_the_us.htm.

46. Briefly, under the U.S. legal system, the FDA-OCI can bring lawsuits against alleged counterfeiters in federal court pursuant to federal law. (State agencies can bring lawsuits in state courts pursuant to state anticounterfeit law.) The FDA frequently brings cases pursuant to 21 U.S.C. § 331, which prohibits the introduction into interstate commerce, or the manufacture within any Territory of the United States, any food, drug, device, or cosmetic that is “adulterated” or “misbranded.”

All counterfeiters convicted of suits brought by the government are subject to criminal penalties. These can include fines paid to the government, injunctions (orders requiring the defendant to cease the illegal behavior) as well as imprisonment. See notes 47-59 and accompanying text, infra. By contrast, civil suits are brought by private organizations and individuals. Counterfeiters found guilty in civil lawsuits are subject to monetary damages and injunctions, but not incarceration.

47. Statement of Randall W. Lutter, Ph.D., supra note 5.

48. Florida Man Convicted in Pharmaceutical Conspiracy, Associated Press available at http://www.kansascity.com/mld/kansascity/news/local/13899851.htm (Feb. 17, 2006). The Florida man’s company and several subcontractors produced counterfeit labels for bottles of LIPITOR and other prescription drugs, which were distributed throughout the United States, according to the U.S. Attorney’s office. Although the man’s company went bankrupt in 2003, the U.S. Attorney felt that he was a “small, but important, cog” in the machine because his role was “critical to the success of the whole criminal enterprise, which makes him just as culpable as those who played larger roles.” Id.
distribution of prescription drugs and possession with the intent to distribute controlled substances.49

• In September 2005, an individual from the United States was indicted for importing and distributing counterfeit drugs from China, including VIAGRA and CIALIS.50 As a result of the collaborative effort of U.S. and Chinese authorities, eleven individuals will be prosecuted by the Chinese government for their involvement in manufacturing and distributing counterfeit VIAGRA, CIALIS, and LIPITOR. In addition to the arrests, Chinese officials recovered 600,000 counterfeit VIAGRA labels and packaging, 440,000 counterfeit VIAGRA and CIALIS tablets, and 260 kilograms of raw materials used to manufacture counterfeit drugs.51

• In August 2005, three businesses and eleven individuals were indicted for their involvement in a $42 million dollar conspiracy to sell counterfeit, smuggled and misbranded LIPITOR and other drugs.52 As part of this investigation, the FDA recalled more than 18 million LIPITOR tablets, ranking as one of the largest recalls in the history of criminal investigations of counterfeit medications.53

• In early 2005, three men pleaded guilty to smuggling millions of dollars worth of LIPITOR.54 These guilty pleas were the result of an ongoing FDA-OCI investigation.


50. Id. This joint OCI and U.S. Immigration and Customs Enforcement (ICE) investigation was particularly significant because it also involved the direct assistance of OCI and ICE in China to determine the source of the counterfeits. Id.

51. Id. In January 2005, a Southern California man pled guilty to importing counterfeit VIAGRA tablets from China and manufacturing 700,000 counterfeit VIAGRA tablets at a lab in the United States and his accomplice was convicted of similar charges in September 2004. The total value of the counterfeit VIAGRA pills in this case is more than $5.65 million. Id. On March 25, 2005, an individual pled guilty to charges of conspiracy, trafficking in counterfeit goods, and a felony violation of the Federal Food, Drug and Cosmetic Act for conspiring with a Beijing manufacturer to import thousands of counterfeit VIAGRA tablets into the United States, which he would then resell. The individual was sentenced to 18 months in prison, followed by three years probation, and was fined $6,000. Id.

52. Id. This information was taken from a press release given by the U.S. Attorney’s Office for the Western District of Missouri.

53. Id.

54. United States v. Cruz, No. 4-05 Cr. 21 (W.D. Mo. Jan. 21, 2005). The men also pleaded guilty to conspiracy to smuggle the same.
involving the manufacturing, smuggling, and interstate distribution of counterfeit drugs.55

- In January 2005, a San Diego man was sentenced to serve a 51-month prison term and forfeited substantial cash proceeds for his role in operating a large Internet pharmacy scheme—WorldExpressRx.com.56 At least fourteen other individuals are being prosecuted in California or Florida as part of this international conspiracy.57

- On June 16, 2004, an indictment was unsealed in San Diego that charged an individual with conspiring to unlawfully distribute human growth hormone and trafficking in counterfeit goods.58 According to the indictment, this individual obtained counterfeit SEROSTIM and sold it to bodybuilders who did not possess lawful prescriptions for the drug.59

These are but a few examples of the U.S. government’s enforcement efforts coming together with foreign governments and other individuals to prosecute pharmaceutical counterfeiters. Notably, drug companies were instrumental in assisting the government in tracking down and prosecuting the counterfeiters.

2. Private Initiatives

Private pharmaceutical companies also have taken action against counterfeiters and counterfeit drugs. Broadly, their efforts can be categorized as prevention, education, and enforcement.

55. Id. To date, eight people have been indicted; four have pleaded guilty, and another was convicted by a trial jury. Similarly, an FDA-OCI undercover operation led to the arrest and September 2004 conviction of a Belize citizen who was sentenced to 10 months incarceration and one year probation for counterfeiting LIPITOR tablets. That defendant was charged with violating Title 21, U.S.C. § 331 (a)—Introduction into Interstate Commerce of a Misbranded Drug. See Statement of Randall Lutter, supra note 5.

56. See supra note 49.

57. Id. The counterfeit drugs included a variety of products that were made in Mexico, with some of the ingredients shipped from India, China and Pakistan and entered the United States via the Bahamas. Id.

58. Id. Similarly, on March 9, 2004, an Austin, Texas man pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Id. Two other persons involved in these offenses were previously convicted and sentenced. SEROSTIM is approved by FDA for use in the United States to treat AIDS wasting disease. Id.

