China

Contributing firm
Rouse

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Selection, clearance and registration

China follows the 'first to file' rule for the registration of trademarks and the options to protect unregistered marks are limited and far from effective. It is crucial for pharmaceutical companies to register the trademarks of the drugs that they produce and market in China, given the strict regulatory rules. Though compulsory registration of trademarks for drugs is no longer required by the Trademark Law and the Pharmaceutical Administration Law, such trademarks must be registered before they can be approved by the State Food and Drug Administration (SFDA). The Provisions on Administration of Drug Insert Sheets and Labels issued by the SFDA clearly state that it is prohibited to use unregistered marks in drug insert sheets and labels (Article 27).

Any visual sign that is capable of distinguishing the origin of goods can be registered as a trademark. This includes words, logos, letters, numerals, three-dimensional signs or combinations of colours. The draft Trademark Law Amendments further extend registration to single colours and sounds. Generic drug names are not registrable as trademarks. The naming of generic drugs takes into consideration the World Health Organisation's international non-proprietary names for pharmaceutical substances. Generic drug names are listed in the Pharmacopoeia and Drug Standards issued by the SFDA.

Pharmaceutical companies should prioritise the registration of marks in Chinese characters or Chinese transliteration (if the original language is not Chinese). Under the relevant SFDA rules, only Chinese characters are permitted to be used for drug names. Multinationals tend to register marks in their original language without simultaneously registering the Chinese transliteration, which may cause huge problems when launching the products in China.

Unregistered marks may be vulnerable to being declared generic, which puts their owners at risk of losing control over their brands. For example, in *Bayer v Xinan Pharmaceutical Co* (File 1, 2009, SPC *Xing Ti Zi*), which involved the Chinese name San Li Tong for Saridon, Bayer (formally F Hoffmann-La Roche AG) did not register the Chinese transliteration and the other party (the Chinese partner in the production of Saridon) registered the similar mark SAN LIE TONG. Bayer filed a cancellation action, but lost the case before the Supreme People's Court. One of the key defences accepted by the court was that the Chinese name San Li Tong had been listed as a generic drug name and so should not even be considered a trademark, since unregistered marks are not permitted for use in relation to drugs.

It is often a challenge for pharmaceutical companies to reconcile the parallel registration process of a trademark, which requires registration of the sign at the Trademark Office (TMO), with that of the product name with the SFDA. No cross-reference search is available between the two, although in practice the SFDA will

require a report on the availability of the trademark when filing an application for a drug name. Preliminary searches for proposed marks can be carried out on the TMO's official website (sbcx.saic.gov.cn/trade-e). Data searches are also available on the SFDA website for registered product names (eng.sfda.gov.cn/WS03/CL0755) – although these cover neither pending applications nor similarity searches. Given the considerable time needed to register a trademark (usually between 12 and 18 months), it is advisable to file alternative marks in case the proposed mark is rejected by the TMO or opposed by a third party, particularly if the deadline for the launch of the drug allows no time for a fresh application.

Registration of a trademark should cover the necessary classes and subclasses as part of a protective and defensive strategy. Goods in different subclasses (or groups) may be deemed dissimilar and therefore open to competitors to register in different subclasses. In *Jiu Zhi Tang Pharmaceutical v Changzhou Dazhong Co Ltd*, the defendant registered a mark similar to that of the plaintiff for disinfectors in Class 5, subclass 0501, group 6; the plaintiff filed a cancellation action based on its registration for drugs in Class 5, subclass 0501, group 1. The court dismissed the claim as the goods were found to be dissimilar.

Parallel imports and repackaging

The Trademark Law does not expressly provide for the legality of parallel imports – as opposed to the Patent Law, which makes it clear that it is not an infringement to import patented goods if they are sold by patentees (Article 69). The current prevailing opinion is that parallel imports do not infringe trademarks. The reported cases in which the plaintiffs have won infringement claims do not indicate that parallel imports are *per se* infringing. For example, imports of Unilever's LUX soaps were held to be infringing by the court, not on the grounds of illegality of parallel imports, but because the defendant failed to provide admissible evidence that the goods were genuine in the country of purchase; the goods were therefore deemed counterfeit. In another notable case, the court held that the import of Michelin tyres was infringing, based on the reasoning that the tyres, produced for the Thai market, failed to meet China's compulsory safety standards and could therefore harm consumers and damage the plaintiff's reputation.

