Featured Article

Trademark Protection and Enforcement Pathways for Pharmaceutical Products in China

In the pharmaceutical sector, trademarks not only represent corporate goodwill and core competitiveness but also serve special social functions, such as guiding patients in using medications safely, identifying drug sources, and safeguarding public health. A distinctive pharmaceutical trademark serves as a trust bridge connecting pharmaceutical manufacturers, medical institutions, and consumers. Because of the unique nature of pharmaceutical trademarks, their protection involves distinctive features that differ from those of ordinary trademarks.

At the same time, with the booming development of China's pharmaceutical market, increasing emphasis is being placed on brand building in the industry. Driven by substantial profits, trademark infringement and counterfeit practices in the pharmaceutical sector remain rampant, severely disrupting market order and posing potential threats to patients' lives and health.

This article aims to outline the legal framework for pharmaceutical trademark protection in China, highlight its special characteristics compared to trademarks for ordinary goods, summarize the main challenges and difficulties in current enforcement practices, and provide a reference for pharmaceutical companies and rights holders in developing effective trademark protection and enforcement strategies.

I. Legal Framework and Special Regulations for Pharmaceutical Trademark Protection

China's pharmaceutical trademark protection system consists of multiple levels of laws. It follows general trademark protection principles but also creates rules specific to pharmaceuticals.

Under the Trademark Law, a submitted trademark must be distinctive and easy to identify. For pharmaceuticals, there is tension between this requirement and the desire to describe the product's function. Marks that indicate the function, use, or main ingredients—or that consist of just the generic name or shape—generally cannot be registered because they lack distinctiveness. China maintains strict examination standards for distinctiveness. As a result, many pharmaceutical trademarks are rejected for lacking distinctiveness or being potentially misleading.

The principle of non-functionality states that trademark protection should not hinder normal product use or give a technical advantage. This is crucial when examining non-traditional trademarks, such as specific colors or capsule shapes, for pharmaceuticals.

As a special category of goods, pharmaceuticals are subject to greater public-interest scrutiny during trademark registration. Article 10, Paragraph 1, Item (7) of the Trademark Law explicitly stipulates that "signs that are deceptive and likely to mislead the public as to the characteristics, such as the quality, or the place of origin of the goods" shall not be used as trademarks. For instance, the China National Intellectual Property Administration (CNIPA) once rejected the trademark "Ostelin" on the grounds that it conveyed the meaning of "calcitriol" and was therefore deceptive under the aforementioned provision. However, the Beijing Intellectual Property Court later overturned this decision, ruling that CNIPA lacked sufficient evidence to prove that the trademark conveyed the meaning of "calcitriol."[1] This case illustrates that the CNIPA applies a relatively stringent standard under Article 10, Paragraph 1, Item (7).

A more critical aspect lies in the delineation between pharmaceutical generic names and trademarks. According to the Pharmaceutical Administration Law and the Principles for Naming Chinese Pharmaceutical Generic Names, a drug's generic name is a nationally standardized, legally prescribed designation with public domain attributes. No enterprise may register or monopolize its use as a trademark. Once a term becomes a pharmaceutical generic name, it can no longer be used as a trademark for drugs. However, under specific circumstances, if a generic name has acquired distinctiveness and established a direct

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association with a particular trademark holder, it may still be eligible for trademark registration, as illustrated in the case of "百艾洗液" (Bai'ai Lotion)[2].

