1. Introduction

Pharmaceutical production is a research and development (R&D) driven industry. The potential and profit of pharmaceutical companies are very dependent on the adequate protection of Intellectual Property Rights (IPR). IP is the most effective way to protect R&D and is a powerful weapon to use in the pharmaceutical market in China.

This guide will focus on the principal IPR issues/provisions in the field of pharmaceuticals, namely in the areas of patent, trademark, copyright, and trade secrets.¹

2. Patent

With the exception of medical devices which can be protected as utility model patents (10 years), most pharmaceutical innovations are protected by invention patents (20 years). A pharmaceutical company must continuously monitor the patent status of the related subjects of its own products, conduct an accurate analysis on technology in patent documents, decide on technological circumvention, and design an R&D strategy on filing a series of patent applications around its own innovations.

¹ Relevant laws, rules and regulations relating to pharmaceutical IPR in China are as follows: Patent Law, Trade Mark Law, Copyright Law, Anti Unfair Competition Law, Regulations on Administrative Protection of Pharmaceuticals, Regulations on Protections of New Varieties of Plants, Regulations on Protection of Traditional Chinese Medicines, Regulations on Administrative Protection of Pharmaceuticals, Provisions for Drug Registration, and etc.
2.1 Conduct a patent search

Chinese Patent Law now holds absolute examination criteria when judging novelty of an invention or utility model application. This means that any time a technology has been disclosed in publications or otherwise publicly used in China or abroad before the filing date in China, it will be disqualified from patentability because it will no longer be considered new.

Before carrying out R&D in China, it is advisable to conduct a ‘freedom to operate’ (FTO) patent research thoroughly to ensure that there is no risk of infringing another party’s patent rights or on-going patent application. It is also required to undergo a comprehensive novelty and inventiveness assessment before filing a patent application by using the professional patent search service provided by a patent agency. Finally, it is essential to monitor newly published non-patent documents and patent documents that may provide further information about the state of the art.

2.2 Draft a qualified application text to comply with the examination criteria on pharmaceuticals in China

There is a myriad of special protocols that must be followed in the examination of invention patent applications in the field of chemistry. For instance:

(a) Sufficient disclosure of the technical solution of the invention

Inventions in the field of pharmaceutical science are required to be verified by experimentation, and the description should include specific embodiments. In the case of an invention of a new compound, for instance, it is required to specifically record (1) the chemical/physical property parameters to clearly identify the claimed compound; (2) the preparation method of the compound, particularly, the raw materials, procedures, conditions and specially adapted equipment used for carrying out the method; (3) specific medical use or pharmacological action of the compound and relevant testing methods to prove the technical solution as described can solve the technical problem or achieve the technical effect as expected.

2.3 Enforcement

Infringement issues are handled by the courts and validity issues are handled by the Patent Re-examination Board (PRB). A patent is presumed valid unless it is pronounced invalid by the Board. According to Chinese Patent Law, where a dispute arises from alleged infringement of the patent right of the patentee, the patentee or any interested party may institute legal proceedings in the People’s Court, or request the local Patent Administration Departments (PAD) to handle the matter. If a PAD rules that there has been an infringement, it may order the infringer to stop the infringing act immediately. If the infringer is not satisfied with the order, he may file an appeal in the People’s Court.

2.4 Case Study

Glivec, i.e. Imatinib mesylate, developed by Novartis A.G. of Switzerland, is one of the most effective antitumor drugs, and is the first approved drug for targeted therapy of CML (chronic myeloid leukemia). Glivec received its approval in China in 2002 and achieved a huge market value. Glivec’s original patent for pharmaceutical compound (ZL93103566.X) expired in May 2013. Several generic products have since been approved in China, and a number of companies’ generic product-applications are in the approval process. However, Novartis has managed a well-designed patent strategy for Glivec’s all-around protection and has paved the way for achieving high value of the drug. Around the core patent of the compound, Novartis continues to develop and obtain a number of relevant patents so as to extend the persistent monopoly for the drug, including a variety of new crystals, new indications of disease (such as the treatment of gastrointestinal stromal tumors (GIST) and thyroid cancer), sustained-release dosage forms, combinations with other API, which contribute to Glivec’s dominance over generic drugs, by constantly reinforcing the patent protections. If the Chinese pharmaceutical companies use these follow-up patent technologies, there will be possible infringement litigations.

In 2013, Chitai Tianqing Pharmaceutical Group of China got its generic drug “Genike” Imatinib mesylate capsules approved in the listing, Novartis raised an infringement litigation in Beijing, and sued Chitai Tianqing infringing its Chinese patent ZL.01817895.2, which protects imatinib mesylate for the treatment of GIST’s as a new indication. Chitai Tianqing showed on its web page of “Genike” the GIST indication, and Chitai Tianqing also included GIST-related information in its drug brochures and advertising materials. Those commercial activities were sued for having infringed the Novartis’ patent. Novartis won both the first instance and the second instance regarding the infringement. However, at the same time, Chiatai Tianqing filed a request for invalidation against the patent ZL01817895.2. Finally, Chitai
Tianqing and Novartis reached a settlement, Chitai Tianqing withdrew its invalidation request against the patent, while Novartis shall not pursue economic compensation from Chitai Tianqing.