An exclusive licensing agreement may be held insufficient to claim infringement. In *Beijing FAHUA YISHANG Trading Co Ltd v SHIJI HENGYUAN Company,* the plaintiff was granted an exclusive licence agreement from AN GE Shares Co Ltd, the French owner of the AN GE mark for garments. The defendant offered and sold AN GE garments imported from an authorised distributor in Hong Kong. The court held that an exclusive licence agreement did not prohibit the distribution of AN GE-branded garments by other operators. However, the presiding judge stated *obiter dicta* that if the imported goods were of a different quality from that of the domestic goods, or if there were misleading or false elements in the label or advertising, that may be actionable under unfair competition law.

Imports of drugs must be approved by the SFDA, which requires sample testing by the National Institute for Control of Pharmaceutical and Biological Products, expert evaluation and clinical trials. Repackaging of imported drugs must also be approved by the SFDA. The repackaging companies may file an application with the SFDA's provincial or municipal branches.

Anti-counterfeiting and enforcement

In China, there are three main avenues for anti-counterfeiting enforcement: criminal prosecution by the police (the Public Security Bureau), administrative action through the SFDA or other relevant government agencies, and civil litigation in the People's Court. Additionally, Customs plays an important role in detaining counterfeit drugs crossing the border. Each route has its strengths and weaknesses. Choosing which is appropriate depends on the nature and complexity of the case. The key is to have a strong enforcement strategy that takes advantage of all available options.

Pharmaceutical companies are increasingly instigating criminal prosecution cases as an enforcement option against serious counterfeiters because of these proceedings' greater effectiveness as a deterrent. One significant development is the removal of the criminal threshold for counterfeit drugs under the Criminal Law Amendments, effective as of May 1 2011. Under the old law, it had to be established that the counterfeit drug "may cause sufficient harm to human health". The amendments abolished this threshold, allowing criminal prosecution against any party that produces and/or sells counterfeit drugs. This amendment may encourage pharmaceutical companies to pursue more criminal actions against producers of counterfeit drugs.

In practice, problems with criminal prosecutions still exist in terms of lack of consistency and transparency. Close monitoring and lobbying may often be required for a prosecution to be successful, particularly if local protectionism is involved. Brand owners can use the opportunity to file a victim's statement to present the claim and push for maximum sentencing.

A successful raid action to detain counterfeit drugs and offenders is critical to criminal prosecution. The raid action can be carried out by the Public Security Bureau or jointly with the SFDA, and is usually followed up by verification of seized drugs by brand owners, sample testing by official test institutes and provision of pricing information of genuine goods. After a criminal investigation and the arrest of any suspects, the Public Security Bureau transfers the case to prosecutors, who then file a prosecution with the People's Court.

Administrative enforcement by the SFDA and other agencies can be used to tackle straightforward and minor infringements. Despite smaller fines that do not have much of a deterrent effect, the administrative system is in most cases regarded as the cheapest and quickest way of seizing counterfeit goods to prevent further distribution. An administrative raid can also be used as an evidence-gathering tool for civil action or a negotiated settlement.

As the courts in China become more experienced in handling IP infringement, civil litigation becomes an increasingly important means of enforcing IP rights. It is particularly useful if the case involves less straightforward infringement, or if the plaintiff pursues damages, as the administrative agencies will generally not handle a damages claim. Another advantage of civil action is the possibility of forum shopping – that is, the infringement case can be heard outside the infringer's home jurisdiction and thus local interference can be minimised if the infringing goods are found outside the infringer's home town. Civil relief includes an injunction order and a damages award based on the illegal profit of the infringer or the losses of the plaintiff, or statutory damages of Rmb500,000 (approximately $79,300). The draft Trademark Law Amendments have raised this to Rmb1 million (approximately $158,600).

