

Fakes and counterfeits in Latin America

Catherine White takes a look at counterfeit goods crossing the US border.

“Intellectual Property Right protection isn’t just about fashion; it’s also about protecting the American public”. That’s the view of Jennifer Climenhaga, the office of field operations liaison to the Office of Public Affairs in the US. Jennifer knows all too well about safety after she and US Custom Border Patrol officers (CBP) were involved in an inspection which uncovered lighters with no safety switches. The lighters were not, of course, in line with US regulations, so the seizure ended what could have been a string of horrific accidents.

The CBP not only look at ways to combat safety issues but ways to also hinder counterfeit goods, a problem that is growing in both the US and Latin America. Unfortunately, counterfeiting is an increasing illegal activity and a crime that costs US businesses \$200 billion to \$250 billion yearly¹.

As a result, US companies need to understand how best to protect their intellectual property within the region. Notably, efforts from the international community such as the International Trademark Association (INTA) and the World Intellectual Property Organisation (WIPO) have made life a little easier for business leaders because of recent improvements favouring the enforcement and protection of IP. WIPO conducted the *Global Congress on Combating Counterfeiting and Piracy in Mexico* in December 2009, and INTA held a roundtable on *Unfair Competition and Infringement of Trademark Rights* in August 2010.

It is well known that nowadays counterfeiters have gone beyond traditional fashionable products like trainers, sunglasses, watches

and handbags, cheap transmission fluid made to look like oil or brake linings made of compressed grass. They also deal in aviation, medical devices, software, CDs, DVDs, alcohol and pharmaceutical products.

Julian Harris from International Policy Network highlighted that consumer demand for counterfeit goods changes with economic fluctuations. In poorer countries there are counterfeit “life saving drugs”, which are sub-standard copies of pharmaceutical treatments for drugs like HIV drugs and anti-malarial drugs. In wealthier areas there are counterfeit “lifestyle drugs” like fake Viagra and weight loss pills.

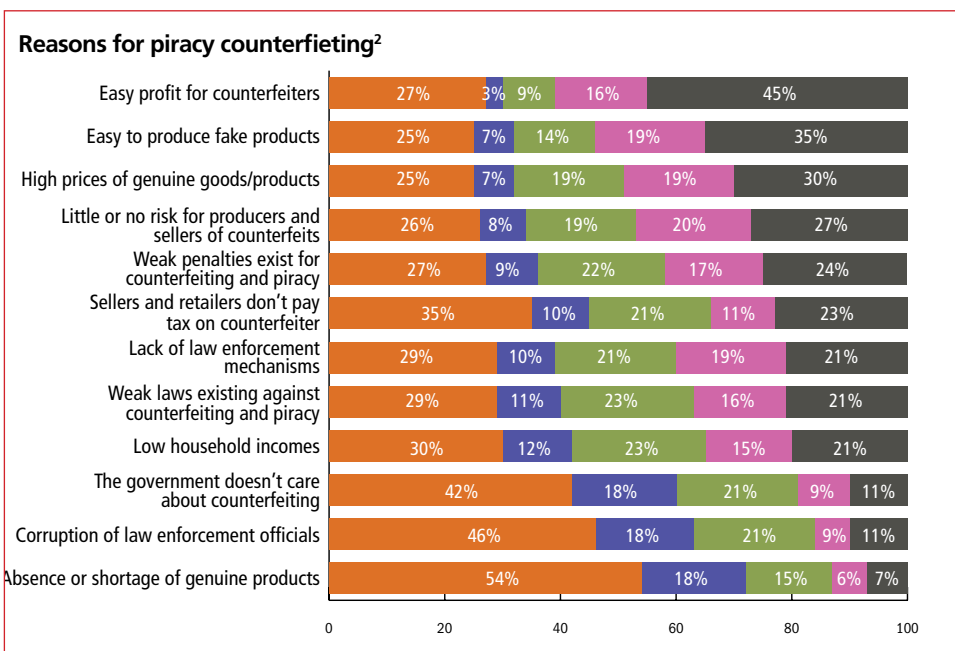
Consumers also purchase counterfeit prescription drugs over the internet because it is more convenient. It is a popular practice in the US, made easier by the fact that drugs can be purchased from Canadian websites which act as a convenient smoke screen for selling counterfeits to other parts of the world. These internet drugs then end up on the gray market throughout the US and Latin America because expiry dates can easily be doctored and consumers are looking for a ‘bargain’.