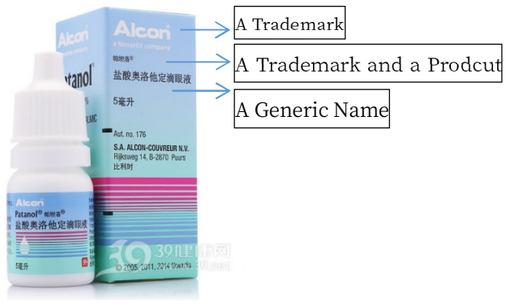
Beyond the Trademark Law, the protection of pharmaceutical trademarks is embedded within a broader legal framework, including the Pharmaceutical Administration Law and the Regulations on Drug Labeling and Package Insert Management. The intersection of multiple legal domains frequently gives rise to several common issues in pharmaceutical trademark protection:

1. Whether Registered Trademarks Must Be Used on Pharmaceuticals:

While neither the Trademark Law nor the Pharmaceutical Administration Law explicitly mandates the use of registered trademarks on pharmaceutical products, Article 27 of the Regulations on Drug Labeling and Package Insert Management clearly prohibits the use of unregistered trademarks in drug labeling and package inserts. Therefore, in practice, pharmaceutical companies are required to provide the registered trademark that will actually be used on the product when submitting new drug applications to regulatory authorities. This indicates that trademarks used on pharmaceuticals must be registered and approved by the China National Intellectual Property Administration.

2. Regarding Drug Names and Pharmaceutical Trademarks:

Typically, a drug has a chemical name, a generic name, and a product name. The chemical name refers to the precise name based on the chemical structure of the active ingredient, assigned according to internationally accepted chemical nomenclature rules. The generic name is the official name designated by the Chinese Pharmacopoeia Commission in accordance with the Principles for Naming Chinese Pharmaceutical Generic Names, and it serves as the common name for drugs with identical active ingredients or formulations in China. The product name, on the other hand, is designated by pharmaceutical manufacturers for sales and branding purposes to help consumers distinguish between similar products produced by different companies. Product names can be registered as trademarks. Consequently, in practice, product names and pharmaceutical trademarks often overlap.



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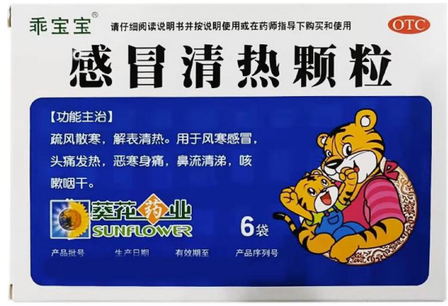
3. Differences in Drug Naming Among Original Drugs, Generic Drugs, and OTC Products

Original drugs refer to brand-name medications that are first developed and successfully marketed through original research. These drugs have both a generic name and a product name, but they may not necessarily have a chemical name. This is because original drugs include both chemical and biological medications, and many biological drugs do not have a traditional chemical name. In traditional Chinese medicine (TCM), there is also the concept of innovative TCM drugs. These drugs are typically not composed of a single active ingredient, which is why they often lack a chemical name.

In China, generic drugs are categorized into chemical generic drugs and biosimilars. Similarly, in the TCM field, there are TCM products with the same name and formula. For the reasons mentioned above, generic drugs and TCM products with the same name and formula may also lack a chemical name. Regarding chemical generic drugs, their generic names should be consistent with those of the original drugs, but their packaging must not cause confusion under the Anti-Unfair Competition Law. For biosimilars, specifically recombinant therapeutic biotechnological products, China follows the principles adopted by most countries internationally. Both domestically marketed original biological products (biological original drugs) and non-original biological products (including biosimilars) with identical active ingredient structures and mechanisms of action share the same generic name. Chemical generic drugs and biosimilars are not permitted to use product names.

OTC (Over-the-Counter) drugs can have product names and generic names but may lack a chemical name. This is because OTC drugs mainly include chemical drugs and TCM products, and TCM-based OTC drugs typically do not have a chemical name. Additionally, while biological drugs have entered the OTC market, their complex mechanisms of action and higher safety risks have resulted in relatively few globally approved OTC biological drugs.



(An OTC traditional Chinese medicine has a generic name but no chemical name.)

Pharmaceutical trademarks are subject to unique legal provisions, creating a distinct legal framework for their protection. This framework also poses several practical challenges.

