

Chapter 2

Pharmaceutical Intellectual Property Rights in China

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2.1 Introduction

Based on the market size and its fast-growing rate, China is expected to become the second largest drug market in the world by 2015 with a growth rate over 25 % per annum in the next 3 years. Therefore, China is expected to attract more overseas pharmaceutical companies. At the same time, pharmaceutical products rely heavily on the protection of intellectual property rights (IPR), so it is essential for those overseas pharmaceutical companies to have a comprehensive understanding of the corresponding laws and regulations, to adjust their strategy for IPR protection to better benefit from their products in the Chinese market. Up to date, China has gone through a few milestone IPR changes and has established a relatively comprehensive legal system in relation to IPR protection. The core IPR protection is through the implementation of the patent laws and regulations. The state IP office of China and its branches are the key IPR executing agents (Liu 2009). The intellectual assets are protected by patents, administrative regulations (Table 2.2), trademarks, copyrights, and trade secrets (Qu 2010). The patent law (Amendment to Patent Law 2008) is the most important one for IPR protection, which adopted the international standard of novelty examination to conduct drug patent review and approval. In terms of drug patent administration, new articles of parallel importing,

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compulsory licensing, and the exemption (Bolar exemption) for drug clinical trial and its dossier application are added. To enforce drug patent protection, the new patent law increased administrative penalties for patent violations. These newly added articles provide stronger protection for the IPR.

The Chinese environment for the protection of intellectual property right is considered complicated by many companies, especially for the small to medium-sized companies or those just entered into Chinese territory recently; Many overseas and multinational pharmaceutical companies are concerned that their imported or locally manufactured pharmaceuticals produced in China will be imitated or copied, or their intellectual property will be infringed. However, there are many similarities between the Chinese IPR compared to the western world IPR protection.

2.2 Historic Milestones of Patent and New Drug Protection Regulation Changes in China

In 1984, China issued the Patent Law. On April 1, 1985, the Chinese Patent Law entered into effect (Patent Law 1984). However, the Patent Law did not provide patent protection for pharmaceuticals until it was amended in 1993. During the period from 1984 to 1993, drugs were primarily protected by administrative measures (Fig. 2.1, Tables 2.1 and 2.2).

In 1993, China issued patent protection law for pharmaceuticals. The patent law was revised on September 4, 1992 for the first time and the revised Patent Law became effective on January 1, 1993. The duration of patent was extended for regular

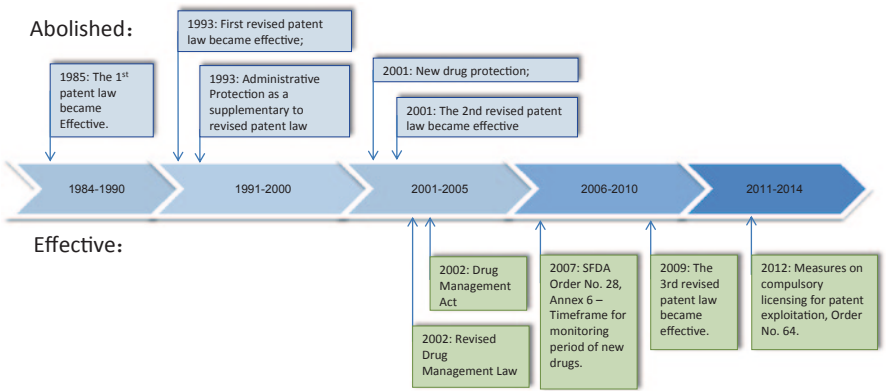


Fig. 2.1 Historic development outline of intellectual property protection in China

Table 2.1 Patent protection in China

Drug listing date	Protection period (Years)
1987–1993	15
1993–Present	20

Table 2.2 Administrative new drug protection in China

Drug listing date	Protection period (Class I) (Years)
1985–1999	8
1999–2002	12
2002–Present	5

patents from 15 to 20 years, and for utility model and design patents from 5 to 10 years, with no further extensions. Chemicals and pharmaceuticals were removed from the list of unpatentable subject matter. Some of the administrative protection measures remained effective in addition to patent protection for pharmaceuticals due to specific historical reasons. This patent law significantly stimulated local pharmaceuticals' innovative activities for new drug (The Amendment of the Patent Law 1993).

