China

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Selection, clearance and registration

Regulatory bodies

The following government bodies are in charge of the registration and use of pharmaceutical trademarks and/or products:

- The Trademark Office and the Trademark Review and Adjudication Board (TRAB) are responsible for pharmaceutical trademark registrations;
- The State Food and Drug Administration (SFDA) controls the quality of drugs and medical devices;
- An SFDA special committee is responsible for the establishment of a national standard for pharmaceutical products; and
- The State Administration of Traditional Chinese Medicine (SATCM) is in charge of the quality management of traditional Chinese medicine.

The Trademark Office and the TRAB are two parallel departments administratively controlled by the State Administration of Industry and Commerce (SAIC), while the SFDA and the SATCM are managed by the Ministry of Health.

This article will not discuss the issues relevant only to traditional Chinese medicine.

Requirements

Neither the Trademark Law nor its Implementing Regulations require compulsory registration for pharmaceutical trademarks. Instead, Article 6 of the Trademark Law and Rule 29 of the Implementing Regulations provide that other national laws, regulations and/or administrative requirements set up by the relevant administrative authorities may determine which trademarks should be registered before being used on products. Further, Article 27 of the Rules for Management of Labels and Directions of Use for Pharmaceuticals published by the SFDA stipulates that neither unregistered marks nor pharmaceutical product names refused by the SFDA can be used on pharmaceutical directions of use or labels.

Pharmaceutical trademarks must meet the same requirements as other trademarks, as set forth in, among others, Articles 10, 11 and 31 of the Trademark Law. The state, rather than provinces or cities, sets the standards for pharmaceuticals. These standards consist of the "Pharmacopoeia of the People's Republic of China" and the pharmaceutical standards promulgated by the SFDA. Pharmaceutical names listed in the state pharmaceutical standards and international non-proprietary names (INNs) are the generic names of the pharmaceuticals. Generic names may not be used as trademarks for pharmaceuticals.

The Rules for Management of Labels and Direction of Use for Pharmaceuticals set out how a registered mark should be used on a pharmaceutical label. The trademark should be placed in the corner of, or alongside, the label. If the trademark includes word elements, each word should cover no more than one-fourth of the space used for the generic name of the pharmaceutical.

Non-traditional trademarks
The Trademark Law protects any visual sign capable of distinguishing the source of the goods or services. Any word, design, numeral, three-dimensional symbol and combination of colours can be registered as a trademark if it is distinctive enough. Sounds, smells and tastes cannot be registered as trademarks.

Combinations of colours and three-dimensional symbols have been protectable in China since 2001. As these types of mark are relatively new, they are subject to special requirements to determine their distinctive character. Thus, colours are registrable only in combination, not as single colours, and three-dimensional marks are assessed by a panel rather than a single examiner.

Parallel imports and repackaging

Key issues
There is no law or regulation in China specifically governing parallel imports, in particular in relation to pharmaceutical trademarks. However, China's attitude toward the parallel import of pharmaceutical products is normally one of tolerance, as shown in Rule 8 of the Compulsory Licence of Patents Relating to Public Health Issues, published by the State Intellectual Property Office and in effect since January 1 2006. The rule provides that any party buying outside of China pharmaceuticals patented in China to cure infectious disease may import such products into China without requesting a licence from the State Intellectual Property Office, as long as the products were bought from the patentee or its licensee.

Enforcement
In the absence of specific laws governing the issue, individual courts may take different approaches, resulting in contrasting decisions as illustrated in the following two cases.

In June 1999 Unilever Shanghai sued Guangzhou Import and Export Trading Co (GIET) before the Guangzhou Intermediate Court, alleging infringement of its LUX mark. The LUX mark is owned in China by Unilever Netherlands. In 1998 it granted Unilever Shanghai the exclusive licence to use the mark in China.

Unilever Shanghai claimed that without authorization GIET had imported and sold in China soaps made in Thailand bearing the LUX mark. The LUX soaps imported and sold by GIET in China were genuine products, authorized for manufacture and sale in Thailand. However, the court ruled that Unilever Shanghai is the exclusive licensee authorized to use the LUX trademark in China and GIET's importation of LUX products into China amounted to trademark infringement.