II. Enforcement and Criminal Protection of Pharmaceutical Trademarks

The protection system for pharmaceutical trademarks follows a "dual-track" model—administrative and judicial—similar to that of regular trademarks. At the administrative level, pharmaceutical trademarks are governed by various laws, including the Trademark Law, the Anti-Unfair Competition Law, and the Pharmaceutical Administration Law. Drug regulatory authorities and market supervision departments have the authority to investigate and penalize infringements within their respective jurisdictions. Additionally, customs officials can detain suspected infringing pharmaceuticals under the Regulations on Customs Protection of Intellectual Property Rights.

In terms of judicial protection, the enforcement of pharmaceutical trademarks primarily occurs through civil and criminal litigation. The criteria for determining infringement in civil litigation and the factors considered in trials largely mirror those in general trademark infringement cases; these will not be discussed further here. Instead, the following discussion will concentrate on the criminal protection of pharmaceutical trademarks.

1. Major Crimes Involving Criminal Protection of Pharmaceutical Trademarks

China's *Criminal Law* includes specific provisions under Chapter III, "Crimes of Disrupting the Order of the Socialist Market Economy." The relevant offenses mainly fall into two categories:

First Category: Drug-Related Crimes

- Article 141: Crime of Producing, Selling, or Supplying Counterfeit Drugs
- Article 142: Crime of Producing, Selling, or Supplying Substandard Drugs
- Article 142(1): Crime of Obstructing Drug Administration
- Article 145: Crime of Producing or Selling Medical Devices That Do Not Meet Standards

Second Category: Trademark-Related Criminal Crimes

- Article 213: Crime of Counterfeiting Registered Trademarks
- Article 214: Crime of Selling Goods with Counterfeit Registered Trademarks
- Article 215: Crime of Illegally Manufacturing or Selling Illegally Manufactured Registered Trademark Identifiers

2. Judicial Determination of Key Concepts

In the first category of drug-related crimes, the first step is to determine whether the product in question qualifies as a drug, and to define what constitutes a counterfeit drug or a substandard drug. A drug is defined as a substance used for the prevention, treatment, or diagnosis of human diseases, intended to regulate physiological functions, and specified with indications, functional indications, usage, and dosage. This definition encompasses traditional Chinese medicines, chemical drugs, biological products, and others. Therefore, only if the product is classified as a drug can it potentially be involved in the aforementioned drug-related crimes. If the product lacks the attributes of a drug, the legal provisions for drug-related crimes cannot be applied.

However, the attribute of being classified as a drug does not necessarily mean that the product contains drug ingredients. In practice, relevant authorities may conduct tests to determine the presence of drug ingredients. Furthermore, whether a product qualifies as a drug can depend on several factors, including whether the seller has marketed it as a therapeutic drug in product instructions or during the sales process, as well as consumers' perceptions at the time of purchase. Even if a product does not contain drug ingredients, it could still fall under the category of drug-related crimes.

For example, in Case 1 from the "Typical Cases of Crimes Endangering Drug Safety," published by the Supreme People's Court, titled "Huang Moulin et al. Producing and Selling Counterfeit Drugs—Using Non-Drugs Such as Chili Oil to Produce 'Huang Daoyi Huoluo Oil' and Other Drugs,"[3] the court determined that the defendants' act of selling non-drug substances, such as chili oil, under the guise of drugs constituted the crime of producing and selling counterfeit drugs.

According to the provisions of the Pharmaceutical Administration Law, the following circumstances constitute counterfeit drugs:
(1) The ingredients contained in the drug do not conform to those specified in the national drug standards;
(2) Non-drug substances are passed off as drugs, or one type of drug is passed off as another;
(3) The drug has deteriorated;
(4) The indications or functional indications stated on the drug exceed the prescribed scope.
Substandard drugs refer to:
(1) Drugs whose ingredient content does not comply with national drug standards;
(2) Contaminated drugs;
(3) Drugs without clearly marked or with altered expiration dates;
(4) Drugs without clearly marked or with altered batch numbers;
(5) Drugs that have exceeded their expiration dates;
(6) Drugs with unauthorized additions of preservatives or excipients; and
(7) Other drugs that do not meet drug standards.