59. Id. SEROSTIM is a prescription drug containing the active ingredient “somatropin,” a form of human growth hormone. Id.
a. Prevention and Education

In 2004, Sun Microsystems developed a special pharmaceutical-based radio frequency identification (RFID) software for drug authentication.\[^{60}\] This RFID drug authentication software is a tool that enables pharmaceutical companies to combat counterfeiting and to gain efficiency throughout the supply chain. In effect, the technology allows a company to verify a drug package’s validity and authenticity as it moves through the supply chain, from the manufacturer to the hands of the consumer at the point-of-sale.\[^{61}\]

One company very active in the fight against pharmaceutical counterfeiting is Pfizer, Inc., manufacturer of VIAGRA and LIPITOR. Pfizer incorporated RFID technology into its VIAGRA packaging in the United States to help track product from manufacture to end-user.\[^{62}\] Likewise, Purdue Pharma, maker of OXYCONTIN and PALLADONE, launched a program to integrate RFID tags in drugs sold to two of its largest customers, Wal-Mart and drug wholesaler H.D. Smith. Under the program, Purdue added an RFID label to every 100-tablet bottle of its OXYCONTIN pain reliever that is shipped to those two companies.\[^{63}\]

Other companies have also been active in combating counterfeits. In 2003, Bristol-Myers Squibb (BMS) began labeling its anti-cancer drugs with “DNA codes,” “genetic fingerprints,” as short as 20 units long, offering “more than a billion different combinations,” that are authenticated using a small hand-held reader. The DNA codes ensure authenticity and genuineness throughout the production and distribution line, from the

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\[^{60}\] Sun Microsystems, Sun Helps Fight Drug Counterfeiting with RFID Technology, New RFID Solution Enables Pharmaceutical Companies to Track and Verify Drug Packages and Helps Prevent Diverting and Counterfeiting of Products (November 14, 2005), available at http://www.sun.com/smi/Press/sunflash/2005-11/sunflash.20051114.3.html. The Sun RFID Drug Authentication Solution uses a scalable architecture that helps companies to start with EPC-based drug authentication for initial pilots and then evolve to more complex, pedigree-based drug authentication solutions. Id. The EPC Authentication verifies point-of-sale EPC information, stored in an RFID tag, against a repository of valid codes, which provides a more secure and complex system that requires verification and authentication of each drug item at every step of the drug supply chain. Id.

\[^{61}\] Id.


production plant to patient consumption. Other control mechanisms used by drug companies, such as AstraZeneca, include surveillance of market and supply chain activities and educating patients and health care professionals about vigilance in examining medications and product packaging.

The Internet has become a powerful tool in educating end-user consumers about counterfeiting. Pfizer uses its website to inform the public on how to spot counterfeits and what a person should do if they suspect a product is counterfeit.

b. Enforcement

In 2004, Pfizer launched a campaign against sellers of illegal generic and counterfeit VIAGRA as well as distributors of VIAGRA-related spam. The company sued operators of 18 Internet sites selling illegal copies of LIPITOR. In 2005, Pfizer teamed up with Microsoft to target illegal sellers of VIAGRA and international spam rings.

Many companies, such as Amgen, have worked with the trade organization Pharmaceutical Research and Manufacturers of America (PhRMA) to develop a voluntary program to report counterfeit drugs to the FDA. Under the program, initiated in 2003, participants have agreed to notify the FDA’s Office of Criminal Investigations within five business days of deciding that its product has most likely been counterfeited.

PhRMA has taken additional steps in combating counterfeits. Among other things, it has urged the FDA to implement

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64. BMS HIV Drugs Now Labeled with DNA-Based Markers (last visited Feb. 23, 2006), http://www2.dupont.com/Packaging/en_US/applications/medical_pharmaceutical/biomolecular_marker_bms.html. The technology was developed by identif GmbH, a subsidiary of Erlangen/Germany based november AG.


regulations requiring wholesalers to provide customers with a product’s pedigree, invited the health care community to join PhRMA in opposing legislative proposals that would ease the entry of counterfeit drug products into the United States, and formed a task force to determine the additional steps that the industry and government can take to stop the distribution of counterfeits.71

Most companies also have quality control teams that monitor the supply chain and take action when counterfeits are suspected. AstraZeneca, for instance, has a team comprised of eight different departments that notifies local and international regulatory agencies, suppliers, and retail pharmacies, analyzes suspected products, and when necessary, withdraws batches of suspect product when counterfeits are suspected.72

B. Canada

Because of Canada’s continuing problems with intellectual property monitoring and enforcement, the USTR has placed it on the Watch List in the 2006 Special 301 Report. Although Canadian law provides that “[n]o person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety,”73 and allows criminal action against anyone who forges a trademark or engages in such deceptive behavior,74 there has been little use of criminal law to prevent counterfeit goods.75

The greatest concern with pharmaceutical counterfeiting lies with Internet pharmacies importing drugs into the United States.76 The issue of Internet pharmacies is highly contentious


72. Id. The team is comprised of representatives from the local marketing company, and the security, legal, quality control, medical, regulatory, global supply director, and product communications departments.

73. Food and Drugs Act, R.S.C. 1985. c. F-27, s. 9.


76. In Canada, most provincial governments negotiate contracts directly with drug companies on behalf of their citizens, while most European nations offer universal drug coverage. See Patricia Barry, Why Drugs Cost Less Up North: Important Differences in American, Canadian Systems Produce Big Price Disparities, AARP Bulletin (June 2003), available at http://www.aarp.org/bulletin/prescription/a2003-08-12-whydrugs.html; Dr. William McArthur, Prescription Drug Costs: Has Canada Found the Answer? National Center for Policy Analysis, Brief Analysis No. 323 (May 19, 2000), available at http://www.ncpa.org/ba/ba323/ba323.html. Therefore, Canadian Internet pharmacies sell prescription drugs almost exclusively to individual American consumers. See John
and politicized. According to the Center for Medicines in the Public Interest,77 Health Canada, the country’s national health agency, has been “up front about saying they cannot possibly monitor drug shipments across the United States border.”78 Others have countered that the risk of counterfeiting in Canada is merely an illusion. According to Andy Troszack, Vice-President of the Canadian International Pharmacy Association, “There’s a larger potential for a U.S. citizen to be exposed to counterfeit drugs by purchasing them within the United States than by getting them from within Canada.”79 A spokesperson for Health Canada has also added that counterfeiting is largely an American phenomenon.80

Additions to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. strictly limit the types of drugs that may be sold within and imported into the United States, creating a relatively “closed” drug distribution system.81 Nevertheless, online drug sales from Canada to the United States—illicit or otherwise—have reached more than $800 million a year.82

One major area of concern is transshipment—where drugs are sent to Canada from countries around the world and then passed off to U.S. customers through Internet sales. Many of the countries from which these drugs originate are already on the USTR’s watch lists.

