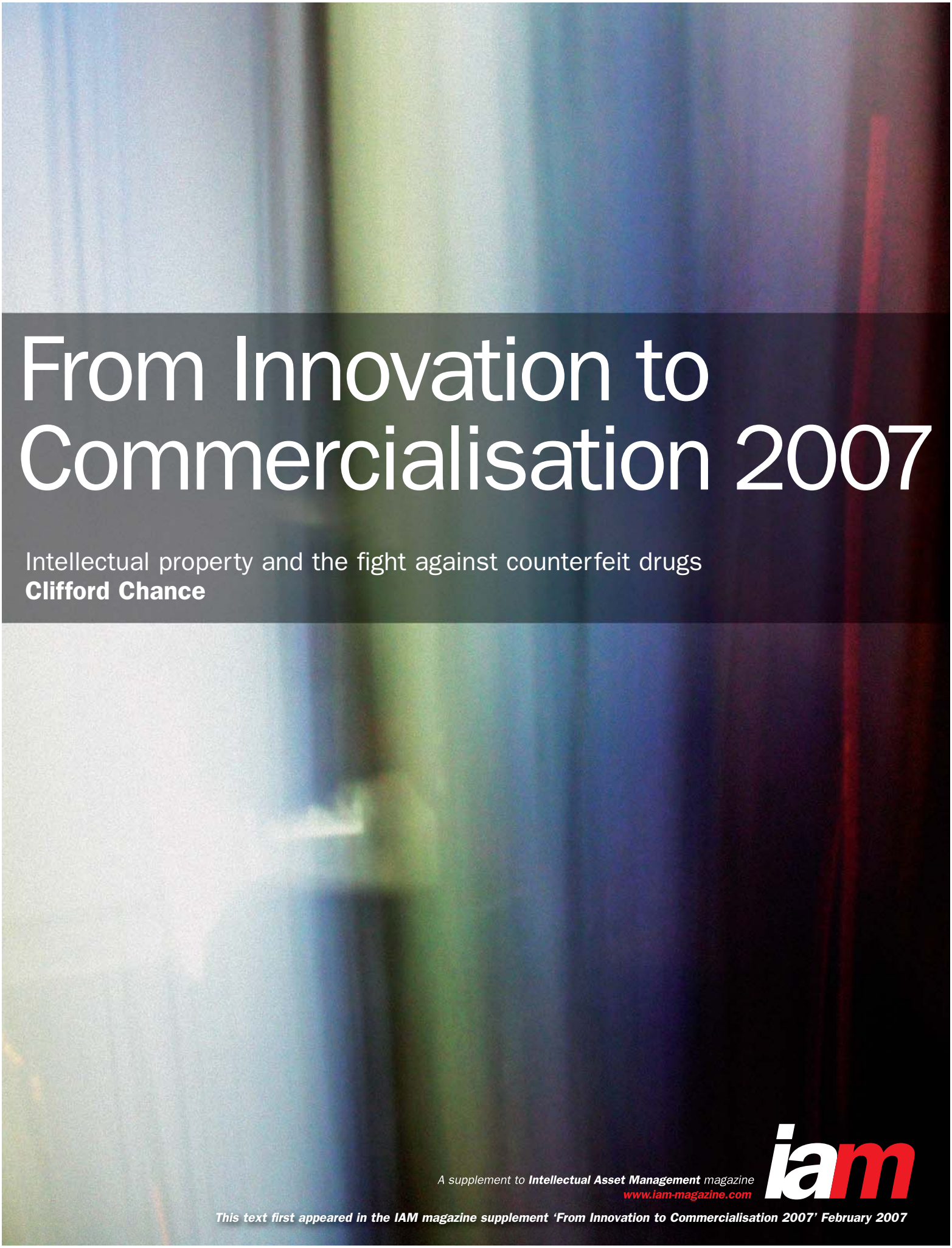

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Intellectual property and the fight against counterfeit drugs

Clifford Chance

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Intellectual property and the fight against counterfeit drugs

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Counterfeit drugs, and the criminal businesses of making, distributing and selling them, are a global scourge. Recent World Health Organisation (WHO) estimates suggest that while in some developing countries more than 30% of medicines are counterfeit, in developed countries with effective regulatory mechanisms and market controls counterfeits account for less than 1% of the market value. Like other pirated and counterfeit goods, the prevalence of fake medicines is increasing globally and is projected to become a US$75 billion industry globally by 2010.

