China

Contributing firm
CCPIT Patent and Trademark Law Office

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Selection, clearance and registration

A drug can have three names in China: the generic name, the trade name and the trademark. Generic names and trade names are administrated and approved by the State Food and Drug Administration (SFDA), while trademarks are registered with the China Trademark Office (CTMO) and administrated by both the CTMO and the local administrations for industry and commerce.

Generic names originate from the national standards published by the SFDA and *The Pharmacopoeia* compiled by the Chinese Pharmacopoeia Commission. These national standards are regularly revised to reflect developments in the pharmaceutical industry, and *The Pharmacopoeia* is re-compiled every five years or so, incorporating some new adjustments. The latest (ninth) edition took effect as of July 1 2010 and lists 4,567 medicines – 1,386 more than the 2005 edition.

Since June 1 2006, only patented drugs and drugs with new active components and new chemical structures can have a trade name. The trade name must be composed of Chinese characters only; shapes, letters, numerals and signs cannot be incorporated in the name. The following also cannot be included in the trade name of a drug:

- characters that exaggerate or suggest a curative effect;
- characters that describe the body parts that may be affected;
- characters that refer directly to the function, quality, raw materials or other characteristics of the drug;
- Chinese translations of international non-proprietary names;
- characters which are similar to any generic name of a drug or trade name owned by a third party;
- characters which are identical or similar to a geographic term; and
- characters which cannot be registered as a trademark under the Trademark Law.

Every approved trade name and its status in the approval process can be searched for on the SFDA's website. This facility is convenient for verifying whether a trade name has been approved, but it cannot be used to search for conflicts with prior names, as is possible on the CTMO's website. A request for registration of a pharmaceutical trade name should be submitted to the SFDA together with the request for registration of the drug itself. To prevent a trademark that has been legally registered by one party from being approved as a trade name by another party, the SFDA now requires the formal results of a trademark search issued by the official search centre of the CTMO, in order to confirm that the applicant has fulfilled its obligation of due diligence, has conducted sufficient searches of prior trademarks and has found no identical or confusingly similar trademarks registered for identical products.

The information published on the SFDA website confirms that foreign pharmaceutical companies are more active in protecting the names of their drugs.

> **“Three-dimensional trademarks used on drugs can now be registered, a notable example being Pfizer’s famous Blue Diamond”**

Likewise, the vast majority of trade names for foreign drugs have also been registered as trademarks.

Currently, there are about 2,100 officially recognised well-known trademarks in China; about 100 of these fall into Class 5, far exceeding the average in other classes. The largest groups of trademarks registered by foreign applicants are found in Classes 25, 9, 35, 7, 3 and 5. Trademark applications in Class 5 are more likely to be refused than those in other classes, since many applicants tend to use wordings that are directly descriptive of the curative effects of the drug or the particular body parts that may be affected, in order to attract consumers’ attention. Smells, colours and sounds are not registrable, although the ongoing revision of the Trademark Law is expected to green-light trademark registration for such marks. Three-dimensional trademarks used on drugs can now be registered, a notable example being Pfizer’s famous Blue Diamond.

As drug trade names and trademarks are administrated by two different institutions and there is no unified search system that covers both institutions, the same wording is sometimes registered by one applicant as a drug trade name and by another as a trademark. The *Xinkang* case, recently settled in March 2010 after 10 years of dispute, is typical in this regard.

In 1993 Lunan Pharmaceutical Group submitted an application to register its new drug isosorbide mononitrate with ‘Xinkang’ as the trade name. The application was approved on July 11 1994. On July 24 1994 Livzon Pharmaceutical Group submitted an application to the CTMO to register XINKANG as a trademark for medicines in Class 5; registration was approved in December 1995. On October 15 2004 Lunan filed a non-use cancellation with the CTMO against the XINKANG trademark. The evidence which Livzon presented attesting to use was considered invalid by the CTMO and the trademark was cancelled accordingly. Livzon appealed to the Trademark Review and Adjudication Board (TRAB), which upheld the cancellation. Livzon appealed before the court.