In August, 2000, the Patent Law was revised on August 25, 2000, for the second time and the revised Patent Law came into force on July 1, 2001. As the result of the negotiations with WTO, China committed again to review and revise the Patent Law. Accordingly, the Standing Committee of the People's Congress passed the second amendment bill on August 25, 2000, and the amendment became effective on July 1, 2001. China succeeded in making accession into WTO on November 12, 2001. This second amendment made the Patent Law in compliance with the TRIPS Agreement, the Patent Law was revised to grant patentee the right to prevent others from "offering for sale" patented products or products obtained directly by patented processes (The Amendment of the Patent Law 2000).

In October, 2001, to encourage the local pharmaceuticals innovation of new drugs, the Chinese government provided a great incentive to take up innovation activities. The State Food and Drug Administration (SFDA) extended the drug protection period: Class I of drugs protected period extended from 8 to 12 years; the protection periods of Class II and III new drugs extended their protected periods from 6 and 4 years to 8 years; Class IV drugs extended their protected period from 3 years to 6 years; For Class V new drugs, SFDA increased the protection period to 6 years.

The implementation of a certain period of protection for the production of new drugs is similar to and consistent with the international standards. During the protection period, only the manufacturer, who had the drug license approved by SFDA could make the exclusive product with the same formulation and dosage form.

In addition, to encourage pharmaceuticals to develop new drugs, SFDA is to establish a new drug review system: including (1) Class I confidential drug, anti-cancer drugs, and anti-AIDS drugs will be approved under expedited procedures; (2) The evaluation process for the first in class drugs for the treatment of difficult or severe diseases will be accelerated; (3) the approval process will also be accelerated for technological innovation, that may significantly reduce the generic drug costs or improve their qualities.

In 2002, the administrative "New drug protection" issued in 2001 was replaced with the "Revised Drug management Law" and "Drug Management Act", i.e., "New Drug Monitoring Scheme". Part of the reasons is that upon re-entry into the WTO,

new drug protection became inconsistent with the intellectual property protection systems under Trade-Related Aspects of Intellectual Property Rights (TRIPs).

The New Monitoring Scheme focuses on monitoring new drugs for safety and effectiveness by providing market exclusivity to the supplier of that new drug. The period of market exclusivity was reduced from 12 years to 5 years for the Class I new drugs, and less than 5 years for other Classes of new drugs. Overall, the intellectual property protection becomes more consistent with the current international standards. It should be noted that this Monitoring Scheme only applies to drugs manufactured in China, see Tables 2.3 and 2.4.

In December 2008, the Patent Law was revised (The Amendment to Patent Law 2008) for the third time and the revised Patent Law came into force on October 1, 2009 (Table 2.1). This amendment further strengthened the legal protection to inventors in China. The new contents are designed to shift China's economy patterns from manufacturing and exports towards technology and innovation.

The revised Patent Law made the definitions of invention, utility model and design much clearer. China's patent law requires that invention patents and utility model patents to possess novelty, creativity and practical applicability. The required standards were further raised in the revised Patent Law. To grant a Chinese patent, China patent office adopted the "absolute novelty" standard that is used internationally, i.e. the invention is not known publicly either inside or outside China prior to the date of application for a patent. For the invention patent, a finished drug must be defined in terms of usage, i.e. the applicant must clearly state in the application for the diagnostic or therapeutic indications of the drug (Zhang 2008). A finished drug or biological product or API is eligible for product invention patent application.

In general, the revised patent law in 2008 brings the Chinese standards closer into conformance with international practice. For the multinational pharmaceutical companies, this patent law is even more important since it becomes the only protection for imported drugs.

