

GLOBAL ATTACK

Cross-border co-operation and addressing counterfeit medicines and pharmaceuticals in Latin America, Asia and worldwide: we poll a global panel of experts at Baker & McKenzie for a front-line picture of the war against counterfeiting.

The level of threat directly affecting IP and brands that needs to be taken seriously by in-house counsel and brand managers at pharmaceutical and biotechnology companies is immense, as the experts' answers to these fundamental questions reveal.

How will improved cross-border co-operation on counterfeiting prevention help alleviate the problems of counterfeit medicines and pharmaceuticals?

Richard Gough and Elisabeth Coffey—Sydney

Online pharmacies are a growing problem in the cross-border trade in counterfeit medicines, particularly for a country such as Australia, where medicines are subsidised and large shipments are rare. Effective border control by customs authorities and the global co-ordinating role taken by the World Customs Organization are critically important in addressing the problem, but in reality, enforcement authorities,

legal regimes and pharmaceutical companies around the world are playing catch-up, and have only recently begun to grapple seriously with the issues. For example, the threshold question of jurisdiction over online trade has not been sorted out in many countries, being commonly determined by factors such as the location or domicile of the host and the countries targeted for website sales and delivery. This can make enforcement rather slow and clumsy, while online traders pick their jurisdictions and exploit the gaps in regulatory and enforcement regimes. For pharmaceutical companies taking a strategic approach, this is difficult and new territory, requiring multi-jurisdictional investigations and legal action. It involves a different mindset, with the emphasis on mapping what is happening across borders, identifying the hottest links, and leveraging results and information in real time as it comes in from actions and customs seizures. The level of co-ordination, organisation and response across borders between the separate elements—legislation, enforcement agencies,

pharmaceutical companies—will have to improve markedly before there is any significant progress.

Paul Rawlinson—London

There is increasing alarm at the extent of trade in counterfeit medicines destined for, or at least in transit through, major EU countries. Even more worryingly, this trade can and does infiltrate authorised channels of distribution. The EU has, in part, harmonised its measures to combat this through the Counterfeit Goods Regulations, allowing customs recordations to be filed throughout the EU and, further, by way of harmonisation of legal remedies through the EU Enforcement Directive, although more needs to be done, on the ground, to make this cross-border co-operation really effective. Also, recent European Court of Justice (ECJ) decisions (such as *Class International*, which held that goods merely transiting through an EU country are not liable to be enjoined on the grounds of trademark infringement) militate against a zero tolerance policy trend and are sending a message that the EU is a safe harbour for trans-shipment of counterfeit goods. This cannot be what was intended, and there needs to be a more rigorous review of EU policy in this respect.

Is the ability to prosecute for counterfeiting adequate?

Kevin O'Brien—Washington DC

Not as a matter of priority. In the United States, federal prosecutions are handled primarily by the US Attorney's offices located throughout the country. Due to limited resources, the US Attorney's offices are often interested in large and important targets at or near the top of the criminal enterprise. Counterfeiting investigations by their nature, however, often must begin with street-level violators, and substantial time and resources are required for a brand owner to proceed up the supply chain to identify larger, more lucrative targets. It is often the case that federal prosecutors have neither the budget nor the manpower to assume the prosecution of the lower ranks, thereby limiting action against the more important defendants.

Esther Flesch—Sao Paulo

The Brazilian government has recently taken effective action to deal with pharmaceutical-related counterfeiting, including by increasing penalties, which range from R2,000 to R1.5 million (\$1,200 to \$920,000). Brazilian IP laws now comply with modern international treaties, and the available remedies have reduced piracy levels. Counterfeit product is subject to police, customs and sanitation authority control, triggered without the involvement of IP rights owners. Most counterfeit drugs in the Brazilian market come from Asia, usually entering through Paraguay and Uruguay. Recent joint



actions of the Brazilian National Agency for Sanitary Surveillance (Anvisa) and the federal police seized nearly two tons of counterfeit drugs used in the treatment of erectile dysfunctions. In 2007, Anvisa and the Brazilian federal police carried out Operation Placebo in 60 different locations where there was counterfeiting activity. According to the Brazilian Intellectual Property Protection Association, there is on average one arrest for counterfeiting every three days, and five indictments are filed daily. The picture is far from perfect, though, with the length of legal proceedings being an impediment to prosecution for counterfeiting. Even in a clear case, it takes much too long for offenders to be convicted and for IP owners to recover damages, and in the meantime, the IP owner has to cover the costs of the proceedings.

To what extent is there a growing awareness of IP protection among Asian-based pharmaceutical companies and a willingness to follow the international rules of business conduct? In particular, are there any initiatives that would help prevent counterfeiting in this region?