Strong intellectual property rights and enforcement mechanisms are crucial in the fight against fake drugs. This article discusses economic and social issues affiliated with counterfeit pharmaceuticals and outlines IP-based solutions for fighting fake medicines in select jurisdictions around the world.

Counterfeit drugs

Counterfeit drugs are "deliberately and fraudulently mislabelled with respect to identity and/or source", according to the WHO. They include products with the wrong ingredients, no active ingredients, insufficient active ingredients, or with the correct ingredients in fake packaging, any or all of which may also contain contaminants of varying toxicity. Counterfeit medicines otherwise appear to be the same as the drugs they mimic, with generally indistinguishable packaging, pill colour, size, shape and other identifying characteristics. For the purposes of this article, we differentiate counterfeit or fake drugs from authentic or genuine drugs by these criteria, as there is no universally accepted definition.

Fake drugs endanger the health and lives of those patients who take them by poisoning them with incorrect or contaminating ingredients, and by failing to treat serious conditions because they are less effective than the genuine products. Counterfeits are by nature of unknown safety and efficacy, and are reported to be directly responsible for killing many people around the world each year.

The public's confidence in authentic pharmaceuticals can be undermined by counterfeits, damaging trust in health professionals and healthcare systems generally. As the reputation of the pharmaceutical industry suffers, fake drugs have the potential to further reduce revenues. Moreover, as a form of IP theft, counterfeit drugs deprive genuine manufacturers from legitimate compensation for their inventions and brands, further endangering incentives for investment in future R&D and innovation.

National agencies, together with customs agents and public prosecutors, shoulder the primary responsibility for prevention and control of counterfeiting. Private companies lack the power to intervene directly and are not held responsible for the harms caused by counterfeit medicines. That has not precluded individual companies, however, from joining in the campaign to combat fake drugs. One way they contribute is through obtaining and enforcing IP rights.

IP rights

The pharmaceutical industry relies on IP rights to aid in the recovery of the substantial investments necessary to create and market new drugs. In addition to other measures, strategic acquisition and enforcement of IP rights can assist companies in their efforts to protect themselves and their consumers from unscrupulous counterfeiting criminals.

In terms of counterfeiting prevention and enforcement, trademark and patent rights provide the most relevant IP protection. Trademark law protects against the unauthorised use of a product's name or appearance in a manner which is confusingly similar to that used by the legitimate owner. Counterfeiting occurs when the fake product appears to be made by the authentic manufacturer, even upon close inspection. Trademark owners can sue anyone who makes, sells or distributes counterfeit medicines for infringement of their marks.

Patent law, on the other hand, protects against the unauthorised manufacture, use or sale of an authentic medicinal product or process. If the counterfeit drug actually contains the active ingredient or otherwise infringes related methods claims, the patent holder can enforce its rights against infringers. Patent rights, however, may not help in combating fake drugs with no active ingredient.

In many countries, IP violations may also be the subject of criminal prosecution, resulting in fines and/or imprisonment, while other criminal laws may be used to punish related activities. IP rights also commonly intersect with customs laws, providing another means for interrupting the flow of counterfeit drugs, given the global nature of their manufacturing and distribution channels.

United States

IP rights are strongly protected and enforceable in the United States. Drug companies can combat counterfeiters by enforcing their IP rights in several ways. First, they may seek to protect their registered and/or common law trademark rights in federal district courts or in state courts. In the case of federally registered marks, authentic manufacturers may also obtain pre-litigation injunctive relief, including in "*ex parte*" proceedings brought by the rights holder without notice to (and in the absence of) the infringer to prevent concealment or destruction of evidence. Companies may similarly enforce their patent rights against counterfeiters in the federal district courts, and may seek temporary restraining orders and seizure orders from the courts, in addition to other pre and post-litigation injunctive relief and damages.