Pharmaceutical tourism is also a growing problem, especially from the US to Mexico. Consumers buy prescribed medication at cheaper prices or buy the same medication without a valid prescription. Consumers seek the medication offered in another country because it is not approved in their home country or the formulation is different resulting in a lower price.

In 2008-2009 the Patients Association teamed up with the Medicines & Healthcare Products Regulatory Agency and Pfizer to support the *Get Real, Get A Prescription* campaign, which was a hard-hitting campaign to raise awareness on the dangers of pharmaceutical tourism, urging people to take responsibility.

Katherine Murphy director of the Patients Association commented that pharmaceutical tourism was on the rise because “people are not aware of the consequences and dangers of using unregistered websites” or counterfeit sellers. In addition, it was difficult to know the difference between a genuine site and a fake one.

Murphy said that consumers purchased fake drugs because it was cheaper and “the easy option”. However, she stressed that people were unaware of the risks involved because many fake drugs have very little documentation or information about the



WHY LATIN AMERICA?

The Americas are a hotspot for counterfeiting for a number of reasons:

- Historically, the countries have experienced political unrest and economic depression resulting in the trade and export support of fake products;
- Corrupt authorities intensify the problem; bribery is a common practice and where products are being counterfeited it can sometimes be difficult to pursue civil cases if the law is weak or there is no fair process in the region's courts; and
- Poorer consumer's source counterfeits because genuine products are too expensive.

“Latin America ranked second highest out of five regions for pharmaceutical crimes such as counterfeiting and theft.”

side effects. She said that it was extremely hard for people to spot fake drugs as they are cleverly disguised. Wayne Roberts director of global security (Latin America) at Pfizer added that many patients “are unaware of the risks associated with counterfeit medicines and many view counterfeiting as a victimless crime”.

A 2009 study by the Pharmaceutical Security Institute (PSI) revealed that Latin America ranked second highest out of five regions for pharmaceutical crimes such as counterfeiting and theft. It is important to note that the countries with seemingly low incidence totals are not necessarily unaffected, but maybe relatively unaware of the issue due to lack of funding or competing law

enforcement priorities. PSI arrested 1,468 people who were involved in counterfeiting, illegal diversion (false statements or declarations) or theft of pharmaceutical drugs in 2009.

Medical counterfeiters frequently adulterate products with active ingredients such as acetaminophen giving temporary pain relief but this can result in death, for example in Argentina in 2004, several women died after receiving a fake iron-based medicine to treat anaemia. The International Policy Network (IPN) created a programme called *Keeping it Real* to reduce deaths from fake pharmaceuticals, urging retailers to:

- Check the quality of drugs by using new technology such as the spectrometer – a device to determine if a drug contains the correct ingredients; and
- Tackle counterfeiting eg, private companies help to educate the public on the dangers of pharmaceutical counterfeits.