Nevertheless, in *Fahuayilin Trading Company v Beijing Century Hengyuan Technology and Trading Ltd*, the court held that parallel importation does not always constitute unfair competition. Fahuayilin Trading Company has exclusive authorization from AN'GE Diffusion to use the trademark AN'GE in China on clothing. It brought proceedings against Century Hengyuan on the basis that the latter was selling clothing in China bearing the AN'GE mark. The clothing came from a company in Hong Kong, which is the authorized distributor of AN'GE clothing in that territory.

Fahuayilin alleged that Century Hengyuan's conduct was unfair competition. The court disagreed. It held that the licence arrangement between Fahuayilin and AN'GE Diffusion did not cover the wholesale market. Fahuayilin's exclusive right did not, therefore, allow it to prevent Century Hengyuan from legally importing and selling AN'GE clothing wholesale in China.

Anti-counterfeiting and enforcement

Prevention
Chinese law usually provides two avenues to litigate trademark infringement and counterfeiting issues – namely, administrative action and judicial procedures. Thus, an action against infringement or counterfeiting may be brought before either the Administration for Industry and Commerce at provincial or district level for administrative resolution, or before a court for compensation.

Chinese law provides for severer penalties for infringers and counterfeiters of pharmaceutical trademarks than for any other types of mark because pharmaceuticals have a closer relation to and greater influence on public health.

The Chinese Pharmaceuticals Administration Law, its Implementing Rules and the Chinese Criminal Law, among others, regulate two main issues – namely, fake medicines and inferior medicines.

A 'fake medicine' is defined as:

- one whose components are different from those prescribed by state pharmaceutical standards; or
- a non-medical substance being passed off as a medicine or one medicine being passed off as another.

An 'inferior medicine' refers to a drug whose components do not conform to the quality required under the state pharmaceutical standards.

Any manufacturer or seller of fake drugs may face:

- the seizure of all the income generated by the sale of the products;
- a fine ranging from twice to five times the illegal income;
- the cancellation of the pharmaceutical approval document so that the defendant may no longer manufacture or sell any pharmaceutical products; and
- a prison term of between three and 10 years, or life imprisonment or even the death penalty (as well as a fine and the confiscation of assets) if the fake products seriously harm human health.

The manufacture and sale of inferior medicines are considered less serious than those of fake medicines. Accordingly, the most severe punishment in such cases will be life imprisonment.

All pharmaceutical products must display an approval number, which is evidence that the drugs company is allowed to make and/or sell pharmaceuticals. All approval numbers start with Chinese characters that mean 'national pharmaceuticals approval number', followed by either the letter 'H' (for pharmaceuticals made up of chemical preparations) or the letter 'C' (for traditional Chinese medicine). After the initial letter comes a series of numbers. Any pharmaceutical product that does not feature the said approval numbers is either fake or inferior.

Enforcement
Producers of genuine drugs should take the following steps when trying to enforce their trademark rights.

Identifying the source of counterfeit pharmaceuticals
Counterfeit pharmaceuticals abound, even in hospitals and pharmacies. However, the source of counterfeits is their manufacturer; the genuine trademark owner should therefore do its best to try and identify that manufacturer.

Taking immediate and effective action
This is particularly crucial where the identified source is a small operation that can easily move and set up in another location. Thus, the trademark owner should consider where and against whom to take action. It is recommended to file actions first against medium-sized counterfeiters in large cities where judges will be more experienced.

Collecting evidence
Brand owners should design strategies as to how to gather evidence before taking any action. It is highly advisable to request a local public notary to notarize any evidence, as well as ask the local Administration of Industry and Commerce to help record officially such evidence. As mentioned above, counterfeiters move quickly and take evidence with them. Therefore, it is important to be flexible in the approach to collecting evidence.

Seeking penalties
Although the Criminal Law provides the death penalty for the production and sale of fake medicines, such penalty will be granted only where very restrictive criteria are met. Thus, in practice the producers and sellers of fake drugs are sometimes sentenced as producers and sellers of inferior (rather than fake) medicines.

Advertising

Regulatory framework
The Advertising Law, the Pharmaceuticals Administration Law, the latter's Implementing Rules (2002) and other rules published by the relevant bodies govern the requirements and procedures for, and management of, drug advertising. Further, the Standard on Examination and Publication of Pharmaceutical Advertising (2007) and the Measures on Examination of Pharmaceutical Advertising (2007) provide specific rules for the examination of the advertising activities of pharmaceutical companies and the penalties to be imposed on those breaching the rules.