2.3 Current Effective Rules for New Drug Protection

Patent Protection

In China, the accepted types of patents include inventions, utility models, and industrial designs. Invention patents are available to both product and method inventions. The term for invention patents (compound patent) is 20 years and the term for utility model and design patents is 10 years, from the filing date of patent application (Standing Committee of the National People's Congress 2008). A product patent for a drug entitles the patentee the exclusive right to manufacture, market, and sell the drug. The measurements of the patent acceptance are based on the novelty, inventiveness, and industrial applicability. A finished medicinal product typically consisting of active ingredients is generally eligible for product invention patents (Fig. 2.2). Active ingredients in a drug are also eligible for separate product patents.

Table 2.3 Historical market exclusivity under the administrative new drug and patent protection for chemical drugs

Classification of new drugs	1985 Drug controlling law (Years)	1999 “New drug registration act” and “Notice on new drug protection and technology transfer” (Years)	2002 New drug protection in “revised drug management law,” “Drug Management Act” (Years)	Patent protection
New chemical entity that has not been approved anywhere in the world	8	12	Transitory protection 5	15 Years (–1993) 20 Years (1993–)
Approved abroad, but not in the foreign pharmacopoeia, not imported to China	6	8	4	None
New combination of registered drug	4	8	3	None
Approved on the foreign pharmacopoeia, imported in China, but not produced in China (not approved in China since 2002)	3	6	3	None
New use of already registered drug	3	6	3	None

Note 1: On introduction of the “Revised Drug Management Law” and “Drug Management Act” in 2002, “new drug protection” was repealed. The “new drug monitoring” period was introduced in 2002 and become effective in May 1, 2002

1. Drugs that passed clinical test on September 15, 2002 were given market exclusivity for the period of “new drug protection” in the 1999 scheme

2. Drugs that applied for to the government, but had not passed a clinical test yet, nor sold in China, were given a “monitoring period” in the new 2002 scheme

Note 2: The classification of drug categories is unique in China. In history, the classification was modified a few times, e.g. it has been classified into 5 categories in 1999, 6 categories in 2002, 2005 and 2007. The contents of the categories are also different depending on the versions of the Act (Deng 2004; Chen 2007) `

The product invention patent for a finished drug must be defined in terms of usage (indication), i.e. the diagnostic or therapeutic use of the product. In China, a new drug usually will satisfy the inventiveness requirement if its active ingredients are novel or it delivers new beneficial effects compare to the existing treatments.

Table 2.4 New drug monitoring period

Monitoring period	Chemical drug	Therapeutic biological product	Preventative biological products
5 (Year)	1. Among those not yet marketed domestically or oversea:	1. Biological products not yet Marked domestically or oversea	1. Vaccine not yet marketed domestically or oversea
	1.1 Drug substance and its preparations made by synthesis or semi-synthesis		
	1.2 Preparation of new active chemical monomer extracted from natural sources or by fermentation		
	1.3 Preparation of optical isomer obtained from known drugs by chiral separation or synthesis		
4 (Year)	1. among drugs not yet marketed domestically or oversea:	2. Mono-clonal antibody	2. DNA vaccine
	1.4 Drug with fewer Components derived from Marketed multi-component drug;	3. Gene therapy, somatic cell therapy as well as the preparations	3. An already marketed vaccine with new adjuvant. Change of carrier of combined vaccine
	1.5 New compound formula preparation;	4. Allergen products	4. Non-purified vaccine, or full cell vaccine (bacteria, virus) changed into purified vaccine, or combined vaccine
	2. Preparation with change in route of administration but not yet marketed domestically or oversea	5. Multi component products with bioactivity extracted from, or by fermentation from human and/ or animal tissues and/ or body fluid,	5. Vaccine with strains not yet approved in China (except for vaccine for influenza, vaccine for leprosirosis and others)
	3. Among the drug marketed overseas but not domestically:	6. New combination product made from the already marketed biological products	6. Vaccine already marketed overseas but not yet marketed domestic
		7. A product that is marketed already overseas but not yet marketed domestic	7. Combined vaccine prepared with vaccine already marketed domestic
	3.1 preparation marketed overseas, and/or preparation with change in dosage form of the preparation but without change in route of administration	8. Micro ecological product, where some of the strains used for preparing of micro ecological products not yet approved	8. Re-combination vaccine with protective antigen spectrum different with the marketed one