On March 11 2005 Lunan filed an action with the TRAB arguing that it had submitted an application to the SFDA to register the pharmaceutical trade name ‘Xinkang’ before Livzon had filed its trademark application, and that it therefore enjoyed prior and exclusive rights to the name. According to a Ministry of Health document entitled “Notification on Further Enhancing the Administration of Drug Standards Trade names”, pharmaceutical trade names must be approved by the SFDA before a trademark application is filed with the CTMO. Lunan claimed that since Livzon had filed a trademark application before obtaining SFDA approval of the trade name, it had acquired the trademark “by fraud or any other unfair means” under Article 41, Paragraph 1 of the China Trademark Law, and the trademark should thus be cancelled. Livzon argued that the Ministry of Health document sets out rules at the ministerial level and cannot impose limitations on trademark registration procedures under the administration of the CTMO; the trademark registration should thus be maintained. After six years of administrative disputes, both parties launched further infringement lawsuits in the courts, culminating in a retrial before the Supreme Court.

The judges of the IP Tribunal of the Supreme Court finally put an end to the protracted dispute by mediating between the parties. Lunan obtained the XINKANG trademark through assignment from Livzon for a consideration of $162,000. The action which Lunan had filed was thus closed. The case generated considerable interest at the IP Tribunal, as had a settlement not been reached it would have been difficult to resolve the dispute and reconcile the conflict between the laws on trademarks and trade names and the drug administration regulations. Not all such cases would generate such interest at the Supreme Court and be mediated in this way.

The CTMO endeavours to approve trademark applications within 12 to 18 months. It is highly recommended that pharmaceutical companies file trademark applications in China as early as possible, to avoid their trademarks being registered as trade names by others. Pharmaceutical companies can choose a word mark to be used as a trade name after obtaining registration. Furthermore, in addition to Class 5, certain other classes are crucial to pharmaceutical companies (eg, Class 10 (medical devices), Class 30 (nutritional products for non-medical use), Class 32 (beverages), Class 35 (advertising and imports and exports) and Class 44 (medical services)).

Parallel imports and repackaging

According to the new Patent Law and Article 6 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, parallel imports are now legal under certain conditions. However, parallel imports are not mentioned in the proposed revision to the Trademark Law. As a result, it may be anticipated that most cases involving parallel imports will not be regarded as infringement. However, this may be interpreted by different courts on a case-by-case basis.

Drugs packaging must be approved by the SFDA and must use Chinese characters.

An insert sheet must be attached to the smallest package provided by the drug manufacturer for marketing purposes.

Anti-counterfeiting and enforcement

The counterfeiting of pharmaceutical products is penalised with greater severity than other infringements. In reality, however, quite a few lawbreakers still violate these laws. This is reflected in the proposed revisions to the Trademark Law, which will increase the statutory damages for trademark infringement from Rmb500,000 to Rmb1 million in cases where the damages cannot otherwise be determined.

The counterfeiting of pharmaceutical products for human consumption constitutes a crime which is punishable by fixed-term imprisonment of up to three years or criminal detention. If the crime is serious, a fine may be imposed concurrently or independently; if the crime is especially serious, a fixed term of imprisonment of between three and seven years may be imposed in addition to a fine.

If the infringer clearly knew that the pharmaceutical products it manufactured and sold were counterfeit, and it did so intentionally in a manner that was "sufficient to seriously harm the health of a human body" or to "seriously harm the health of a human body", its actions will constitute a crime of endangerment of public security, which in extreme cases is subject to the death penalty. Pharmaceutical products are crucial to the wellbeing of the public. After the melamine milk powder incident in 2008, a judicial interpretation was issued which stipulates that "if counterfeit or inferior pharmaceutical products manufactured or sold are mainly targeted at pregnant or breeding women, infants or patients in critical condition", this is considered to constitute a crime of manufacturing and selling counterfeit or inferior drugs.

Advertising

Pharmaceutical advertising is strictly administrated and monitored. It is regulated by the Drug Administration Law, the Advertising Law and the Examination Criteria for Drugs, among others. All pharmaceutical advertisements must be reviewed and approved, and each approval remains valid for one year only. Searches of approved advertisements can be conducted on the SFDA website. Advertisements for prescription drugs can be published only in "medical or pharmaceutical academic journals that are allowed by the state to publish advertisements for prescription drugs". Currently, 533 such academic journals are available. Advertisements for prescription drugs cannot be published in public media.

