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## **IP Strategies to Combat Distribution of Counterfeit Drugs**

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Counterfeit products are no longer restricted to Gucci purses and Rolex watches. The pharmaceutical sector has seen an alarming rise in the number of counterfeit products entering traditional distribution and supply chains. As a result, consumers unknowingly purchase counterfeit pharmaceuticals from their local pharmacy and receive little or no therapeutic benefit, or worse, die as a result of ingesting the counterfeited product.

Pharmaceuticals are counterfeited in a number of ways: they may contain the wrong or no active ingredient, or be adulterated with random mixtures of harmful toxic substances or components.<sup>1</sup> Branded, generic, herbal remedies and over-the-counter drugs and formulations all have been counterfeited. The copied drugs are manufactured to look like the branded product to trade off the goodwill and product integrity developed by the original manufacturer. The small size of drugs and other pharmaceutical products make them relatively easy to copy, difficult to identify and easy to transport across borders.

### **Branded Drugs are Particularly Vulnerable**

Although counterfeit drugs have infiltrated all types of industries, brand-name drugs are especially vulnerable because of their significant market potential and profit margins.<sup>2</sup> Lifestyle drugs, anti-cancer medicines, antibiotics, hypertension and cholesterol-lowering drugs, hormones, steroids and pain-killers all have been counterfeited.<sup>3</sup>

### **Global Impact and Economic Injury**

Fake medicines are estimated to be a \$32 billion global business.<sup>4</sup> Although counterfeit medicines have been distributed through every economy, Asia and specifically China, is reported to be the largest source economy. In addition to the transnational nature of the problem,

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<sup>1</sup> CDER. *FDA Consumer Education: Counterfeit Medicine*. US Food and Drug Administration: Rockville, MD, 26 January 2006; [www.fda.gov/cder/consumerinfo/counterfeit\\_text.htm](http://www.fda.gov/cder/consumerinfo/counterfeit_text.htm).

<sup>2</sup> Bagozzi D. Fact Sheet No. 275: *Counterfeit Medicines*. World Health Organization: Geneva, Switzerland, 14 November 2006; [www.who.int/mediacentre/factsheets/fs275](http://www.who.int/mediacentre/factsheets/fs275).

<sup>3</sup> Executive Summary: *The Economic Impact of Counterfeiting and Piracy*. Organization for Economic Development: Paris, France, 2007; [www.oecd.org/dataoecd/13/12/38707619.pdf](http://www.oecd.org/dataoecd/13/12/38707619.pdf).

<sup>4</sup> Bagozzi D. Facts Sheet 275: *Counterfeit Medicines*. World Health Organization: Geneva, Switzerland, 14 November 2006; [www.who.int/mediacentre/factsheets/fs275](http://www.who.int/mediacentre/factsheets/fs275).



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counterfeit drugs are estimated to comprise up to 10% of the total drugs on the market.<sup>5</sup> According to the U.S. Food and Drug Administration, the number of counterfeiting drug cases rose from 9 in 1997 to 58 cases in 2005. It is estimated that over 50% of drugs purchased over the internet are fake.<sup>6</sup>

The economic impact is not limited to the manufacturers' lost sales and profits. Innovation, through the development of new products, has long been recognized as a driver of economic growth. Without confidence that the resources invested in innovation can be adequately protected, investors may be less likely to fund research supporting innovation and the development of new products. This chilling effect is particularly pronounced in the pharmaceutical sector because of the substantial differential between the high cost of research and development and the low cost associated with producing the counterfeited product.

### **Government Initiatives and Private Redress**

A number of international government initiatives have been established to combat the growing problem of counterfeits. The World Health Organization (WHO) and the U.S. Food and Drug Administration have specific programs to make it more difficult to manufacture and distribute counterfeit pharmaceuticals.<sup>7</sup> Criminal actions by governmental entities also help impede counterfeiting and can provide a powerful deterrent. For example, on August 31, 2007, Johnson & Johnson, Inc. announced that a Shanghai Court fined and sentenced Su Zhiyong, Chinese business man, to 3 ½ years in prison for selling approximately 1 million counterfeit OneTouch™ test strips. The counterfeit strips were found in 35 U.S. States, Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia and Turkey.<sup>8</sup>

Such governmental efforts reduce the public health threat of counterfeit drugs but will not provide economic redress to those whose products are being copied. Enforcement of privately held intellectual property rights can however, address economic harm while at the same time, remove the copies from the market.

Proactive procurement of intellectual property is the first step toward seeking private redress for economic harm. Patents, trademarks and copyrights, collectively referred to as intellectual property (IP), vary in scope, duration, geographical reach, as well as the investment of time and

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<sup>5</sup> Id.

<sup>6</sup> Id.

<sup>7</sup> Main Findings: *Moving Up The Value Chain – Staying Competitive in the Global Economy*. Organization for Economic Development: Paris, France, 2007; [www.oecd.org/dataoecd/13/12/38707619.pdf](http://www.oecd.org/dataoecd/13/12/38707619.pdf).

<sup>8</sup> Combating Counterfeit Drugs: A Report of the Food and Drug Administration, February 2004, available at <http://www.fda.gov/oc/initiatives/counterfeit/report-02-04.html>, last accessed on July 16, 2007.