Lastly, given that China remains one of the main sources of counterfeit drugs internationally, customs measures are a useful element in an enforcement strategy, as most seizures by Customs are proactive discoveries of illegally exported goods. Essentially, the customs seizure system

relies on the central recordal of trademarks with the General Administration of Customs, as well as follow-up training of customs personnel and contact with key local ports. The 'white list' (or Chinese licence information) must be updated on the customs online database to facilitate inspections and avoid delaying exports of authorised goods. A prompt verification system is necessary, as seizures must be followed up within three days with a formal verification that the goods are counterfeit and payment of a bond. General bond arrangements with Customs are helpful, to avoid having to make separate payments for each seizure.

Advertising

All drug advertising must first be approved by the SFDA's provincial or municipal branches and recorded with the SFDA and the local Administration for Industry and Commerce. Approved advertising is given an approval number that is valid for one year.

Prescription drugs may be advertised only in professional medical or pharmaceutical publications designated by the SFDA and Ministry of Health, which jointly announce the list of such publications from time to time. This list comprises around 550 designated publications and is accessible on the SFDA website. The advertising of certain drugs such as narcotic drugs, psychotropic substances, medicinal toxic drugs and radioactive drugs is prohibited.

The content of drug advertising must be based on the drug insert sheets as approved by the SFDA. Any change to this content requires fresh approval by the SFDA. Generic drug names must be indicated as such in drug advertising. For drug advertising to promote relevant trademarks, the generic drug names must be used simultaneously. Moreover, the size of the space for the trademarks should not be more than one-quarter of that for the generic names. Unregistered marks are prohibited from being advertised.

Generic substitution

Domestic pharmaceutical companies in China overwhelmingly produce generic drugs. It is estimated that 95% of drugs produced by domestic drug companies are generic drugs.

Generic drugs can be produced when the validity term of patented drugs has expired. Under the Administrative Measures of Drug Registration issued by the SFDA, applicants other than the patentee may file an application for production two years prior to the expiry date of the patent and the SFDA may issue the approval number after the patent expiry date. However, it is possible to produce patented drugs prior to the expiry of a patent if a compulsory licence is granted. Although, in practice, no compulsory licence has been granted so far, patent law makes it possible to do so in cases of national emergency or if it is in the public interest to do so.

The approval process for the production of generic drugs involves site inspections by the SFDA's provincial or municipal branches, sample testing of three batches of the drug and examination at an SFDA drug evaluation centre. Generic biological products must undergo the approval process for new drugs rather than the usual approval for generic drugs.

Online issues

Online trading of drugs is subject to strict examination and approval by the SFDA. Business-to-business service platforms must be approved by the SFDA, while online trading by pharmaceutical manufacturers and distributors of their own drugs must be approved by the SFDA's provincial or municipal branches. Business-to-consumer sales of drugs are permitted only for over-the-counter drugs. Approved companies are searchable on the SFDA website, which indicates that about 95 approvals have been granted.

The Online Information Service for Drugs also requires approval by the SFDA's provincial or municipal branches, whether free of charge or not. Upon approval, the SFDA issues an internet drug information service certificate, which can also be searched on the SFDA website.

Domain name registration of relevant trademarks and corporate names is advisable, to promote the products and prevent cybersquatters from registering the same mark, including under the '.cn' and '.com.cn' domains, or the domain name in Chinese characters. Additionally, Chinese internet keywords may also be considered for registration, which is useful for directing internet user searches to a predesignated website when keywords are entered in the internet search bar.

Recovery proceedings for domain names can be conducted through either administrative complaint or court litigation. The former is quicker and cheaper. However, the administrative option is available only within two years of the date of registration of the domain name. After that, brand owners may file civil litigation with a Chinese court. WTR

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August Zhang qualified as a lawyer in 1989. He has extensive experience of IP litigation and enforcement, especially in the areas of trademark, copyright and unfair competition, and is frequently ranked among China's leading IP lawyers. His expertise lies in complex civil litigation and criminal enforcement in various industries in China, with a particular specialism in the pharmaceutical industry.

After obtaining his first law degree from a leading law school in China, Mr Zhang was awarded the Chevening Scholarship and in 1994 received an LLM degree from Essex University, England. He was a visiting scholar at the London School of Economics in 1995 and has been an honorary law professor at China Southwest University of Finance and Economics since 2003. He regularly publishes and is interviewed on China IP issues by international and domestic publications.