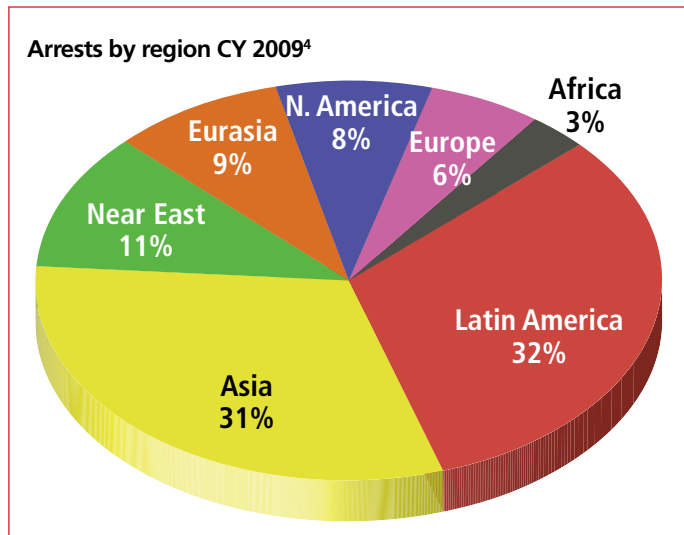
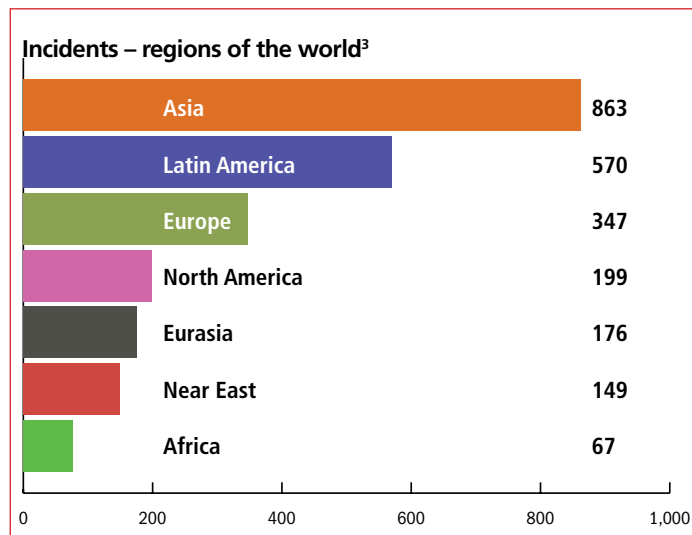
Harris commented that fake products are also prevalent in Latin America because it is impossible for customs to check every vehicle when crossing the border, so contraband slips through the net. Furthermore it is unrealistic for border agencies to manually check everything and as organised crime is growing, breakthroughs against counterfeiting rely heavily on intelligence and focusing attention where fakes are most likely to be found instead of solely trying to control a whole supply chain.

A survey conducted by Gallup found that 10% of Americans thought corrupt police were a major reason behind the increase in counterfeiting and 30% blamed the high prices of genuine products for counterfeiting practices.

Diana Muller and Maria Savio of Gottlieb, Rackman & Reisman noted that consequently, the Latin American governments are recognising that counterfeiting results in:

- Loss of tax revenue: The Venezuelan Internal Revenues and Customs Agency (SENIAT) began to apply administrative rulings on the observance of intellectual property rights to imports and customs clearance of merchandise. The agency prohibited the release of any infringing product and the circulation of counterfeit goods;
- Serious health concerns; and
- Lack of foreign investment from the industrial world in Latin America.

Pfizer, the world's largest research-based pharmaceutical company is no stranger to counterfeits. Roberts said in 2009 Pfizer seized 8.5 million fake pills bound for Latin America. Consequently, the company works tirelessly to expose fakes and stop the threat of future counterfeits. In an attempt to realise this goal Pfizer



IP STEPS TO FOLLOW

Muller and Savio outlined IP protection steps:

Companies can adopt a plan to protect their individual interests in Latin America by:

- Identifying particularly problematic areas for their industry eg, Colon Free Zone (Panama) and Port of Paranagua (Brazil) and keep any eye on what's happening globally;
- Educating customs authorities. The authorities are normally receptive to training and education by IP owners – resulting in successful seizures of pirated goods;
- Understanding the local laws and becoming familiar with civil or administrative procedures. It is important to understand how laws are applied and what administrative or civil procedures there are;
- Producing advertising in Spanish or Portuguese for consumers in Latin America to educate people on how to spot counterfeits and explaining the risks;
- Maintaining an enforceable and understandable IP portfolio by registering trademarks in Latin American countries and protecting IP rights eg, patents and copyrights; and
- An effective IPR border enforcement strategy requires an assessment on key counterfeiting challenges. All businesses seeking help from CBP on how to enforce their IP rights at the border need to complete the trademark and copyright recordation process. Once their IP rights are recorded, they can then engage directly with the relevant CBP offices to ensure their concerns are understood by the CBP decision makers.

“In “Mexico and Brazil, there are many reports of drivers and their shipment escorts being roughed up and killed on occasion”.”

Global Security has implemented an aggressive, pro-active anti-counterfeiting programme to detect and disrupt major manufacturers and suppliers of counterfeit Pfizer medicines. The company disrupts the flow of counterfeits in the global market by attacking the source.