Recourse to the regular courts does not always, however, provide sufficient ability to stop fake drugs, especially when it may take several years to resolve an infringement action. Further, medicines purchased from Internet "pharmacies" that conceal their actual physical address are estimated to be counterfeit in over 50% of cases, according to recent WHO estimates. Obtaining evidence where sales are conducted over the Internet can prove especially difficult, particularly where such evidence is located overseas, raising additional legal questions of extraterritorial application of substantive and procedural laws.

Where fake drugs are imported into the US from other countries, trademark and patent rights can be enforced to block counterfeits from entering the country. Companies may record their registered trademarks with the US Customs and Border Protection in order to target, intercept, detain, seize and forfeit shipments of counterfeit goods. They can also enforce their patent rights in so-called "Section 337" actions before the US International Trade Commission (ITC). The ITC has the authority to conduct investigations in response to claims that counterfeiters are importing fake drugs into the US, and to grant exclusion orders to stop infringing imports from entering the US.

In addition to IP-based solutions, drug companies can safeguard their products through technical anti-counterfeiting measures such as RFID track-and-trace authentication and other regulatory measures. Effective and secure supply and distribution relationships can also further prevent fake drugs from entering the supply chain by reducing opportunities for counterfeits to enter distribution channels at each point of exchange. Private companies may also work with the multitude of state and federal government agencies (including those involved in the Strategy Targeting Organized Piracy "STOP!" initiative) that collaborate in a multi-layered system to assist in the arrest and conviction of counterfeiters.

Europe

In the European Union, seizures of counterfeit products have increased tenfold since 1998. Many seizures have intercepted fake drugs destined for the world's poorest countries (commonly "essential drugs" such as antibiotics), while other seized drugs are intended to remain in the European Union (typically "lifestyle" drugs such as weight-loss tablets and impotence therapies).

Contributing to the problem, the European Treaty specifically provides for "parallel trade", a lawful trade activity allowing drugs produced in one EU Member State to be imported by an intermediary into another EU Member State without the

authorisation of the original IP owner. While pricing differentials create the incentives driving these importing activities by intermediaries, legal repackaging and re-labelling in the context of parallel trade present an entry point to distribution channels for counterfeits.

In contrast to the rest of Europe, IP rights suffer from a lack of consistent protection and enforcement in Eastern Europe, the gateway to the key centres for production of counterfeit drugs of Russia and Asia. IP enforcement takes on added significance in new Eastern European Member States with borders susceptible to counterfeiters; having entered the common market at a vulnerable point, fake drugs can easily evade detection and removal efforts.

Pharmaceutical companies can enforce their patent rights in the EU Member States in order to combat counterfeits. Preliminary injunctions may be obtained from national courts in clear cases. Likewise, trademark law provides robust opportunities to counter fake drugs, given that compared to patent law, trademark law in the EU is largely harmonised. Importantly, expedited relief in the form of injunctions and other remedies is comparatively easy and inexpensive to obtain. By coordinating legal actions across the Member States, companies can achieve the best results.

Piracy Regulation (EC) 1383/2003, which embodies EU border protection laws, furthers anti-counterfeiting measures available within the enlarged European Community and has led to improved enforcement of IP rights. The regulation improves communications between rights holders and customs (in conjunction with the recently amended Customs Code Regulation (EC) 648/2005). It also extends the scope of "*ex officio*" procedures to the benefit of genuine drug manufacturers.

Directive (EC) 48/2004 on the enforcement of IP rights is intended to harmonise the standards of IP enforcement between the Member States. Significantly, the level of protection afforded IP rights holders has been strengthened in national legislation across the Union. For example, laws now provide for improved access to searches and seizures, as well as to recall and destruction remedies.