Before publishing an advertisement, drug producers must obtain approval from the Food and Drug Administration (FDA) at local, provincial or city level. The relevant administration will issue an advertising registration number. In the absence of such a number, an advertisement may not be placed.

Prescription drugs may be advertised in medicinal and pharmaceutical magazines approved jointly by the Ministry of Health and the SFDA, but must not be advertised through mass media or publicized in any other form.

Considerations
A number of serious issues have emerged in relation to pharmaceutical advertising, in particular, the practice of making false or exaggerated claims as to the drug's efficacy, or advertising a drug without the prerequisite authorizations (eg, registration numbers). In order to improve the situation, the SFDA has worked together with the SAIC to publish in 2007:

- the Standard on Examination and Publication of Pharmaceutical Advertising; and
- the Measures on Examination of Pharmaceutical Advertising.

Furthermore, the SFDA also published the Measures on Credit Management of Advertising Enterprises for Pharmaceuticals, Medical Devices and Health Foods. The measures, which came into effect on January 1 2008, aim to keep a record of pharmaceutical companies' advertising activities. The advertising is ranked into three tiers and the tiers are determined by the level to which the advertising complies with the rules and regulations. The rankings are published annually.

Pharmaceutical companies should be particularly alert to the following situations and requirements:

- They must obtain approval to advertise any trademarked or generic prescription drug before publishing the advertisement; and
- No consulting or medical service company whose business name is identical to a prescription drug's generic name, commercial name or registered trademark may advertise its services through the mass media.

Generic substitution
According to Article 54 of the Pharmaceuticals Administration Law, the packaging of pharmaceuticals must be labelled and include directions for use. The generic name of the medicine must also be displayed on either the label or directions. The Measures on Prescription Management provide that physicians must use generic names approved by the SFDA. The relevant generic name must also be used in the directions for use of over-the-counter drugs. If the drug has not obtained a generic name, the commercial name of the drug can be used in the prescription.

Online issues

e-pharmacies
The sale of prescription drugs on the Internet is not authorized. As of December 2008, the SFDA had approved 10 websites to provide over-the-counter drugs online. This means that any other website promoting or selling drugs does so illegally.

The 10 authorized websites are:

- www.yaofang.cn;
- www.818shyf.com;
- www.jxdyf.com.cn;
- www.4ujk.com;
- www.baiyjk.com;
- www.yunnanbaiyao.com.cn;
- www.daoyao.com;
- www.511yd.com;
- www.eelbx.com; and
- www.51yao.com.cn.

Domain names
Drug companies should try to register their names and trademarks as domain names and internet keywords as early in the name/trademark selection process as possible. Unlike the drug approval process before the SFDA or trademark registration before the Trademark Office, both of which require the submission of significant amounts of detailed information, the registration of domain names or internet keywords requires nothing more than a copy of the applicant's business licence.

Thus, pharmaceutical companies should register their trademarks, business names and other relevant identifiers as '.cn' country-code top-level domain names if China is an important or potential market. When a pharmaceutical company's trademark has been registered as a '.cn' domain name by a third party, it may file a request for transfer of the domain name within two years of registration of the domain name. No extension of time is available. The request for transfer must be made to the China International Economic and Trade Arbitration Commission (CIETAC). CIETAC will then examine the request, as well as the counter-arguments submitted by the defendant; CIETAC will consider each of the following questions before issuing a decision:

- Is the disputed domain name identical or confusingly similar to the complainant's name or mark in which the complainant has civil rights or interests?
- Does the holder of the disputed domain name have any right or legitimate interest in respect of the domain name or major part of the domain name?
- Has the holder of the disputed domain name registered or been using the domain name in bad faith?

CIETAC will order the transfer of the disputed domain name when the first and third questions can be answered in the affirmative and the registrant has no legitimate right or interest in the domain name. WTR

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Grace Li received her BA degree from Beijing Foreign Studies University and her master's degree of law from Hong Kong City University. She has been practising in the IP field since 1998, starting her career with China Patent Agent (HK) Ltd in 1998 before joining Kangxin Partners PC in 2004. She now heads the firm's trademark practice.

Ms Li is particularly experienced in the prosecution and enforcement of trademarks, IP customs protection, and administrative actions against infringement. She also specializes in IP litigation and domain name dispute resolution.

Considered a leading expert in her field, Ms Li frequently gives lectures on intellectual property and advises clients on IP protection strategies.