Joe Simone—Hong Kong

The counterfeiting of pharmaceuticals in China has grown in scope and scale over the last decade, with a widening range of drugs being exported and sold domestically. The Internet has facilitated the globalisation of pharmaceutical counterfeiting, making it easier for buyers and sellers to find each other. China is a major source of finished product and of bulk chemicals used to manufacture counterfeits in other countries. The central government has introduced a range of new measures in response to the fact that both Chinese drug companies and consumers are victims, with the level of fakes in the market sometimes rising as high as 30 percent, and to the recent international attention generated by reports of defective pharmaceutical exports. These include heightened inspection of pharmaceutical enterprises (which has led to the closure of hundreds of substandard factories); more resources for enforcement against larger counterfeiting rings, including those with international distribution; greater focus on syndicates that promote sales globally through

the use of the Internet; and consolidation of the ministries that handle pharmaceuticals inspections and approvals. Despite these measures, the scale of pharmaceutical counterfeiting appears to be increasing, and pharmaceutical companies are encouraging the implementation of a wider range of initiatives. These include:

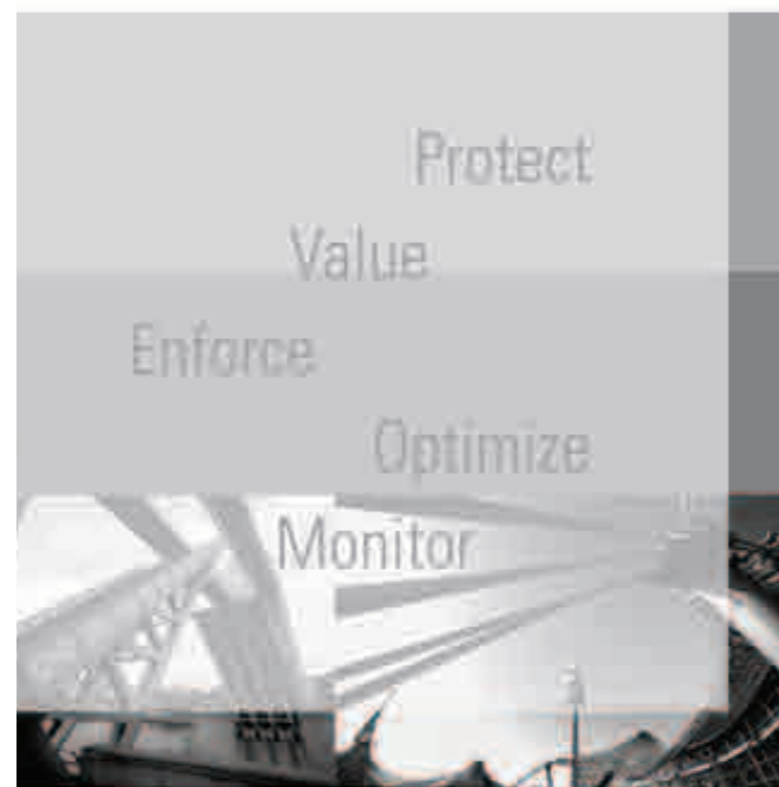
- establishing more specialised local police and prosecutor IP enforcement teams, at least in hot spots such as Chaoyang/Shantou, Guangzhou and Shenzhen
- increased manpower and resources for police for deeper investigations of counterfeiting rings
- increased co-operation between Chinese and foreign customs and police, including by ensuring that intelligence is communicated more quickly
- amending the PRC Criminal Code to eliminate the current thresholds for criminal prosecution (the lowest currently being RMB50,000 or \$7,000);
- giving administrative enforcement authorities greater powers and training to investigate cases more deeply and to facilitate more effective co-operation with Chinese police and prosecutors
- introducing more effective administrative controls on producers of chemicals that are commonly used for pharmaceuticals, and on hospitals and pharmacies to minimise the risks of purchase and distribution of counterfeit drugs, and
- introducing stringent controls on China-based websites that offer any type of pharmaceutical (finished or otherwise) without regulatory approval.

Pharmaceutical companies must play their part in the reform process through increased co-operation over lobbying and by pooling intelligence on individual targets. Companies are encouraged in particular to work with INTERPOL by supplying data on known and suspected counterfeiters under its new data collection pilot programme. There are increasing reports of counterfeiting of Asian-based pharmaceutical brands, most recently of anti-malarial preparations widely distributed in Cambodia. Global pharmaceutical companies



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2, place d'Estienne d'Orves
75441 Paris cedex 09 - France
Tel: 33 (0)1 53 20 14 20 - Fax: 33 (0)1 53 20 14 91
Email: paris@lavoix.eu

COUNTERFEITING INVESTIGATIONS BY THEIR NATURE, HOWEVER, OFTEN MUST BEGIN WITH STREET LEVEL VIOLATORS, AND SUBSTANTIAL TIME AND RESOURCES ARE REQUIRED FOR A BRAND OWNER TO PROCEED UP THE SUPPLY CHAIN TO IDENTIFY LARGER, MORE LUCRATIVE TARGETS.

should identify and work with the bigger victims of counterfeiting among their Asian counterparts by pooling data and pursuing joint lobbying initiatives.