Table 2.4 (continued)

Monitoring period	Chemical drug	Therapeutic biological product	Preventative biological products
3 (Year)		9. Products with not completely same structure products and not yet marketed at domestic or overseas (including amino acid locus mutation/ absence, modification caused by a different expression system, deletion, changed interpretation, as well as chemical modifications of the product) with the already marketed	
		10. Products with a method of preparation different with the already marketed one, (such as use of different expression system, host cells)	
		11. Products first time made with DNA recombination technology (such as use of recombination technology to replace the synthesis technology, tissue extraction or fermentation technology)	
	3. Amongst the drug marketed overseas but not in China:	14. Biological products with change in route of administration (excluding 12)	9. Vaccine manufactured with the change of the other approved expression or the other approved cellular stroma. Vaccine using new process, which is proved to improve the safety and effectiveness of the vaccine based on the data of laboratory
	3.2 Combination preparations, and/or with changed dose form, but no change of administration route		

Table 2.4 (continued)

Monitoring period	Chemical drug	Therapeutic biological product	Preventative biological products
	3.3 Preparations with changed administration route and marketed ex-China;		10. Vaccine with change of de-activator (method of deactivation) or de-toxicitor (method of de-toxicity)
	4. Drug substance and itspreparation with changed acid or alkaline radicals (or metallic elements), but without any pharmacological change, and the original drug entity already approved in China		
	5. Change in dosage form of existing drugs marketed in China, but without change in route of administration, where special technology is used, such as targeted delivery preparation, sustain or controlled release preparation		
			11. Vaccine with change in the route of administration

Note: This table is simplified based on Provisions for Drug Registration (SFDA Order No. 28)—Annex 6: Timeframe for monitoring period of New Drugs. No monitoring period will be established for the drugs other than those listed