In addition to private IP rights enforcement measures, additional tools include the anti-counterfeiting technologies and secure supply relationship options described above. Regulatory frameworks provide further opportunities for private action. For example, unfair competition laws such as the German Medicines Advertising Act (*Heilmittelwerbegesetz*) provide other avenues for legal relief.

Close coordination and cooperation between private and public entities is necessary to effectively combat this growing plague. This is particularly true in the EU, where the potential for fake medicines is heightened by weaker borders, parallel trade and increasing Internet sales. At the same time, the number and diversity of enforcement partners are compounded significantly. Companies can improve their outcomes by also coordinating with other partners and international agencies to disrupt production and distribution of fake drugs.

China

Counterfeit drug businesses comprise manufacturing, wholesale, retail and export in China. Many popular drugs are susceptible to counterfeiting in China, whether they are produced internationally or locally, or for domestic or international markets. Drug counterfeiting problems are most prominent in the East Guangdong, Hebei, Henan, Anhui, Jiangxi, Sichuan and Shanxi provinces.

After joining the World Trade Organisation, China reformed its major IP laws on patents, trademarks and copyrights in early 2000. These reforms have brought the standard of Chinese black-letter law on IP rights further into line with international standards. For example, new rules now allow IP owners to obtain pre-litigation injunctive relief (similar to interlocutory injunctions in common law jurisdictions), which was previously unavailable. Pharmaceutical companies are increasingly using these improved legal remedies in Chinese courts to enforce their IP rights.

Drug companies most commonly combat counterfeit problems by enforcing their trademark rights under the PRC Trade Mark Law or PRC Unfair Competition Law. In obvious cases, many select an administrative mechanism to enforce their rights, a unique feature of IP rights enforcement in China. The government body responsible for handling the administrative complaints of trademark owners is the Administration for Industry and Commerce (AIC). It has the power to investigate administrative complaints, conduct raid actions and seize the counterfeit drugs, impose a fine on the infringer and request the infringer to cease the infringing activities. The administrative route is popular because the complaint can be dealt with relatively

quickly without going through lengthy and complicated proceedings. However, for the same reason, the AIC is reluctant to accept complaints that might involve more complicated facts.

In more complex cases, trademark owners can seek relief before the local intermediate people's court. While a court action takes longer to resolve, pharmaceutical companies can apply for pre-litigation injunctive relief under the new IP legislation to stop or minimise any irreparable harm that might occur during the interim period.

To prevent fake drugs being imported into and exported out of the country, Chinese Customs has the authority to seize counterfeit drugs and the power to investigate and dispose of fake drugs under certain circumstances. A trademark owner can make use of Customs' authority either by recording its rights in advance with Customs or by filing a request on an *ad hoc* basis when it receives intelligence of potentially infringing activities.

Besides utilising the above channels to combat drug counterfeiting problems, pharmaceutical companies can also enlist other government and administrative bodies to assist by providing leads to (or filing complaints with) the Public Security Bureau (the police), the State Food and Drug Administration and the Bureau of Quality and Technical Supervision. These bodies are responsible for investigating and prosecuting infringers for violation of the PRC Criminal Code, the PRC Drug Administration Law and the PRC Product Liability Law respectively. Penalties for violating these laws vary from imposition of fines to imprisonment.

Looking forward

As illegitimate organisations grow in sophistication, threats to the security of the world's pharmaceutical marketplaces increase. Among the methods available to drug companies, the protection and enforcement of IP rights provide useful tools to fight counterfeit drugs. Strategic application of these tools can help to block counterfeits when and where most effective.

Still, the world needs tougher laws globally to combat fake medicine: both tougher penalties for counterfeiting and better enforcement of IP rights. To gain the upper hand against counterfeiters, pharmaceutical companies, public prosecutors and other industry stakeholders need to coordinate their efforts on several fronts, including the enforcement of IP rights across multiple jurisdictions.

The harms inflicted by counterfeit drugs not only negatively impact on individual patients and pharmaceutical companies, but can also erode public trust in general. The tools available to industry stakeholders, including enforcement of IP rights throughout the world, will aid in the fight against fake drugs.

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