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,
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](image)

**Table 2.1** Patent protection in China

| Drug listing date | Protection period (Years) |
|-------------------|---------------------------|
| 1987–1993         | 15                        |
| 1993–Present      | 20                        |
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.
Pharmaceutical Intellectual Property Rights in China

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 2.3 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.
| Monitoring period | Chemical drug | Therapeutic biological product | Preventative biological products |
|-------------------|--------------|-------------------------------|---------------------------------|
| 5 (Year)          | 1. Among those not yet marketed domestically or overseas: | 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 leprospirosis 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 |
|                   | 3.1 Preparation marketed overseas, and/or preparation with change in dosage form of the preparation but without change in route of administration | 7. A product that is marketed already overseas but not yet marketed domestic | 7. Combined vaccine prepared with vaccine already marketed domestic |
|                   | | 8. Micro ecological product, where some of the strains used for preparing of microecological products not yet approved | 8. Re-combination vaccine with protective antigen spectrum different with the marketed one |
| Monitoring period | Chemical drug | Therapeutic biological product | Preventative biological products |
|-------------------|---------------|--------------------------------|---------------------------------|
|                   |               | 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 (Year)          | 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 its preparation 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.
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
2002. The monitoring period of a new drug is 5 years from the date of approval to manufacturing the drug. During a new drug’s monitoring period, the SFDA will not give permission to other enterprises to make, modify or import drugs of the same type to ensure that the protected drug manufacture enjoys certain degree of exclusivity (Figs. 2.3 and 2.4).

Trade Secret
In China, trade secrets are protected mainly under the PRC Anti-Unfair Competition Law (Standing Committee of the National People’s Congress 1993); The protections under this law provide the advantages to the entitled pharmaceutical companies to prohibit others from the following acts: (a) any attempt to obtain the trade secrets from their rights holders by theft, coaxing, coercion or any other unlawful means; (b) disclosing, using or allowing others to use trade secrets being obtained through any of the above means; (c) in breach of confidentiality obligations to the right holders regarding the trade secrets, disclosing, using or allowing others to use the trade secrets; or (d) prohibiting any third party from obtaining, using, or disclosing of other party’s trade secrets when the third party is or should have been aware of the existence of any illegal acts mentioned above. Trade secret provides intellectual property protection in the biological and pharmaceutical sectors from other angle.


**Fig. 2.4** Revoke procedure of administrative protection for pharmaceuticals. (Source: China Food and Drug Administration website with modifications)

**A Registered Trademark**
A registered trademark in China is valid for 10 years starting from the registration date of the trademark. The term of validity of a registered trademark can be extended infinitely upon renewal. In addition to trademarks, some drugs which satisfy certain requirements may also distinguish themselves from comparable products by using a unique drug “commodity name”. However, such drug commodity names must follow the naming rules imposed by the pharmaceutical administrative supervision department.

**Data Exclusivity**
Based on China’s Regulations on Drug Registration, data submitted to the SFDA for approval containing a new chemical entity is protected for 6 years from the date of marketing approval. As such, other companies must create their own data (the full NDA package—following Class I or III new drug requirement) to support a competing drug registration.
2.4 Strategic Consideration of Pharmaceutical Product Protection

Strategic thinking of the pharmaceutical product protection needs integrated information. For the products still have a long period of patent protection, the protection path seems very straightforward. However, many foreign companies often concern about how to protect their pharmaceutical products with only a limited patent protection period left, or simply facing a patent expiration, or without a patent protection.

Up to date, many international companies selected not to apply for patents in China. The consequence is that their pharmaceutical products are not protected by patents in China.

For the drug without a patent or patent already expired, the companies should consider whether there is still a market need, or whether they can still make it as the first in class drug in China since they may still take the favor to set the price high, to block or influence the profit of the latter potential generic versions.

Alternatively, the companies may consider the following strategies:

**Monitoring Period Exclusivity** If the new drug is manufactured in China, the monitoring period exclusivity imposed by SFDA may provide an up to 5 years protective period.

This period may vary from 3 to 5 years depending on the category of the new drug. During the this period, the SFDA will not approve any other companies to manufacture, distribute, or import this drug, unless the competing investigational product has been approved for entering clinical trials in China prior to the beginning of the monitoring period. Since this protection will not apply to the imported drugs, the foreign pharmaceutical companies may consider local manufacturing, or partnering strategies to take the advantage of this protection policy.

**Data Exclusivity** Due to the 6 years data protection, other companies must create their own data (the full NDA package—following Class I or III new drug requirement) to support a competing drug registration. Foreign pharmaceutical companies without a valid patent protection may market their new chemical entity drug in China to take the advantage of this approach. New drugs in the Class I category may leave significant hurdles for competitors to develop their generic version, especially for the drugs without many available publications. Comparatively, new drugs in the Class III category may be easier for other applicants due to the much open policies of the western regulation.