An FDA operation revealed the extent of transshipment problems. In August 2005, the FDA intercepted and examined 4,000 parcels of international mail suspected of containing pharmaceuticals at three different airports—JFK Airport in New York, Miami International Airport, and Los Angeles International Airport.83 These items had been shipped to the United States from India, Israel, Costa Rica and Vanuatu. Of the parcels examined, 1,700, or approximately 43%, had been ordered from allegedly


77. The Center for Medicines in the Public Interest is a non-partisan, non-profit, educational charity located in New York, NY. For more information on the organization, see www.cmpi.org (last visited July 5, 2006).

78. Pitts, supra note 3.


80. Id.

81. Prescription drugs imported for personal use into the United States from Canada violates this Act, if they are either unapproved new drugs (21 U.S.C. § 355), drugs labeled incorrectly (21 U.S.C. §§ 352, 353), or drugs dispensed without a valid prescription (21 U.S.C. § 353(b)(1)).


Canadian Internet pharmacies, and were represented as being of Canadian origin. Of those parcels, about 15% actually originated in Canada. The remaining 85% were manufactured in 27 different countries. Moreover, 32 of the samples, representing three distinct drug products, were determined to be counterfeit.

Beyond transshipment, other counterfeit related problems exist with Internet pharmacies. For instance, if a consumer has an adverse reaction to a counterfeit drug purchased over a foreign Internet pharmacy, that patient has little to no recourse. Either the physical location or operator of the pharmacy is unknown, or the seller is beyond the consumer’s reach. Many of these companies require consumers to sign releases from all liability.

The USTR has noted that Canada’s “weak border measures continue to be a serious concern for IP owners.” Thus, the United States urged Canada to “enact legislation that would provide a stronger border enforcement system by giving its customs officers greater authority to seize products suspected of being pirated or counterfeit,” and to provide “additional resources and training to its customs officers and domestic law enforcement personnel.”

To that end, there has been some cooperation between United States and Canadian organizations counteracting the illicit drug trade. In 2003, the National Association of Boards of Pharmacy (NABP) and the Canadian National Association of Pharmacy Regulatory Authorities (CNAPR) endorsed a statement opposing illegal importation of prescription drugs and committed to working together toward that goal. The two regulatory bodies also called on law enforcement agencies at all levels—federal, state, and local—to promote compliance with pharmacy laws and standards.

Enforcing stricter control over drug sales to the United States is also in the interests of Canada itself. In June 2005, the Canadian government announced plans to limit bulk exports of essential Canadian drugs, in an effort to ensure that drug sales to the United States do not lead to domestic shortages within Canada. Said Health Minister Ujjal Dosanjh, “Canada cannot be

84. It is unclear why drugs of Canadian origin were shipped to the other four countries prior to reaching U.S. shores, but its possible that there were distribution centers of some sort in India, Israel, Costa Rica, and Vanuatu where drugs from all over the world were centralized and eventually resold.

85. FDA, supra note 83.


87. USTR, Special 301 Report, supra note 10.

88. Id.

89. Statement of William Hubbard Before the Comm. on Government Reform, supra note 86.
the drugstore of the United States of America.” 90 Additionally, the Minister suggested that physician colleges should strengthen provisions in their ethics codes that forbid co-signing (or “counter-signing”) U.S. prescriptions, a practice upon which Internet pharmacies depend. 91 As a direct result of these initiatives, a number of online pharmacies have been moving to locations outside of Canada. 92

C. The European Union

The pharmaceutical industry loses a reported 1,554 million Euros in revenue and 292 million Euros in profit each year in the European Union because of counterfeit drugs. 93 Enforcement of existing regulations and laws is a principal concern. Despite the enactment of a 2003 border enforcement regulation (Council Regulation No. 1383/2003), numerous member countries have experienced difficulties in obtaining effective customs cooperation and enforcement, largely due to a lack of enforcement in Eastern Europe. 94

Since 2003, ten new member states have joined the European Union; eight lie along the eastern land border of Europe. 95 Customs authorities, police, and courts in these border countries are critical to stopping counterfeit goods from entering Europe. This is because once goods are circulated in a single market, it is much harder to prevent them from being freely distributed throughout the twenty-five member countries. 96

Some progress is being made. Police actions resulted in the seizure in September 2004 alone of more than 4,000 units of pharmaceuticals and 60,000 Euros. 97 Moreover, on July 1, 2004, an EU Customs regulation on counterfeit and pirated goods, EC No. 1383/2003 (as implemented by regulation 1891/2004/EC), went

90. Krauss, supra note 82.
94. Food Safety, Reed Business Information Food Engineering & Ingredients (Apr. 1, 2005).
95. Id.
97. Id.
into effect. The regulation covers intellectual property rights, as well as protection of plant varieties, geographic indications and designations of origins, and is intended to increase consumer protection.

As with the previous regulation, when goods are suspected of infringing an intellectual property right, an owner of IP rights may apply to the appropriate customs department for action by the authorities. However, under Article 4 of the new regulation, custom officials have the authority to suspend the release of goods or detain them for a limited period of time, even before an application for action has been lodged or approved. This provision affords extra protection to IP holders by giving them additional time to lodge an application for action after suspected counterfeit goods have been detained.

Furthermore, Article II of Regulation EC No. 1383/2003 allows customs officials, in certain circumstances, not merely to detain but to destroy counterfeited goods without the need to determine whether an intellectual property right has been infringed. The holder of the intellectual property rights must first request in writing that customs officials destroy the infringing goods, and that writing must be unopposed for a prescribed period of time. (If such a request is opposed by the owner of the allegedly counterfeit goods, formal proceedings must be initiated to determine whether an intellectual property right has been infringed.)