3. Trade Marks

3.1 Importance of Trade Mark Registration

According to the State Food and Drug Administration (SFDA) rules Drug Insert Sheets and Label Management Rules, unregistered trade marks may not be used in pharmaceutical insert sheets and packages.

Moreover, in a commercial environment, registered marks are usually required for pharmaceutical products. If the pharmaceuticals are sold on famous e-commerce websites such as Taobao, Jingdong, etc., the platforms usually require the commodities to be branded with registered trade marks. Normally, if commodities are planned to be sold on e-commerce websites, the Chinese registration certificate is required by the platforms.

It is therefore essential to register a trade mark on pharmaceutical products before they are put into commercial use.

3.2 Trade Mark Registration for Pharmaceuticals

When one applies for registration in class 5 (Pharmaceutical and veterinary preparations; sanitary preparations for medical purposes) for a mark on pharmaceuticals, the same mark on other relevant goods/services classes is also suggested in order to have full protection of the mark in China. Registration of the trade mark in class 5 does not necessarily prevent others from using or registering similar or identical marks on relevant similar products/services in other classes: similarity of goods in China is fundamentally judged by the goods classification book.

Other than class 5, you may consider registering you trade mark in the following classes:

• Class 35: medical sales, etc.;
• Class 40: processing of medical materials, etc.;
• Class 42: pharmaceutical research, etc.;
• Class 44: medical services, etc.

3.3 Different names of pharmaceutical products

(a) Introduction of drug name, common name and trade name of pharmaceuticals

The drug name of pharmaceuticals includes a common name and a trade name or brand. A common name refers to “China Approved Drug Name”, which is the drug’s legal name approved by Committee of Pharmacopoeia conformed to “Nomenclature Principles of Generic Names of Drugs” in China. A common name helps consumers understand the type and prescription of the pharmaceuticals. Pharmaceuticals with the same prescription or variety of drugs should use the same common name. All pharmaceuticals put into use in the market should use their common name on labels, insert-sheets and packages. As prohibited in the Trademark Law, generic names and common names cannot be registered as a trade mark. For example, “Paracetamol” is a common name of pharmaceutical for curing fever and therefore cannot be trade marked.

The trade name or brand of pharmaceuticals is decided by the manufacturers of the drugs themselves. Under a single common name, several drugs could have different brands. Brands function to distinguish different providers of the same pharmaceuticals and therefore can and should be filed for a trade mark registration. The brand of a drug shall be clearly distinguishable from the common name, so avoid using the same colour, font, etc. For instance, “Motrin” and “Tylenol” are both brands of pharmaceuticals for curing fever. They could share the same common name “Paracetamol”, but by bearing different brands, the two drugs can assist consumers to distinguish the two manufacturers of “Paracetamol” and purchase whichever they like best.
(b) Avoiding the generalisation of your brand

The common name of pharmaceuticals could be used by any manufacturer of drugs only if the drugs’ type, prescription and usage are consistent with the common name. Registered brands of pharmaceuticals shall be exclusively used by the trade mark owner who can prevent other parties from using it. When you’re publicising your pharmaceutical product or service, use the common name to describe its type and a brand to distinguish its source.

It is important to avoid turning your brand into a common name by negligence and thus risking loss of your exclusive trade mark rights (if registered). A classic example of a brand becoming a common name is the case of Aspirin which was once a registered trade mark owned by Bayer. However, over the years, consumers became accustomed to associating the name Aspirin with all pharmaceuticals used for the same treatment. Bayer Company failed in guiding consumers to properly recognise Aspirin as a brand and lost its exclusive trade mark rights in many countries where the word “Aspirin” is regarded as a generic term.

The following actions should be considered to avoid the generalisation of your brands:

• A brand should be as distinctive as possible. It is important to avoid using a name related with the features or functions of the pharmaceuticals. For instance, Motrin is translated as MEI LIN in China without a literal meaning. It does not have any descriptive nature of the drug. Thus, it is not easy for Motrin to be diluted as a common name.

• The owner of pharmaceuticals in China should not claim their trade mark in national criteria, industry criteria, pharmaceutical nomenclature, etc. If a trade mark is listed in pharmaceutical nomenclature and the like, the mark will likely be regarded as a common name and can consequently be used by any party.

• If any competitor uses your brand as a common name, you should take immediate action, such as sending a Cease and Desist letter to the infringer and publicising the infringement in newspapers and magazines, among other actions.

(c) Relevant case study

“舒泌通” (SHU BI TONG, the first character means “comfortable”, the second character means “secretion” and the third character means “fluent”) is a registered trade mark owned by a domestic drug producer A since 2008. Before application for the mark was submitted, “舒泌通胶囊” (the first three characters are the same with the registered mark, the last two characters mean “capsule”), the mark was listed as a common name in Drugs Pharmacopeia by the SFDA in China in 2002. Another company, B, produces “舒泌通片” (the first three characters are the same with the registered mark, the last character means “tablet”) from 2009. The court in China did not think that party B infringed the trade mark rights of Party A. The reason is “舒泌通胶囊” is a common name based on the fact that it has been listed in Drugs Pharmacopeia although it is registered as a trade mark by Party A. Thus, Party B’s use of the common name was deemed lawful. It is therefore advisable to check carefully whether a mark has already been designated as a common name by the SFDA.