**Other Considerations** In addition to the above thought, the foreign pharmaceutical companies may also take the following factors for consideration including: difficulty factors for manufacturing the new chemical or biological entity, trade secrets, registered trademark etc.
2.5 Pharmaceutical Patent Litigation

China surpassed the United States to become the top patent filing country in the world in 2011 by obtaining 526,412 invention patent applications, compared to 503,582 utility patent applications in the US. One of the major reasons is the attractive incentives originated from the Chinese government (Zhao 2012). In 2008, the Chinese government issued the National Intellectual Property Strategy and various incentive programs. Those programs provided generous funding to encourage domestic companies, research institutes, and universities to seek patent protection for their innovations. These incentives have significantly boosted the new patent filings by Chinese domestic companies. While at the same time, China has become the world’s top litigious country for intellectual property disputes since 2005 with a total of 13,424 cases filed with Chinese courts (Figs. 2.5 and 2.6) versus 10,905 cases filed in the U.S. during the same period (SIPO 2006).

China’s Regulations on Drug Registration require a drug manufacturer to declare that it does not infringe any third-party patent when filing a registration application.

![Diagram](source.png)

Fig. 2.5 Infringe settlement procedure of Administrative Protection for Pharmaceuticals (APP). (Source: China Food and Drug Administration website with modifications)
A generic drug manufacturer may file for registration with the SFDA 2 years prior to the expiration of a patent. The SFDA will review the application but withhold approval until patent expiration in China. In addition, a patentee may, on the basis of an infringement judgment, request the SFDA to revoke an approved drug registration.

However, there are still a significant number of international companies have selected not to apply for patents in China. As such, many of their pharmaceutical products are not protected by patents in China.

Once a dispute on infringement happens in China, as in other countries, litigation instituted by intellectual property owners is the most effective way to solve the problem. In general, China has two routes for enforcing IP rights: administrative procedures and judicial actions (Fig. 2.5).

**Administrative Procedures** Depending on the nature of intellectual property rights and infringement, the IP owner can ask the State Administration for Industry and Commerce, the Public Security Department, the Copyright Office, the Trademark Office, or the State Intellectual Property Office (SIPO) to enforce intellectual property rights through inspection, seizure, reprimand, and fines. The administrative decisions in China are subject to judicial review.

It is suggested that upon identifying infringing products, the intellectual property owners can request Chinese customs to seize such products in an effort to prevent their export. To facilitate customs enforcement, the IP owner should record its copyrights, trademarks, and patents with the General Office of Chinese Customs.

**Judicial Actions** China has a four-level court system: (1) the Basic People’s Court; (2) the Intermediate People’s Court; (3) the Higher People’s Court; and (4) the Supreme People’s Court (Bai 2007). See Table 2.5.

The Supreme People’s Court is the highest court in China. It handles appeals from lower courts and issues judicial interpretations and guidelines to clarify legislation or to harmonize lower-court procedures. The Supreme People’s Court has its own intellectual property chambers within the courts to hear patent cases. These chambers have the power to determine permanent injunction, preliminary injunction, and damages.

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**Fig. 2.6** Patent lawsuits in China, 2004–2011. (Source: PRC State Intellectual Property Office White Papers, 2004–2011)
There is one higher people’s court in each province, autonomous region, and certain large cities that have the rank of a province, such as Beijing, Shanghai, and Tianjin.

Each major city has one or two Intermediate People’s Courts, which have jurisdiction over first-instance patent-related civil disputes.

Each county or district in each major city has one Basic People’s Court. China has a “two instance” judicial system—the decisions of the court of first instance can be appealed to the court at the higher level, which makes what essentially is a final decision.

The court has authority to order pretrial injunctions to stop infringement and collect infringement evidence. The court may impose statutory damages, award to the patentee reasonable expenses incurred in halting the infringing act. Upon winning a lawsuit, the IP owner is entitled to an injunction to deter infringement in China. China has become a major ground for patent disputes. More and more Chinese companies and foreign companies are likely to resort to the counts to resolve patent disputes.

| Table 2.5 The four-tier court system and their functions |
|----------------------------------------------------------|
| Pharma | Court System | Function |
|---------|--------------|----------|
| | The Supreme People's Court | The highest court in China; Handling appeals from Higher People's Courts; Issues judicial interpretations and guidelines to clarify legislation or harmonize lower-court procedures. Determine permanent injunction, preliminary injunction, and damages. |
| | The Higher People's Court | One higher people's court in each province and certain large cities that have the rank of a province, such as Beijing, Shanghai, and Tianjin. |
| Infringe Law Suit $\rightarrow$ | | |
| | The Intermediate People's Court | Each major Chinese city has one or two Intermediate People's Courts. |
| | the Basic People's Court | Each county or district in each major city has one Basic People's Court. |
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