In addition to this regulation, the European Commission has passed a number of initiatives designed to address the counterfeiting problem. Specifically, Directive 2004/48/EC (the “Enforcement Directive”) requires all Member states to apply “effective, dissuasive and proportionate remedies and penalties

100. Id., at Introduction, para. 2
101. Id., at Chapter II, Article 5
102. Id., at Chapter II, Article 4. This action is allowed so long as the authorities have “sufficient grounds for suspecting that goods infringe an intellectual property right.” Id.
103. Id. For a more detailed discussion of this law, see Frank Eijsvogels, New Anti-Piracy Regulation Published, IP Intelligence: Europe, 2 (Howrey Europe, Winter 2003), available at www.howrey.com/europe/newsletter/winter2003/IPIntel_Newsletter_120903.pdf.
105. Id.
against those engaged in counterfeiting and piracy,” so as to create a level playing field for rights holders in the European Union.\textsuperscript{106}

Moreover, on July 12, 2005, the European Commission made a proposal for a Directive to align national criminal law provisions against infringements of intellectual property rights and improve European co-operation.\textsuperscript{107} Specifically, the proposal sets a threshold for criminal penalties applicable to the perpetrators of these offenses: “at least four years’ imprisonment if the offence involves a criminal organisation or if it jeopardises public health and safety,” and an applicable fine of at least 100,000 to 300,000 Euros. Member States would still be allowed to apply tougher penalties.\textsuperscript{108}

The battle to stop counterfeits from being imported into Europe is also taking place at the eastern boundaries of four Baltic states—Poland, Slovakia, Hungary and Slovenia.\textsuperscript{109} These efforts by the European Union are vital to prevent the entry into Europe of the counterfeit goods coming from Russia, the Ukraine and Romania, which are not EU Members but which appear to be potential gateways for counterfeit drugs.

In February 2005, the European Parliament approved another EU regulation designed to boost Customs control. This regulation enables Customs offices (offices or officers) to exchange information electronically; it also provides a computerized system for risk management and provides electronic declaration forms for traders.\textsuperscript{110} Finally, the European Union has warned China, Russia and the Ukraine to crackdown on counterfeiters or face possible sanctions at the World Trade Organization (WTO).\textsuperscript{111}

\textbf{D. China}

In recent years, China has made substantial progress in protecting intellectual property rights. Chinese legislators and jurists have worked to establish a legal framework for IP development, guided in part by globally recognized standards such as WTO regulations and TRIPS. While China’s central Government has sought to bring China’s intellectual property laws

\begin{itemize}
\item 108. Id.
\item 109. Euromoney Institutional Investor, \textit{supra} note 96.
\item 111. Id.
\end{itemize}
and regulations in line with China’s WTO commitments and the TRIPS Agreement, some problems persist.

In 2004, the value of Chinese counterfeits coming into U.S. markets seized by the United States increased 47% from $94 million to $134 million.\(^\text{112}\) By 2005, the total share of products of Chinese origin seized by U.S. Customs officials at U.S. borders because they infringed IP rights increased to 69%, from 63% in 2004.\(^\text{113}\) China’s counterfeit products threaten public health and safety in the United States, in China and throughout the world.\(^\text{114}\) This is particularly true because China remains one of the world’s largest sources of drugs, both legitimate and counterfeit. By some estimates, 90% of Western medicines are produced by Chinese manufacturers.\(^\text{115}\)

Two problem areas that continue to beleaguer the country are lack of enforcement of IP laws and lack of legislative transparency.\(^\text{116}\) Enforcement efforts, particularly at the local level, are hampered by poor coordination among Chinese Government ministries and agencies, local protectionism and corruption, high thresholds for initiating investigations and prosecuting cases, lack of training, and inadequate and non-transparent processes.\(^\text{117}\) Moreover, counterfeit cases that have been brought by Chinese administrative authorities have resulted in unusually low fines and there has been a steady decline overall in the number of cases that administrative authorities forward to the Ministry of Public Security for criminal investigation.\(^\text{118}\) As a result, Chinese infringers appear to be undeterred by the risk of criminal prosecution and prison. They simply consider seizures

112. Id.
113. USTR Special 301 Report, China, supra note 10.
114. Id.
116. See IACC, Submission of the International AntiCounterfeiting Coalition, Inc. to the USTR, Special 301 Recommendations 11-33, February 11, 2005.
117. USTR, Special 301 Report, China, supra note 10 (“China suffers from chronic over-reliance on toothless administrative enforcement and underutilization of criminal remedies.”). The USTR has identified several key Chinese “hot spots” where increased attention and resources are required to improve weak criminal, administrative, and/or civil enforcement of various IP rights. These include the Guangdong Province, Beijing City, the Zhejiang Province, and the Fujian Province. Id. See also USTR, 2005 Special 301 Report, Executive Summary, supra note 10. On a brighter note, the number of criminal trademark prosecutions appears to be increasing. See State Intellectual Property Office for the P.R.C., Protecting Drug Developers (2005), available at http://www.sipo.gov.cn/sipo_English/gfxx/irpspecial/t20040531_34266.htm.
118. IACC, Special 301 Recommendations, at 17, supra note 124.
and fines to be the cost of conducting business, and are usually able to resume their operations without much difficulty.\textsuperscript{119}

Compounding the problems associated with lack of enforcement is lack of legislative transparency, which makes it difficult to ascertain whether the criminal prosecutions resulted in seizures, convictions, or any other penalties. Specifically, there remains the critical question of what happens to counterfeit goods seized in police actions. The Chinese government does not disclose this information.\textsuperscript{120}

Nevertheless, China seems to be moving in the right direction with encouragement from its global trading partners, particularly the United States. Specifically, with the assistance of the USTR, China has agreed to take the following measures:

1. Reduce intellectual property infringement across the country;
2. Subject a greater range of violations to criminal investigation and penalties, and apply criminal sanctions to the import, export, storage and distribution of pirated and counterfeit products\textsuperscript{121} and to online piracy;
3. Crack down on intellectual property violators through increased nationwide and customs enforcement actions;
4. Make it easier for intellectual property rights holders to secure effective border enforcement;
5. Improve protection of electronic works by ratifying and implementing the WIPO Internet Treaties;
6. Launch a national intellectual property education campaign; and
7. Establish an intellectual property working group to consult and cooperate with the United States on the full range of intellectual property issues.\textsuperscript{122}

In 2004, China implemented new customs regulations designed to enhance border controls and seizures of counterfeit drugs.\textsuperscript{123} The Chinese Customs General Office approved the “Rules

\textsuperscript{119} Id. at 17-18.
\textsuperscript{120} This was one of the USTR’s problems in China’s compliance with the “transparency” requirement in the TRIPS Agreement (i.e., with “transparency” meaning in sum the publication of the laws and legal decisions enforcing those laws).
\textsuperscript{121} While the terms are often used interchangeably, “pirated” is often used to describe goods or material properly manufactured but unlawfully distributed, while “counterfeit” goods are those that have been both fraudulently produced and unlawfully distributed.
\textsuperscript{122} USTR, 2005 Special 301 Report, China, supra note 10.
of Implementation of the Intellectual Property Customs Protection Act,” which took effect on July 1, 2004.\textsuperscript{124} The Rules stipulate the detailed legal requirements and procedures for Customs recordation of intellectual property, the legal requirements and procedures for IP owners or their attorneys to have customs detain suspected infringing goods at the border, and the procedures for Customs to investigate and handle suspected infringing goods.\textsuperscript{125}

In order to have Customs detain suspected infringing goods, the owner of the IP right must submit sufficient evidence of infringement under the Rules.\textsuperscript{126} For example, sufficient infringement evidence would be evidence that “the relevant goods are about to be imported or exported and that the goods feature a trademark or rely on patents or copyrights owned by the IP owner.”\textsuperscript{127}

In addition, China implemented the “Administrative Measures for the Printing and Production of Trademarks” on September 1, 2004.\textsuperscript{128} The Regulations provide detailed requirements for trademark printing on packaging, the most notable of which requires a company to supply a trademark registration certificate or a trademark license granted by the trademark owner before the trademark may be printed on goods or packaging.\textsuperscript{129} The sample print of a registered trademark must be identical to the design and logo on the trademark registration certificate.\textsuperscript{130} The trademark printing company must establish a record and storage system for the trademarks printed and must keep all records for at least two years.\textsuperscript{131} Violation of the Regulations may expose the trademark

\textsuperscript{124.} These rules replace the previous “Implementing Rules of Intellectual Property Customs Protection.” \textit{Id.}

\textsuperscript{125.} \textit{Id.}

\textsuperscript{126.} \textit{Id.} See Article 14 and 15 of the “Measures of the General Administration of Customs of the People’s Republic of China for the Implementation of the Regulation of the People’s Republic of China on the Customs Protection of Intellectual Property Rights.”

\textsuperscript{127.} \textit{Id.} The IP owner must also provide Customs with a guarantee of funds or letter of undertaking issued by a bank or similar credit institution. \textit{Id.} Receivers and shippers of imported and exported goods, and their attorneys, are responsible for knowing, within reason, the IP status of the goods that they import or export. They must accurately declare the IP status of the goods to customs and submit relevant certification documents if necessary.

\textsuperscript{128.} \textit{Id.} These new regulations replaced the previous regulations, issued by the SAIC, on September 5, 1996.

\textsuperscript{129.} \textit{Id.} See Article 4 of the “Administrative Measures for the Printing and Production of Trademarks.”

\textsuperscript{130.} \textit{Id.}

\textsuperscript{131.} \textit{Id.} See Article 10 of the Administrative Measures for the Printing and Production of Trademarks that “the trademark printing and production archives and the account of ins and outs of trademark signs shall be preserved for inquiry. The preservation period for inquiry shall be two years.”
printing company to trademark infringement liability as provided in the Chinese trademark law.\footnote{132}{See Article 13 of the \textit{Administrative Measures for the Printing and Production of Trademarks} that “where a trademark printing entity undertakes printing business by violating Article 7, and the trademark printed by it is identical or approximately similar to a registered trademark of another party, such act belongs to the trademark infringement act as mentioned in Article 50 (2) of the Rules for the Implementation of Trademark Law. This trademark printing entity shall be punished according to the pertinent provisions of the Trademark Law by the administration for industry and commerce of the locality or of the place of act.”}

In December 22, 2004, China also promulgated new regulations in the People’s Republic of China (PRC) Criminal Code,\footnote{133}{See generally The Supreme People’s Court, The Supreme People’s Procuratorate, Interpretation of the Supreme People’s Court and the Supreme People’s Procuratorate Concerning Some Issues on the Specific Application of Law for Handling Criminal Cases of Infringement upon Intellectual Property Rights, adopted at the 1,131st meeting of the Judicial Committee of the Supreme People’s Court on November 2, 2004, and the 28th meeting of the Tenth Procuratorial Committee of the Supreme People’s Procuratorate on November 11, 2004 (promulgated on Dec. 8, 2004).} detailing the three types of criminal trademark violations: (1) use of a trademark which is identical to a registered trademark, without the owner’s permission; (2) selling commodities labeled with counterfeit trademarks; and (3) replicating portions of a registered trademark without the owner’s permission.\footnote{134}{See, e.g., Wang Jingchuan, \textit{Intellectual Property: Expecting More Mutual Understanding and Cooperation} (May 18, 2005) available at http://www.sipo.gov.cn/sipo_English/gyx/zyhd/t20050523_48027.htm; see also Chinese Criminal Code.} Similarly, the Supreme People’s Court and Supreme People’s Procuratorate (SPP) issued a new judicial interpretation in December 2004 redefining the criteria for (1) commencing prosecutions and (2) imposing criminal convictions.\footnote{135}{Id.}

In March 2005, Premier Wu Yi extended China’s national campaign to crack down on intellectual property infringements in those sectors where trademark counterfeiting and copyright infringement are concentrated.\footnote{136}{Specifically, those sectors include import and export activities, trade fairs and exhibitions, distribution and wholesale markets, brand name processing and publishing. See id.} The next phase of the national campaign will focus on food and pharmaceutical trademark infringements.

