

Kangxin Partners PC

Taking a dual approach to pharmaceuticals

As in most other jurisdictions, in China pharmaceutical companies must navigate a dual system for registration and approval of their trademarks and the commercial names of their products

Like all other trademarks in China, pharmaceutical trademarks are governed by the Trademark Law and the Regulations for Implementation of the Trademark Law. However, due to the nature of pharmaceutical products, pharmaceutical trademarks are also governed by the following laws and regulations, among others:

- the Drug Administration Law;
- the Regulations for Implementation of the Drug Administration Law;
- the Regulations on Administrative Protection for Pharmaceuticals;
- the Provisions for Drug Advertisement Examination;
- the Provisions for Drug Registration; and
- the Rules for Management of Labels and Direction of Use for Pharmaceuticals.

Compulsory registration

Article 6 of the Trademark Law states that “as for any ...goods, as prescribed by the state, that must bear a registered trademark, a trademark registration must be applied for. Where no trademark registration has been granted, such goods cannot be marketed”. The 1984 Drug Administration Law explicitly stipulated that no drug could be sold without trademark registration, except for Chinese traditional medicinal herbs or decoctions. However, the 2001 Drug Administration Law removed this requirement. The only restriction to use now comes from Article 27 of the Rules for Management of Labels and Direction of Use for Pharmaceuticals promulgated by the State Food and Drug Administration (SFDA). This provision prohibits the use of unregistered trademarks or other drug names in the directions and labels of pharmaceuticals without explicit approval from the SFDA.

Substantive examination

Pharmaceutical trademarks are subject to the same rules and procedures of examination by the Trademark Office as other trademarks.

Absolute grounds for refusal

Article 11 of the Trademark Law provides that, like other trademarks, pharmaceutical trademarks cannot “only refer to the generic name, design or model number of the goods concerned”, or “only and directly indicate the quality, principal raw materials, function, use, weight, quantity or other features of the goods”. The generic names of pharmaceutical goods include the drug names listed in the *Pharmacopoeia of the People's Republic of China*.

Relative grounds for refusal

During the substantive examination of the trademark application, the examiner will search the Trademark Office database to determine whether any identical or similar trademark was filed or registered in relation to the same or similar goods prior to the filing date of the application under examination. If a prior mark is found, the new application shall be refused. The applicant will then have 15 days upon receipt of the notification to appeal to the Trademark Review and Adjudication Board (TRAB).

A pharmaceutical trademark is assessed for similarity in the same way as other marks, by comparing factors such as:

- appearance;
- pronunciation;
- meaning; and
- other aspects of such word or device, or their combination.

With regard to the similarity of any designated goods, the Trademark Office

relies mainly on the Classification of Goods and Services to ascertain whether the goods fall into the same subclass or subclasses, using cross-similarity notes. In contrast, the TRAB will normally adopt a more flexible and comprehensive approach to determine whether trademarks, as well as the designated goods, are similar – taking in to consideration, among other things:

- the relevant market;
- the function of the products;
- the main raw material used in making the products;
- the relevant sale channels and venues; and
- the average consumers of the products.

Pharmaceutical marks v commercial drug names

In China, drugs are generally classified under their generic or commercial name – the use of both requires approval from the SFDA. Commercial drug names occupy a unique position in that they are considered as quasi-trademarks, somewhere between the generic name and the trademark of the drug.

In order to use a pharmaceutical trademark as the commercial drug name, the pharmaceutical company must obtain approval from the SFDA to adopt such trademark as the commercial name of the drug.

A major problem emerging in China's pharmaceutical market is the use of multiple names for the same drug. The situation arises, for example, when a drug company adds new, inactive component(s) to a drug, gives the drug a new commercial name and then sells the drug at a higher price. To solve this problem, the SFDA has issued the Notification of Further Standardizing Pharmaceutical Product Names in 2006. The notification requires that the same drug manufactured by the

same drug producer, with the same active ingredients but using a different dose or specification, use the same commercial name.

In addition, under the notification the commercial name should comply with the following principles:

- It shall be composed of Chinese characters only, without any device, Latin letter, number, symbol or other sign;
- It shall not use any word that is banned under the Trademark Law; and
- It shall not:
 - indicate or exaggerate the drug's effect;
 - mention the part of body to be treated;
 - directly state the dose, quality, material, function, use or other features of the drug;
 - directly mention the intended users;
 - indicate the pharmacology, anatomy, physiology, pathology or therapeutics involved;
 - consist of or incorporate the Chinese translation of the international non-proprietary name or its stem;
 - consist of or incorporate any element that is phonetically or visually similar to the generic name of the drug;
 - be the nickname or previous name of the drug;
 - be identical or similar to product names used by others; or
 - be a person's name, geographical name or name of the company producing the drug, or other words with certain meanings.

Further, the law prohibits the use of:

- the commercial drug name alone in advertising; or
- the word mark, without approval from the SFDA, as the commercial drug name.

In light of the applicable law, the commercial name of the drug may be in a weaker position if it is not also registered as a trademark. However, according to Article 31 of the Trademark Law, if the commercial name has been used and promoted for a long time and has acquired a certain reputation, it may be protectable as an "unregistered trademark with prior use and reputation". Moreover, according to Article 5(2) of the Anti-unfair Competition Law, the name may also be protected as a "unique name of a famous commodity", where the commercial name of such drug may also be cited as a prior right against:

- existing trademark applications during



Gloria Q Wu
Partner
Kangxin Partners, PC

Gloria Q Wu received her law degree from Beijing Foreign Studies University in 2005 and received training in international finance and IP law from DePaul University College of Law. She joined Kangxin Partners, PC in 2005 as an IP attorney. Her main practices are in the fields of trademark, copyright and domain names. Ms Wu is highly experienced in IP-related litigation, administrative action, customs enforcement and IP strategy consultancy.

- opposition proceedings; or
- existing trademark registrations during cancellation proceedings.

Use of pharmaceutical marks and commercial names

According to the SFDA Rules for Management of Labels and Direction of Use for Pharmaceuticals, the use of trademarks and commercial names shall comply with the following specific rules:

- The registered trademark of the drug shall be printed on the edge of the drug's label (this requirement is limited to the position of the mark on the label; it does not affect the direction in which the mark itself is displayed). The font size of each word or character making up the trademark shall be no larger than one-quarter of the font size of the words and characters making up the generic name of the drug.
- The commercial name of the drug shall not be written on the same line as the generic name. Its font and colour shall not be more distinctive and remarkable than the generic name. The font size of each character making up the

commercial name shall be no larger than half the font size of the characters making up the drug's generic name.

In light of these requirements, it appears that commercial names enjoy a more favourable treatment in use than pharmaceutical trademarks.

Non-use defence

Article 44 of the Trademark Law provides that a trademark registration may be cancelled if the mark has not been used for three consecutive years in relation to the goods for which it is registered. According to Article 39 of the Regulations for Implementation of the Trademark Law, the mark owner can respond to cancellation proceedings for non-use by either:

- providing evidence of use of the trademark prior to the filing date of the cancellation application; or
- offering proper reasons for non-use.

In practice, 'proper reasons for non-use' of pharmaceutical marks may include the fact that the drug is still under examination by the SFDA and therefore has not entered the market. This explanation would be considered reasonable, thereby overcoming any non-use cancellation action, without having to provide evidence of use to the Trademark Office. [WTR](#)