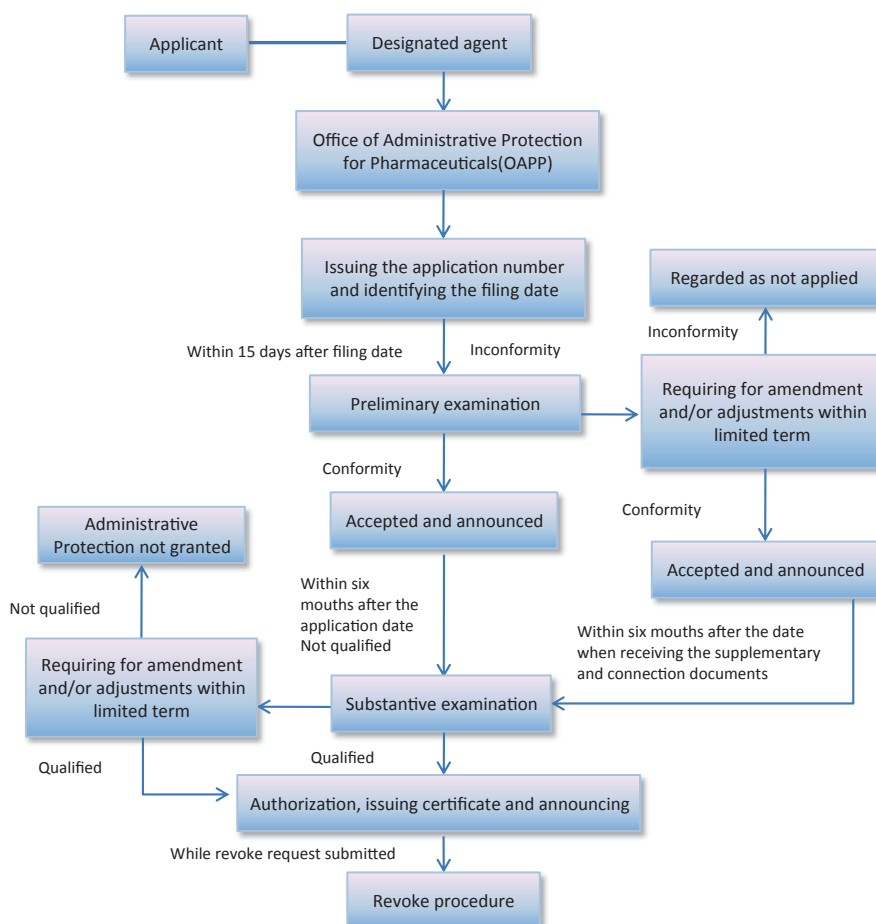


Fig. 2.2 Examination and approval procedure of administrative protection for pharmaceuticals. (Source: China Food and Drug Administration website with modifications)

In the US, European Union, and Japan, the pharmaceutical drug patent terms have been extended due to its long development process before marketing. However, such patent extension has not been accepted in China.

The 2008 Amendments to the Patent Law became effective on October 1, 2009, also specifically provides an infringement exemption for local generic drug manufacturers. The amendments are similar to the “Bolar exemption” in the United States, namely, “manufacturing, using or importing patented drugs or medical devices solely for the purpose of acquiring information necessary for obtaining administrative approval, and manufacturing or importing patented drugs or medical devices for an enterprise for the purpose of seeking administrative approval, shall not constitute patent infringement.” This enables local manufacturer to embark upon the preparation for manufacturing of a patented drug well before the patent expires and to be

ready to compete with the patent holder immediately after the patent expires (see details in the following section).

The innovations of medical devices and instruments and drug packaging are usually protected under utility models or industrial designs.

Measures on Compulsory Licensing for Patent Exploitation—Order No. 64 of the State Intellectual Property Office (2012)

State Intellectual Property Office of China issued a patent law amendment on March 15, 2012. This new law favors the fighting for cheaper drugs. This new law has overhauled parts of its intellectual property laws to allow the Chinese local manufacturers to make cheap generic drugs still under patent protection from foreign pharmaceutical companies.

The Chinese new law “Measures on Compulsory Licensing for Patent Exploitation—Order No. 64 of the State Intellectual Property Office” (SIPO 2012) was issued just after a few months of a similar move called “compulsory license” by India to effectively end the monopoly on an expensive cancer drug made by Bayer AG. Such compulsory Licensing has also previously been issued in Malaysia, Indonesia and Thailand, as well as on multiple occasions by developed countries including the U.S. and EU member countries.

Based on the new patent law, the Chinese government may issue compulsory licenses to eligible local pharmaceuticals to produce generic versions of patented drugs during state emergencies, or unusual circumstances, or in the interests of the public. In addition, the local pharmaceuticals can also apply to export these drugs to other countries. Compulsory licenses are available to nations to issue under the World Trade Organization (WTO) rules in certain cases where life-saving treatments are unaffordable. The effective date of the amended patent law “Measures for the Compulsory Licensing for Patent Implementation” was May 1, 2012.

China and India are ranked as the top two countries for manufacturing active pharmaceutical ingredients (APIs) for years. Western countries buy those APIs from China, and then sell the patented drugs back to China at prices only a very limited Chinese can afford. Technically, it is not a hard work for local Chinese pharmaceuticals to make the generic versions of the majority of the patented drugs. However, the current patent laws still provide a very reliable way for drug protection. This patent law amendment is more likely to affect the drugs for the treatment of medical emergencies or unusual circumstances, or in the interests of the public, such as SARS or AIDS etc. A reasonable balance between the patented drug prices and medical needs may also play a role for the measure on compulsory licensing decision by the Chinese government.

Administrative Protection—Monitoring Period (Marketing Exclusivity)—3–5 years for new drug and new formulation after first approval in China. Only apply for locally manufactured products (SFDA 2007).

In addition to patent protection, China also established a special administrative protection system (monitoring period protection, see Figs. 2.3 and 2.4) for new drugs. SFDA provide administrative protection to pharmaceutical companies by granting licenses and permits, which gives these companies certain exclusive rights. The current administrative protection policies for drugs have become effective since

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