In addition to state action, private civil proceedings are a growing tool for intellectual property enforcement. In 2001, 5,265 civil IP cases were initiated in Chinese courts.\footnote{137}{Jiang Zhipei, \textit{Recent Developments in China’s Judicial Protection of Intellectual Property Rights} (Aug. 18, 2003), available at http://www.chinaiprlaw.com/english/forum/forum43.htm.} By 2002, parties filed approximately 7,800 civil IP cases, including 1,725 patent
infringement, 1,122 copyright infringement, and 504 trademark infringement cases.\textsuperscript{138}

While most of these lawsuits were initiated by domestic entities, non-Chinese companies have also slowly been utilizing the Chinese court system to enforce its IP rights. In 2005, the Beijing No. 1 Intermediate People’s Court upheld Pfizer’s patent rights for VIAGRA, reversing the Chinese patent review board’s decision to allow Chinese drug companies to make sildenafil citrate, the main active ingredient in VIAGRA.\textsuperscript{139} (Previously, six months after Pfizer had introduced VIAGRA to the Chinese market in 2000, an estimated 90\% of Viagra pills sold in Shanghai were counterfeit.\textsuperscript{140}) The Beijing ruling was considered “pivotal for countering piracy of pharmaceuticals” [in China].\textsuperscript{141}

Finally, the Chinese government has cooperated with foreign drug manufacturers to promote intellectual property rights protection. The Shanghai Municipal Food and Drug Administration and Pfizer have formed an alliance to detect and stop counterfeiters.\textsuperscript{142} In April and May 2004, Chinese authorities cooperated with several international drug makers, including U.S.-based Eli Lilly and Germany-based Bayer, in conducting seven operations to seize counterfeit drugs worth an estimated U.S. $8 million.\textsuperscript{143}

\textbf{E. Russia}

Russia is another major counterfeit drug market. Counterfeit drugs have been a growing industry in Russia for years. In 2003, faced with 700 domestic drug manufacturers, 7,000 distributors, and 70,000 pharmacies to monitor, the Russian Federation’s Pharmaceutical Inspectorate acknowledged it was unable to stop counterfeit drug production and distribution.\textsuperscript{144} The Inspectorate identified “the current system of import medicines registration” and the large number of independent pharmacies, almost 80,000

\textsuperscript{138} Id.


\textsuperscript{140} Id.

\textsuperscript{141} Id.


\textsuperscript{143} Carlye Adler, \textit{Which Is Safe to Take? Counterfeit Drugs Are Big Business in Asia. Here’s What You Need to Know to Ensure You’re Not Buying Bad Medicine}, Time Magazine (Asia) (May 31, 2004) at 40.

\textsuperscript{144} Simon King, \textit{Russian Health Ministry Outlines Counterfeit Drug Problem}, World Markets Analysis (June 24, 2003).
nationwide, as reasons for the high volume of counterfeit medicines. However, the Russian Health Ministry did suspend the licenses of 321 pharmaceutical companies for manufacturing and trading in counterfeit medicines.

In 2004, Russian Health Ministry officials estimated that counterfeit medicines accounted for $400 million of the $4.5-5 billion annual Russian medicine market and that about 12% of the medicines were counterfeit. In 2003, Russian law enforcement authorities removed 18 million rubles (U.S. $600,000) worth of counterfeit medicines from the market. The medicines most commonly counterfeited are antibiotics, anesthetics, and medicines for gastrointestinal, cardiovascular, endocrine, and nerve problems. Most of Russia’s counterfeit medicines originate in Russia, while 2% come from other former Soviet republics and 31% from abroad, mainly Southeast Asia.

In June 2005, the Ukrainian and Russian Health Ministries stated their intention to sign an agreement directed at reducing the number of counterfeit drugs that are distributed in both countries by strengthening their cross-border inspection efforts. However, the efficacy of these efforts has yet to be seen.

One of Russia’s current problems is that the Department of Pharmaceutical Inspection—the one that spearheaded the fight against counterfeit drugs in Russia, and was responsible for the capture and withdrawal of hundreds of batches of banned and fake drugs—was abolished in 2004. Instead, the Union of Professional Pharmaceutical Organizations will provide Russia’s

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145. Counterfeit Medicine Market Grows in Russia, RBC Network Corp. (Oct. 24, 2003). Russia's drug registration and importation process is known to be arduous, expensive and inefficient. Registration of a new drug product for import takes at least one year and requires batch-to-batch testing. See Gireesh Chandra Prasad, Russia to Ease Import Rules for Indian Pharma, Economic Times (India) (Nov. 5, 2005). The restrictive standards mean fewer legal drugs can be imported into Russia, pumping up the market for counterfeits. In late 2005, however, Russia promised to ease registration standards to reduce wait time. Id. When such changes will be implemented was uncertain at the time of the writing of this article.


149. Id.

150. See supra note 146.

151. Simon King, Russia and Ukraine to Collaborate on National Drug Supplies, World Markets Analysis (June 9, 2005).

State Customs Committee (RSC) with information that will help trace counterfeit medicines. The RSC has reported that counterfeit drugs are being mixed with legitimate shipments and then imported into Russia, so they are virtually undetectable. The importation of counterfeit drugs into Russia, compounded by the domestic manufacture of counterfeits within Russia, create problems for Russian officials and consumers alike.

With respect to enforcement problems, aside from the size of the country and sheer number of organizations selling counterfeit drugs, the procedure that the owner of a property right must follow to enforce its right is complex. The owner must file a complaint with the State Customs Committee (SCC) and ensure that the information submitted is complete, because the goods may return to the market if the identification is at all non-specific. Once the information is verified, the documents issued by the SCC and the corresponding information are filed with the supervising customs bodies of Russia. What happens to the goods after that remains unclear.