The programme targets both the supply of fake medicines, through partnerships with enforcement authorities, and demand, by raising awareness to the dangers of counterfeits. Even after a matter has been referred to the authorities, Pfizer continues to provide investigative support, including chemical analysis of suspected counterfeits to determine their authenticity.

Pfizer also works with US and Latin American customs authorities to provide training and enhance their ability to distinguish a fake product from a genuine product. The training enables the authorities to spot “common errors” produced by counterfeiters and familiarises

them with Pfizer's anti-counterfeiting technologies incorporated into packaging. Since the inception of their programme, Pfizer has provided training to authorities from at least 87 countries including 17 in Central and South America. Pfizer also provides training to judges and prosecutors from Latin America. The company also has public affairs representatives in each country or region that work with pharmaceutical associations involved in a myriad of education and awareness programmes.

Unfortunately despite its efforts, the group has seen an increase not only in the number of tablets seized annually – from 8.1 million in 2006 to 11.1 million in 2008 – 2009 but in the number of countries in which they have confirmed the presence of counterfeit medicine – from 67 in 2004 to 90 in June 2010, including 14 within Latin America. Within Latin America, Pfizer have to date confirmed breaches of the legitimate supply chain in five countries concerning nine products.

For Pfizer the biggest infringement challenges are exposing shipments of fake drugs hidden in containers transiting several countries, identifying the networks involved and the movement of the containers. The company battles this problem with search and seizure strategies which are the best and most effective border enforcement.

Cargo thefts are also of major concern. A theft is the diversion of goods while in – transit into the hands of thieves and is a crime that costs the US nearly \$8 – 12 billion in stolen goods yearly, according to FreightWatch Security Net. Bill Games, company president, said that the organisation was focused on full trailer thefts but “slippage of boxes out of the back of a trailer while *en route* is also a significant problem”.

Games said that in the USA, cargo theft is a crime of opportunity, created when goods are left unsecured or unattended, eg, a truck left running at a stop while the driver has dinner. Consumer products such as electronics, tobacco and pharmaceuticals are often stolen because they are easy to sell on the gray market. Once stolen, these products are often housed in what appear to be legitimate warehouses but cargo theft of full trailer loads is “an organised criminal conspiracy” and a crime that is increasing as the recession bites. It can be, at times, a dangerous crime too with Games pointing out that in “Mexico and Brazil, there are many reports of drivers and their shipment escorts being roughed up and killed on occasion”.

FreightWatch Security Net combat cargo theft by providing GPD tracking technology that provides supply chain visibility which enables the company's clients to measure compliance with security guidelines (eg, not stopping in ‘red zones’ and following preferred routes). The technology also enables FreightWatch to quickly locate and recover trailers when they have been stolen.

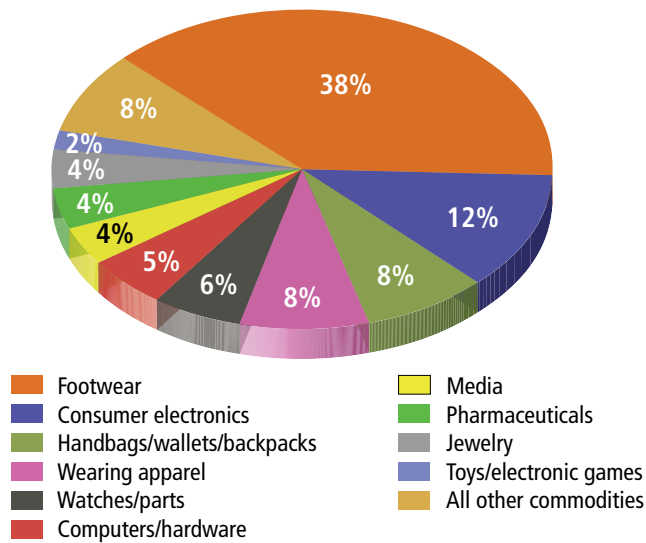
Action to stop fakes

Ironically, authoritative action to battle the cocaine and heroin trade gave birth to the production of counterfeit medicines. As governments cracked down on the narcotics trade, organised crime moved in to the equally lucrative and less risky world of fake pharmaceuticals. The crossborder trade is developing global dimensions, with Colombia's National Institute for the Supervision of Medications & Food (INVIMA) discovering fakes from Indian manufacturers.

