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Intellectual Property

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IP ISSUES IN THE PHARMACEUTICAL INDUSTRY IN CHINA

China is one of the major producers of pharmaceuticals in the world and its pharmaceutical industry is a key contributor to the country's rapid economic growth. However, counterfeits of pharmaceuticals are common. Most would attribute the problem to the inadequate protection of intellectual property rights in the industry. However, in fact, this industry, from the naming of a single drug to the innovative development of new pharmaceutical technology, is interwoven with IP issues. This newsletter discusses the IP protection offered under the current IP regime in China.

NAMES OF THE PHARMACEUTICALS – GENERIC AND COMMERCIAL NAMES

The naming of pharmaceuticals is governed by the Trademark Law and other regulations and provisions from the Supreme People's Court and the State Food and Drug Administration in China (SFDA). In the past, apart from Chinese traditional medicinal herbs, no drugs could be sold without a trademark. However, this requirement was removed by the Drug Administration Law.

Currently, without approval from the SFDA, the use of unregistered trademarks or other drug names on labels of pharmaceuticals is prohibited, per the Rules for Management of Labels and Direction of Use for Pharmaceuticals of the SFDA. Therefore, pharmaceutical trademarks have to be registered like other trademarks before they can be used.

The registration of the pharmaceutical trademarks is subject to same substantive examination as other trademarks. An absolute ground for refusal is that the mark refers to the "generic" names, as listed in the Pharmacopoeia of the PRC, of the goods concerned.

On the contrary, it is common for "commercial names" to be considered quasi-trademarks of the drugs as commercial names are used to refer to the drugs, especially now that there is no longer the requirement that a drug must have a trademark. However, under the law, advertisement of a drug cannot be in the commercial name of the drug alone, and using a trademark as the generic name of the drug requires approval from the SFDA.

There are further guidelines under the Notification of Further Standardizing Pharmaceutical Product Names in 2006 on the commercial names of pharmaceuticals. For example, the same drug manufactured by the same producer with the same active ingredients but adopting a different dose must use the same commercial name. Moreover, the commercial names

- must be composed of Chinese characters only, without any device, Latin letter, number or symbol;
- must not contain any word that is banned under the Trademark Law, such as "red cross" and "red crescent";
- must not consist of or incorporate any element that is phonetically or visually similar to the generic name of the drug.

Therefore, there are more restrictions on the commercial names than the pharmaceutical trademarks and it is more favourable to have the names registered as trademarks.

INGREDIENTS AND PRODUCTION METHOD – WHEN THE PATENT IS IN PLAY

Scientific discoveries, methods for the diagnosis or for the treatment of diseases are not patentable. Pharmaceutical ingredients and products are patentable, only if novel, inventive and of practical application. The patentee enjoys the exclusive right to manufacture, advertise, exploit new ingredients and production methods during the patent term.

The introduction of the Amendments to Patent Law provides an exemption to infringement of patentee's right by allowing generic drug manufacturers to manufacture a generic drug before the patent expires so that they can compete with the patentee.

However, for the purpose of public health, the Patent Administrative Department of the State Council may grant a compulsory license for patented drugs so as to allow production of the drugs, if the pharmaceutical patentee has not exploited or sufficiently exploited the patent without any justifiable reason after the expiration of three years from the grant of the patent and of the expiration of four years from the filing date of application.

CONFIDENTIAL INGREDIENTS AND PRODUCTION METHOD – PROTECTED BY TRADE SECRETS

If the pharmaceutical manufacturers do not want to disclose materials and technology of the pharmaceuticals production, or if they cannot or do not obtain patent registration, they can rely upon the protection of trade secrets.

Under the Anti-Unfair Competition Law, trade secrets includes information (i) which is unknown to the public; (ii) which is capable of bringing economic benefits to the right holder and has practical applicability; and (iii) for which the right holder has taken measures to keep it confidential, e.g. restricting access to the information or having confidentiality agreement with the persons who have access to the information. Therefore, there should be a clause in the staff employment contract stipulating that the formulae or other know-how of drugs or productions are regarded confidential and should not be divulged to other third parties during the term of employment and also after the termination of the employment contract.

Confidential information is not required to be disclosed to the public. There is further no fixed term of time on the protection of trade secrets, and hence there would not be the problem of the influx of generic drugs after the expiry of e.g. a patent right. However, if the confidential information has leaked out and a third party subsequently applies for a patent, the original owner of the confidential information may be prohibited from using the same materials or technology.

DESIGNS OF PHARMACEUTICALS AND THEIR PACKAGING – COPYRIGHTABLE WORK

The packaging of a pharmaceutical may be considered of a special and innovative design. In such case, they would be protected by both the design patent right and by copyright. The major advantage of copyright over the design patent right is that the former arises once the work is created, without any requirement of registration. There is also no requirement that the owner takes any measures to ensure its confidentially.

However, on the other hand, the automatic nature of copyright causes considerable burden to the right owners when they are required prove ownership of their rights upon infringement. In China, there is a recordal system for the copyright which records the details of the copyrighted work and the ownership of the work. It serves as prima facie evidence of ownership if a dispute arises.

CONCLUSION

As discussed, there are various means of IP protection available to the pharmaceutical industry. Drug developers and companies should, therefore, better utilize the current regime to protect their IP rights.