The USTR has also noted enforcement problems with respect to the shutting down of illegal plants and counterfeit product manufacturers, seizure and destruction of equipment used to make pirated goods, prosecution of those responsible for piracy and counterfeiting, strong border enforcement, and bringing Russia’s Civil Code up to speed with existing TRIPS regulations. The United States has promised to continue monitoring Russia’s progress in bringing its IP enforcement in line with international expectations. As in 2005, Russia remained on the USTR’s Priority Watch List in 2006.

Nevertheless, some of Russia’s efforts are working. In November 2004, the Organized Crime Department of Russia’s Interior Ministry disclosed that it had discovered an international criminal group which traded in contraband and counterfeit medicines all over Russia. That particular criminal group had over fifty affiliates in Russia’s regions and their annual turnover was estimated at U.S. $200 million.

153. Id.
154. Customs to Put Barrier to Counterfeit Medicines, RIA Novosti (Feb. 24, 2004).
155. Sergey Talpa, Protection of Intellectual Property in Russia (June 1, 2005).
156. USTR, Special 301 Report, Russia, supra note 10.
157. Id.
158. Id.
159. Id.
160. Counterfeiters Supplied the Entire Russia with Fake Drugs, Kommersant (Nov. 12, 2004).
F. Ukraine

Like Russia, Ukraine suffers from serious deficiencies in its intellectual property rights enactment and enforcement, which adversely affect legitimate pharmaceutical companies worldwide. Ukraine was on the 2006 Special 301 Report as a Priority Watch List Country and was under trade sanctions due to its repeated failures to comply with TRIPS. The United States withdrew Ukraine’s benefits under the Generalized System of Preferences (GSP) program in August 2001 and imposed $75 million worth of sanctions on Ukrainian imports in January 2002.

The Ukrainian State Inspectorate for Quality Control of Medicines contends that Ukraine’s counterfeit drug problem is not as serious as some would suggest. For instance, the State Inspectorate conducted a study in 2004 which concluded that only 0.33% of approximately 122,000 sampled medicines were counterfeit. However, other studies have reported that, on average, 40% of the pharmaceuticals in Ukraine are counterfeit and, for certain medications, counterfeits can be as high as 80%. Moreover, the Ukrainian market for counterfeit drugs is estimated to be worth U.S. $60 million, which is approximately 10% of the total domestic pharmaceutical production.

Additionally, while Ukraine’s Customs Code fines the import and export of infringing goods, and authorizes confiscation of counterfeit goods, the Code does not provide for the destruction of confiscated counterfeit goods, which often allows goods to be placed back into trade channels.

Trademark counterfeiting is a particularly serious problem in Ukraine. The U.S. trademark industry remains concerned over the lack of cooperation by enforcement officials in combating counterfeiting activities. As in the United States and Russia, trademark owners may prevent infringing goods from entering the Ukrainian market by filing an application with Ukrainian Customs authorities to register their goods in the Customs Register. However, unlike most jurisdictions, Ukrainian

161. USTR, Special 301 Report, Ukraine, supra note 10.
162. This sanction was terminated in 2006. See id.
164. Id.
165. Id.
Customs only register “goods” that are subject to Intellectual Property rights rather than particular product brands or trademarks. That is, rather than registering a trademark to be monitored, every category of goods covered by that trademark must be registered separately.\textsuperscript{168} This loophole means that Custom monitors cross border transportation of registered “goods,” but not the entire spectrum of goods bearing the same trademark.\textsuperscript{169} It is more costly and time-consuming to ensure that each individual good has been registered—as opposed to an entire “brand.” Moreover, a non-diligent or semi-diligent brand owner, or one with fewer resources, may fall prey to the danger of unprotected imports.

Ukraine has made some progress in addressing the problem of counterfeiting. In 2003, the Ukrainian Cabinet passed a directive “On the Adoption of the Programme for Combating Manufacturing and Sale of Counterfeit Drugs in the Years 2003 Through 2008.”\textsuperscript{170} In 2004, Ukraine added to its Customs Code a definition of counterfeit goods as well as a section on control of goods containing intellectual property rights across its border.\textsuperscript{171} Notably, in 2006, the USTR lowered Ukraine from the Priority Foreign Country List to the Priority Watch List.\textsuperscript{172}

Nevertheless, enforcement problems continue to be a problem in Ukraine. For instance, in December 2003, the Ukrainian Health Ministry’s State Inspectorate prohibited the sale, storing and use of chloramphenicol sold by the Monpharm pharmaceutical company.\textsuperscript{173} The Ukrainian News reported that chloramphenicol was a counterfeited medicine because it was not actually produced by Monpharm, and therefore, the packaging falsely suggested that it was an authentic approved product.\textsuperscript{174} However, business entities who sold, stored, and used Monopharm’s chloramphenicol

\begin{flushleft}
\textsuperscript{168} Id.
\textsuperscript{169} Id.
\textsuperscript{170} Richard Heath, Report on Anti-Counterfeiting in Selected Countries, Anti-Counterfeiting and Enforcement Committee of the International Trademark Association (May 26, 2004).
\textsuperscript{171} USTR, 2005 Special 301 Report, Ukraine, supra note 10. In addition to criminal sanctions, Ukraine has adopted a new civil code which provides for possible remedies for intellectual property rights violations, including taking provisional measures to prevent IP infringement and to secure evidence, suspending customs clearance of goods the importation or exportation of which involves infringement of IP rights, confiscation of infringing good, and confiscation of materials and equipment used for the manufacture of infringing goods. See Pakharenko, supra at note 167.
\textsuperscript{172} USTR, Special 301 Report, Ukraine, supra note 10.
\textsuperscript{174} Khrystyna Protsiv, Health Ministry Prohibits Sale and Use of Monpharm’s Chloramphenicol, Ukrainian News (Dec. 2, 2003).
\end{flushleft}
were merely advised to check the medicine in stock, withdraw counterfeits from circulation, and notify the Inspectorate.\textsuperscript{175} Counterfeiters, however, are unlikely to voluntarily withdraw counterfeit medicine from circulation, much less notify the Inspectorate of their crimes. This kind of lax enforcement is one reason for continued trade sanctions against Ukraine.