Colombia introduced heftier sentences in July 2010 for pharma counterfeiters. Brazil has also stepped up to the mark. In October 2004, the National Council to Combat Piracy was created with the participation from both the public and private sectors. This is a central agency responsible for the evaluation and implementation of policies to fight counterfeiters. Muller said that the Brazilian local police do not “necessarily work together with the Customs authorities but they do work with the CNP or in private investigations”.

Muller noted that there is no registration system with Customs such

Graph on counterfeit goods by US CBP⁵



“Rising penalties could push the crime further underground. That would result in pharmaceutical drugs “ending up in the control of powerful gangs and resulting in less prosecution”. This risk is very real in poorer countries.”

as in the US, but companies directly or through their lawyers notify the Customs authorities of their IP rights regarding infringed trademarks. Whether a civil action or a criminal action is filed is sometimes a judgment call. In almost all cases the judge may impose an ‘alternative penalty’ which is the substitution of imprisonment with a fine.

Jennifer Climenhaga described the difference between the roles of CBP officers stationed at ports of entry and border patrol agents who secure US borders between the Ports of Entry, and how they work to reduce counterfeiting.

CBP officers scrutinise cargo and determine if it is admissible or if it requires further scrutiny. A CBP officer, when dealing with potentially counterfeit merchandise, has the authority to detain the goods for further evaluation to determine if the item(s) are fakes or genuine.

The CBP also works in conjunction with businesses. Some IP owners are extremely vigilant when it comes to protecting their trademark and often work with the CBP on how to recognise fakes. New Balance, a sportswear company is especially aggressive about its IP rights as well as its reputation for high quality, stringently tested products. Additionally, IP owners often provide training to CBP officers on what to look for.

Pfizer extends this training and has ongoing partnerships with enforcement authorities, Roberts noted. He said that the efforts are

“interactive and an ongoing process”. In addition to the training and testing services, Pfizer work with authorities to develop the most effective strategies to stop the flow of counterfeits.

Pfizer “ensures that our trademarks are properly recorded with customs, for example, provide customs authorities with the legal basis to detain and seize counterfeit versions of our medicines” and “we file and register patents to protect the results of our innovative research”, Roberts added.

In 2003, over 150,000 packages of cigarettes were seized by Brazilian customs and in 2005, Argentina introduced Resolution No 2216/2007, a procedure to control the importation of fake products into the country by launching a system of alerts on the basis of trademark registrations previously recorded. In an attempt to further hinder counterfeiting the Food and Drug Administration (FDA) has recommended pharmaceutical firms redesign their pills. Harris noted that serialisation systems have also been put in place to help track counterfeits. A serialisation code is created for individual products during the production process which can then be tracked. If a product then goes missing, the government investigates.

There are also drug products which have extra barcodes with serialisation data that is registered in the system. Pharmacists can then check the barcode to see if drugs are genuine and in date, filtering out the fakes.

The battle on counterfeiting continues and with South American governmental activities such as “Operation Jupiter” (to combat organised crime groups involved in illegal IP activities in Latin America) improvement is slowly being made. The US Trade Representative’s warning that Brazil and Argentina were on its “priority watch list” also helped to intensify efforts.

Harris argued however that whilst in theory there should be stronger punishments, given the seriousness of counterfeiting, rising penalties could push the crime further underground. That would result in pharmaceutical drugs “ending up in the control of powerful gangs and resulting in less prosecution”. This risk is very real in poorer countries.

The potential fears only make the need to stop counterfeiting more urgent. Fakes must be detected and counterfeiters must be deterred for a country’s reputation and its people’s safety. Roberts stated that Pfizer’s labs have confirmed “the presence of pesticides (boric acid), rat poison (warfarin), brick dust, leaded highway paint, cartridge ink” and “even reports of heavy metal, arsenic and even anti-freeze” in counterfeit pharmaceuticals.

Footnotes

1. International Anti Counterfeiting Coalition.
2. Gallup.
3. Pharmaceutical security institute.
4. Pharmaceutical security institute.
5. US Customs Border Protection.

Author



Catherine White is a staff reporter and sub-editor for Intellectual Property Magazine. She previously worked as an editor and writer for Only Group, London.