Apart from the drug’s name, it is also advisable to file for trade mark registration of your company name, to help consumers distinguish the source of goods. In addition, if the brand of your pharmaceutical product or service were to be diluted or cancelled in future, the registered name of your company could be used as a brand.

4. Copyrights

4.1 Whether pharmaceutical instructions should be protected by Copyright Law

The Supreme Court and the SFDA have the consensus that pharmaceutical instructions should not be protected by Copyright Law, as there is not much room for creativity in the drafting of such notices. The instructions approved for new drugs could not be amended freely by the creator. In addition, unlike works that could exist independently, instructions should always be used together with the products and they could not exist alone.

4.2 Case Study

In 2009, drug company A (plaintiff) sued another drug company B (defendant) because company B issued a pharmaceutical products insert sheet identical with that of A, except for the information of manufacturer. The plaintiff held the defendant was infringing the copyright of its pharmaceutical products insert sheet. In the first and second instances, the courts supported the claim of the plaintiff. However, in the 2013 appeal, the Hunan Higher People’s Court overruled both previous decisions stating that the insert sheets lack of originality and are not copyright protectable.
5. Trade secrets

5.1 For the employee

The state of secrecy includes not only the situation where the obligation to keep secret arises from regulations or agreements regarding confidences but also the situations where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.

Due to the long duration and complexity of R&D of a new drug, the protection of technology know-how is critical for a pharmaceutical company. Employee turnover makes it very important to sign a confidentiality agreement before the employee participates in a R&D project. Inspection and appraisal of computer hard drive and emails of the key employees having access to technical secrets and know-hows is critical. Your company should set up relevant internal rules and physical measures to control the employees’ access, use or dissemination without authorisation of key information, such as experiment reports, searching results, clinical data, as well as drug approval registration documents. You should also think of establishing rules to prevent employees from filing a patent application or publish any scientific articles without authorisation even after they leave the company. A robust monitoring system of disclosure in the public domain can discourage unlawful actions on the part of current and former employees.

However, if an ex-employee has shared trade secrets or filed a patent application, in practice, it is better to reach a settlement instead of embarking on a long and costly law suit. Similarly, it is also a very sensitive to use other IP and/or know-how “brought in” by a new employee. It might lead to IP infringement and further legal actions.

5.2 For partners in technology transfer

Technology of a pharmaceutical patent is always transferred with know-how in a confidential contract, particularly with respect to patents related to the drug preparation process. In real cases, many disputes with business partners/collaborators are often related to misuses of the involved technological secrets by the patent licensee. Once there is a dispute, be sure to collect evidence to demonstrate unauthorised access to the involved technical secrets and similarity of the alleged know-how and the involved technical secrets. Furthermore, carry out a comprehensive investigation before the start of the litigation. Be sure to protect the technology secret during litigation by asking for a close hearing. Collecting evidence on trade secrets theft is difficult and borne by the plaintiff, so you may seek the court’s assistance in issuing an investigation order or evidence preservation during litigation by submitting a reasonable requirement.

To know more ways about protecting trade secrets, read other Helpdesk guides listed below.
Take-Away Messages

- For R&D of a new drug, conduct continuous and comprehensive patent research.
- Design a strategy for filing a series of patent applications with regard to all kinds of possible subject matters.
- Draft a qualified patent application text with experiment/effect data to comply with the examination criteria on pharmaceuticals in China.
- It is important and safe to register a trade mark on pharmaceutical products before they are put into commercial use.
- Full protection on trade marks (registration in multiple-classes) is suggested.
- It is important to avoid your brand being regarded as a common name.
- Take holistic preventative measures to minimise the risk of leaking technical secrets

7. Related Links

Helpdesk Resources:


External Resources:

Chinese Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/


The Supreme People’s Court of the P.R.C.: http://english.court.gov.cn/

China IPR Judgment and Decisions: http://ipr.court.gov.cn/
For free, confidential, business-focused IPR advice within three working days
E-mail: question@china-iprhelpdesk.eu

The China IPR SME Helpdesk provides free, confidential, business-focused advice relating to China IPR to European Small and Medium Enterprises (SMEs).

Helpdesk Enquiry Service: Submit further questions to the Helpdesk via phone, email (question@china-iprhelpdesk.eu) or in person and receive free and confidential first-line advice within three working days from a China IP expert.

Training: The Helpdesk arranges training on China IPR protection and enforcement across Europe and China, including Hong Kong, Macao and Taiwan, tailored to the needs of SMEs.

Materials: Helpdesk business-focused guides and training materials on China IPR issues are all downloadable from the online portal.

Online Services: Our multi-lingual online portal (www.ipr-hub.eu) provides easy access to Helpdesk guides, case studies, E-learning modules, event information and webinars.

Project implemented by:

Download guide:

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