\textbf{G. Latin America}

All throughout Latin America, counterfeit prescription medicines is a big business and one that is often more lucrative than cocaine.\textsuperscript{176} Many consumers have gotten sick and died from counterfeit drugs that were produced in deficient conditions or from unsafe materials. For example, in May 2001, investigators for Columbia’s National Institute for the Supervision of Medications & Foods discovered a thriving drug operation in Bosa, a poor neighborhood of Bogota. A trio of tiny dilapidated houses were producing more than 20,000 counterfeit tablets per day of the flu drug DRISTAN, a generic form of Aspirin known as Dolex, and PONSTAN 500, a popular painkiller made by U.S.-based drug giant Pfizer. The drugs were produced in filthy conditions and many of the pills contained boric acid, cement, floor wax, talcum powder, and yellow paint with high levels of lead—all used to replicate the genuine medications appearance.\textsuperscript{177}

Ironically, the progress that Latin American authorities have made in the past two decades in the war against cocaine and heroine cartels is partly responsible for the surge in counterfeit medicines. As governmental officials have cracked down on the narcotics trade, organized crime has moved into manufacture and distribution of counterfeit medicines, which is nearly as lucrative but far less risky.\textsuperscript{178} If a criminal is caught with a pound of cocaine, he or she faces serious penalties and prison time. But the only penalty for being caught with counterfeit medicine is six months in prison or a slight fine.

Brazil has gone the farthest of the Latin American countries to enact stiff penalties for anyone caught with counterfeit drugs, after the country suffered several deaths due to counterfeit drugs administered to prostate-cancer patients.\textsuperscript{179} In Brazil, counterfeiting drugs is a crime on the level of kidnapping and

\begin{thebibliography}{99}
\bibitem{175} Id.
\bibitem{176} Kerry Capell and Suzanne Timmons, \textit{What’s in That Pill?: In Latin America, Fake Drugs Are as Lucrative as Cocaine}, Business Week (June 18, 2001), available at http://www.businessweek.com/magazine/content/01_25/b3737153.htm.
\bibitem{177} Id.
\bibitem{178} Capell and Timmons, \textit{supra} note 176.
\bibitem{179} Id.
\end{thebibliography}
terrorism, punishable by 10-15 years in jail and a fine.\textsuperscript{180} Brazil has also established the National Agency for Sanitary Control to monitor the safety and quality of medicines.\textsuperscript{181} These are steps in the right direction.\textsuperscript{182} However, as long as the world's poor need cheap medicines and regulators fail to monitor the markets, counterfeit drugs will flourish.

\section*{III. CONCLUSION}

Tougher laws are needed globally to combat drug counterfeits. A number of organizations and agencies have been active and effective in the war on counterfeit drugs. The International AntiCounterfeiting Coalition (IACC) has been instrumental as one of the primary organizations that provides a Special Recommendation Report to the USTR for its Special 301 Report. Another organization is the ICC Commercial Crime Services—Counterfeiting Intelligence Bureau (CIB),\textsuperscript{183} a private business initiative that gathers intelligence, makes undercover inquiries, organizes the seizure of counterfeits, and provides advice and training to its members—mostly large multinational companies, trade associations, law firms and technology producers.\textsuperscript{184} The World Intellectual Property Organization, World Trade Organization, Interpol, Europol, and the Global Anti-Counterfeiting Network (a private, nonprofit organization) are also active and effective. These organizations all agree that tougher laws and changes in perspective are necessary to stop global counterfeiters. Such needed changes include: (1) increased political will to combat intellectual property crimes; (2) proper legislation for \textit{ex officio} border and criminal enforcement; (3) legislation to detain, seize, forfeit, and destroy counterfeit goods being imported, exported and moving in-transit in free trade zones, as well as seizure and destruction of equipment used to produce such goods; (4) more stringent penalties; (5) linking intellectual property crime to organized crime; (6) increased disclosure of information to intellectual property owners to permit legal actions and

\begin{itemize}
\item \textsuperscript{180} Id.
\item \textsuperscript{181} Id.
\item \textsuperscript{182} Id. Some representatives of the big drug companies estimate that of the $19 billion worth of counterfeits sold annually, the vast majority are produced and sold in developing countries, such as Nigeria, Mexico, Ecuador and Haiti. There, demand for cheap drugs is strong, profit margins high—often as much as 3,000%—and penalties for manufacture and distribution are weak. In some African and Latin American countries, as much as 60% of all drugs sold are counterfeit.
\item \textsuperscript{184} Id.
\end{itemize}
investigations in third-world countries; and (7) transparency regarding the results of enforcement actions (raids, administrative and judicial proceedings).

To win the war against counterfeit drugs, the United States, its global trading partners, the private sector and all related public interest organizations must coordinate their efforts to eliminate counterfeiters. Countries must enact tougher counterfeiting-prevention laws and then enforce them. Private companies must take advantage of local customs laws requiring trademark registration and/or sufficient trademark identification as a precursor to filing suit. The private sector also needs to be more active in teaching consumers and healthcare providers how to spot counterfeits. Similarly, the private sector needs robust mechanisms for consumers, hospitals and physicians to report potentially counterfeit drugs. Finally, new global initiatives can go far in establishing a powerful system of global detection and enforcement that may eventually put the counterfeiters out of business.

The damage done by the counterfeit drug trade is massive and affects individuals, companies and the economic systems of entire countries. Recent efforts at cooperation between foreign governments and regulatory agencies—such as the joint efforts of the National Boards of Pharmacy and Canada’s National Association of Pharmacy Regulatory Authorities—are encouraging. More such efforts are needed. The private sector has also been willing to take steps to prevent counterfeiting. Implementing technologies, such as radio frequency identification and DNA labeling of drugs, may be costly, but will have long term benefits for the entire industry. Finally, all parties should be vigilant in enforcement mechanisms—whether it be governments’ passing legislation and enforcing anti-counterfeiting laws on the books, private companies keeping a tight rein on their supply chain, or patients’ being well educated about counterfeits and closely examining the products they consume. By working together, the world can win the war against counterfeit drugs.