In China, self-treatment has existed for thousands of years and is widely acclaimed as convenient, cheap and effective. According to a survey, 75% of Chinese consumers tend to select publicly known brands when purchasing over-the-counter (OTC) drugs, while 64% choose drugs that they have seen in advertisements. Advertisements for OTC drugs account for a large proportion of all pharmaceutical advertisements. In China, pharmaceutical companies usually seek to capitalise on the popularity and influence of celebrities by having them endorse their OTC drugs. In order to prevent consumers from blindly following these celebrities and to prevent celebrities from neglecting their obligation of due diligence in accepting such endorsements, the Interpretation on Several Problems in Applying the Laws to Cases regarding the Manufacture and Sale of Counterfeit or Inferior Pharmaceutical Products provides that celebrities will be held as accomplices if they clearly know that the advertised products are counterfeit or inferior pharmaceutical products. These provisions have forced celebrities to be more circumspect in endorsing OTC drugs.

The trade name of a drug cannot be advertised separately in China. If the trade name of a drug is used in a written or broadcast advertisement, the generic name for the drug must also be shown. Unregistered trademarks cannot be included in pharmaceutical advertisements and registered trademarks cannot be advertised as the name of the drug (excluding those which are in textual form and have been approved as trade names). In written and broadcast advertisements, the trade name cannot be more than half the size of the generic name, the font and colour of the generic name of the drug must be clearly identifiable and the word trademark cannot be more than one-quarter larger than the generic name.

To protect the interests of children, pharmaceutical advertisements cannot include names and images of children, and cannot be targeted at children.

Generic substitution

Obtaining trademark protection is more important for generic drugs, as since June 1 2006 these cannot have trade names in order to help consumers to distinguish between them.

Drug insert sheets and labels must be reviewed and approved by the SFDA. Unregistered trademarks and other drug names that have not been approved by the SFDA cannot be used on drug insert sheets and labels. Generic names must be used by physicians, although in practice many doctors tend to use trade names.

Online issues

The state has relatively strict procedures for approving sales of OTC drugs via the Internet. Only 12 websites thus far have been approved to sell drugs in this way (www.eelbx.com, www.51yao.com.cn, www.511yd.com, www.daoyao.com, www.unnanbaiyao.com.cn, www.baiyjk.com, www.818shiyf.com, www.yaofang.cn, www.jxdyf.com.cn, www.4ujk.com, www.yplsw.com and www.plyh.com.cn). Prescription drugs cannot be sold online. Consumers can search the SFDA website to determine which websites are allowed to sell drugs to individual consumers.

Some entities sell counterfeit OTC drugs online, or post falsified information about drugs, which can not only cause monetary loss, but also potentially harm the health of consumers. When returning drugs for a refund, the postal service is likely to request an approval for mailing pharmaceutical products, which is difficult to obtain for ordinary consumers. The only available regulatory document on the online sale of pharmaceutical products is the SFDA's Interim Provisions on Approving Transactions of Pharmaceutical Products on the Internet, which do not yet constitute regulations. It is therefore suggested that consumers be cautious when purchasing pharmaceutical products on the Internet. WTR

Biographies

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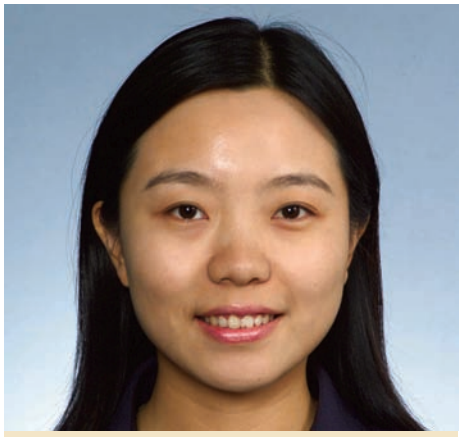

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Jessica Xu joined CCPIT Patent and Trademark Law Office in 1997 and works as a trademark attorney and attorney at law. She graduated from Heilongjiang University and studied IP law at Trinity College Law School from 2002 to 2003, with sponsorship from the European Patent Office and European Union.

Ms Xu is particularly experienced in trademark prosecution, enforcement, IP litigation, licensing and administrative protection of trademarks. She also specialises in the recognition and protection of well-known trademarks, providing legal opinions on anti-unfair competition and other IP-related matters. Ms Xu has handled a large number of trademark oppositions, disputes, cancellations and litigation. She has represented many well-known brand owners in protecting their trademarks in China and developing their branding strategies. Ms Xu has been ranked as Asia's Leading Lawyer in the Chambers Asia Awards 2010.

Ms Xu is co-author of *Trademark Laws and Practices Throughout the World*.