To what extent are contentious issues concerning pharmaceutical IP in Latin America being addressed, and what do you consider to have the greatest potential impact on counterfeiting in this sector in the region?

Esther Flesch—Sao Paulo

Since Brazil has participated in the World Trade Organization, pharmaceutical IP rights have been controversial, being highlighted in the national news and legal debates. The Brazilian government tends to be aligned with international trends regarding IP protection, adopting international rules, but there has been considerable debate about compulsory licences of patented pharmaceuticals. This mainly affects anti-viral drugs, and especially those used in the treatment of HIV, with pharmaceutical companies announcing losses of R\$1 billionn (\$615 million) from compulsory licences. On the other hand, under the patent pipeline system, drugs protected by overseas patents may be protected in Brazil without thorough analysis by the Brazilian National Institute of Industrial Property. Pipeline patents can be used to attack counterfeit medicines, but given the current controversy, it is hard to predict the actual effect on the incidence of counterfeit drugs.

What improvements in supply chain management are most helpful in helping to avoid fakes? (Answers from a legal/contractual, and a physical marking and tracking perspective.)

Stephen Jones—London

Ideally, a manufacturer would be able to control every stage of the supply chain between the manufacture of the product and its delivery to the end user. Any breaks in the chain allow opportunities for entry of counterfeits. Parallel imports (grey goods) provide a route into the supply chain that can be exploited by counterfeiters, particularly where repackaging of the product is permitted to allow entry into a different market. To this end, the EC Commission's recent consultation on counterfeiting of medicines goes so far as to consider whether a ban on repackaging is needed. Given that counterfeit products have been found in the legitimate supply chain via wholesalers and pharmacies in the UK and elsewhere, tightening of controls is clearly needed. The use of sophisticated labelling and tracking devices can help, but not if the relevant materials can be removed during repackaging.

What brand protection considerations need to be made when licensing pharmaceutical manufacture to third parties?

Stephen Jones—London

Quality control is paramount in any licensing situation, to ensure that the quality of the product is consistent and retains the values associated with the brand. In a pharmaceutical manufacturing licence, it is a given that the manufacturing processes must be tightly controlled. But also necessary are controls over the packaging and distribution of the product, to ensure that the product does not become available outside the legitimate supply chain. The makers of fake products need supplies of genuine goods to legitimise their operations and sell alongside counterfeits, and even surplus or discarded packaging can be misappropriated and put to use by counterfeiters. Therefore, all involved in the manufacture and distribution of product need to be vigilant to avoid loopholes for the unscrupulous.

Do you believe that the industry is winning the war against counterfeiting? If there was one thing you could do to improve the situation, what would it be and why?

Kevin O'Brien—Washington DC

Statistics published by a wide variety of sources confirm that brand owners are not currently winning the war against counterfeiting. The estimated volume of counterfeits as a percentage of legitimate trade has not materially declined in recent years, despite the dramatic increase in overall global trade, and counterfeit medicines appear to be on the increase. Border agencies such as US Customs and Border Protection have not increased the volume of seizures to substantially reduce the overall levels. One

measure that could be taken to improve the situation would be to impose vicarious liability on supply chain participants for damage caused by counterfeiting. Supply chain participants profiting from counterfeit trade include air/rail/sea carriers, importers, customs brokers, freight consolidators, common carriers, port authorities and terminal operators. Under current law, recovery of damages from these middlemen is difficult or impossible.

Application of joint and several liability would incentivise these supply chain participants to police their businesses and ensure that they are not profiting from or facilitating the illegal actions of others.

Conclusion

Realistically, the battle for supremacy over counterfeiters will probably never be won. But more priority is clearly needed from governments for action to counterfeit medicines and pharmaceuticals. Measures now being taken in various jurisdictions are helping firms to navigate the hurdles in an industry constantly jeopardised by the fraudsters. The catch-up game must continue.

Richard Gough, Kevin O'Brien, Esther Flesch, Paul Rawlinson, Joe Simone and Stephen Jones are partners and Elisabeth Coffey is senior associate at Baker & McKenzie. The firm can be found at www.bakernet.com. Richard Gough can be contacted at: richard.gough@bakernet.com.



Richard Gough

Richard Gough heads the Australian firm's pharmaceuticals industry group. He has 20 years' experience handling IP litigation, dispute resolution and enforcement for market-leading companies. This has involved a wide range of industry sectors, including pharmaceuticals and medical devices. Richard edits the firm's *Asia Pacific Legal Developments Bulletin*, and is the author of the Australian chapters of *Trade Secrets Throughout the World* (Thomson West) and the forthcoming *Survey Evidence and the Law Worldwide* (Butterworth Lexis-Nexis). He was named as one of Australia's best lawyers in a recent survey published in the *Australian Financial Review*.

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