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money required to obtain and enforce.<sup>9</sup> It is useful at the outset for businesses to assess which form of IP protection is appropriate for a product and anticipate how illicit copying of their products and/or packaging may occur. Important considerations in this initial assessment include the type of product, the nature of the likely copying, the geographical scope of intended distribution and the duration of the exclusivity period needed to protect against copiers.<sup>10</sup>

## Patents

A patent allows the patentee to exclude third parties from making, using, importing, selling, or offering for sale patented products or methods of manufacture or use for a finite period of time, typically no more than 20 years from the date of initial patent filing. Patent protection must be obtained on a country-by-country basis. It is used to prevent others, for that geographical area and without the consent of the patent holder, from manufacturing and/or selling exact and close copies of the patented technology.

Pharmaceutical patents are usually considered the first line of defense in protecting intellectual capital because patents can prevent others from manufacturing, using, selling and/or importing products that have the same or equivalent active ingredient or formulation. However, as compared to other intellectual property, patent rights are expensive to enforce and a final, enforceable judgment may only be obtained years after a lawsuit is filed. Patent holders must prove in civil litigation that the alleged copier is making or selling a product that is described in the patent. This requires a detailed review of the patent document and correspondence between the patent applicant and the patent office. Frequently, technical experts are retained to opine on technical terminology and the meaning of phrases or terms during this phase of the lawsuit. Only after this initial review is the alleged infringing technology compared to the property right defined during the initial phase of the proceeding. Thus, the patent can only prevent others from manufacturing, using, selling or importing products that are exact or close copies of the patented technology. Rarely, however, are counterfeit medicines close copies of the original. For example, counterfeit medicines often do not contain the same, or perhaps the same amount of the genuine, patented formulation. Therefore, a patent will not prevent the making or selling of a look-alike counterfeit drug that does not contain the same or similar active compound or formulation.

In addition, a patent is granted to an “innovator” and therefore manufacturers of generic drugs, frequently manufactured after drugs have gone off-patent, cannot use patents to prevent distribution of counterfeited generics.

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<sup>9</sup> Under appropriate circumstances, misappropriation of trade secrets can provide economic redress. For a general discussion of trade secret protection, and its comparison to other forms of intellectual property, see Medd and Konski, *Workplace Programs to Protect Trade Secrets*, *Nature Biotechnology* (2003) Vol. 21:201-203.

<sup>10</sup> *Id.*



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## Copyrights

Copyrights prevent others from copying and claiming authorship of original works. Copyright protection is granted to original works of authorship that have been fixed in a tangible form of expression. Works of authorship include literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. Titles, names, and short phrases are generally not copyrightable. Ownership of a copyright is secured from the time of creation and the work need not ever be published. Similar to patent protection, copyright protection is available on a country-by-country basis and requires a registration process to enforce the right against third parties. In terms of the use of copyrights to secure protection from counterfeiters, copyrights on package inserts may be useful but is of limited effectiveness in preventing the counterfeit from reaching the public or providing redress for economic harm.

## Trademarks

Because trademarks seek to prevent exactly what counterfeiters seek to obtain, i.e. the economic benefit and investment in product integrity of the manufacturer, a strong trademark is the most valuable type of intellectual property that can be used to combat counterfeiting. Similar to patents, trademarks are enforceable on a country-by-country basis, and therefore trademark protection must be obtained in each country where the product is made or distributed.<sup>11</sup> However, in contrast to patents, trademarks are not limited to a finite period of time but can extend as long as the trademark is used in commerce in connection with the product.

Trademarks are used to identify the source of goods or services. Words, names, numbers, symbols, devices, designs, sounds, and colors that function as brands to distinguish the source of goods and their packaging may be registered as trademarks. The colors of pills as well as their shape may be trademarked. In contrast to patents, a trademark cannot be obtained on the process of making the product or medicine and does not protect the innovation of the underlying product. However, trademarks are available to generic manufacturers who identify their products with a unique logo or other identifying mark or property.

Misappropriated trademarks mislead consumers by copying the unique name, logo, product packaging, shape and/or color used by the manufacturer on the genuine product or packaging, thus confusing consumers as to the actual source, and quality, of the product. Therefore, all unique aspects of the product and packaging should be considered as worthy of trademark protection and the company's trademark should be applied as frequently as possible, e.g., on the pill itself, on both inner and outer packaging, etc. All modifications of the label, such as the product logo or other unique identifying descriptive marks should be protected in the language of the country where the product is to be sold.

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<sup>11</sup> Unlike patents, some countries recognize a trademark right without a formal application and review process, although other procedural requirements typically must be met in such cases as demonstrating proof of sale of the product within the relevant jurisdiction.



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As compared to patents, obtaining and enforcing trademark rights are typically less costly, and a final enforceable judgment is usually obtained faster than in a patent infringement action. Indeed, evaluation of whether a trademark is likely to be infringed can be limited to a visual inspection rather than a complicated analysis of the patented technology. Most significantly, however, in many countries trademark owners can have the counterfeit goods and accompanying documents, and even sometimes manufacturing equipment immediately seized at the outset of the lawsuit. Such powerful preliminary remedies are generally not available in patent lawsuits and can lead to swift resolution of the action.

### **Conclusion**

The rise of counterfeit medicines is a threat to public health and the economic investment made by innovators and generic manufacturers in the pharmaceutical industry. All manufactures of medicines can limit their economic harm by proactively assessing their product and available intellectual property options and anticipating counterfeit designs and products. After this initial assessment, appropriate intellectual property protection can be pursued in the relevant markets and countries. Although patents and to a lesser extent copyrights can be useful in combating counterfeiting and addressing economic harm, a strong trademark is the strongest intellectual property tool for combating counterfeiting.