From this comparison, it is evident that substandard drugs may contain genuine ingredients but do not meet the required quality standards. This can lead to reduced or unstable efficacy, which

3 https://www.court.gov.cn/zixun/xiangqing/412212.html

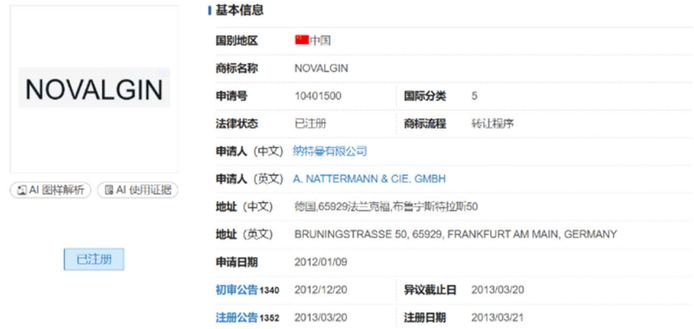
negatively impacts therapeutic expectations and medication safety. In contrast, counterfeit drugs contain false ingredients or are produced and sold without authorization, posing a direct threat to life and safety. This is illustrated in Case 5 of the "Typical Cases of Crimes Endangering Drug Safety," published by the Supreme People's Court. In this case, suspects sold non-drug substances—such as foaming agents, water, borneol, and brilliant blue—disguised as tinidazole gargle, thereby committing the crime of producing and selling counterfeit drugs.

The second category of trademark-related criminal focuses on the unauthorized use of a trademark that is identical to a registered trademark for the same type of goods or services. Key considerations in such cases include whether the trademark in question is identical or visually indistinguishable from another party's registered trademark, as well as whether the goods involved are identical to those approved for use under that registered trademark[4].

A common misconception is that if the infringing product contains effective drug ingredients and is not classified as counterfeit or substandard, it cannot be prosecuted under drug-related crimes. Instead, such an act should be addressed as the crime of counterfeiting a registered trademark. For instance, in the "NOVALGIN" case[5], since the product in question was a genuine medication, a court in Shanghai determined that the defendant's act of producing and selling goods bearing an identical trademark to a registered trademark for the same product constituted the crime of counterfeiting a registered trademark.

4 According to the Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in Handling Criminal Cases of Infringement of Intellectual Property Rights, the following circumstances shall be recognized as constituting "the same goods or services":
(1) The name of the goods actually produced or sold, or the name of the services actually provided, is identical to the name of the goods or services approved for use under the registered trademark of the rights holder.
(2)The names of the goods differ, but they are identical or substantially identical in terms of function, purpose, main raw materials, target consumers, sales channels, etc., and are generally regarded by the relevant public as the same goods.
(3)The names of the services differ, but they are identical or substantially identical in terms of purpose, content, method, target audience, location, etc., and are generally regarded by the relevant public as the same services.

The determination of "the same goods or services" shall be made by comparing the goods or services approved for use under the registered trademark of the rights holder with the goods actually produced or sold, or the services actually provided, by the actor. At the same time, with regard to the comparison of trademarks, the Interpretation requires that the trademark in question be identical to the counterfeited registered trademark or substantially indistinguishable from it. This includes:
(1)Altering the font, capitalization, or horizontal/vertical arrangement of the registered trademark.
(2)Changing the spacing between characters, letters, numbers, etc., in the registered trademark.
(3)Changing the color of the registered trademark, without affecting the distinctive features of the registered trademark.
(4)Adding only generic names, model numbers, or other elements lacking distinctiveness to the registered trademark, without affecting the distinctive features of the registered trademark.
(5)Being substantially indistinguishable from the three-dimensional signs or planar elements of a three-dimensional registered trademark.
(6)Other circumstances where the trademark is substantially indistinguishable from the registered trademark and is sufficient to mislead the relevant public.
5 (2020) HU 0107 Crim. First Instance No. 397



3. Concurrent Application of Pharmaceutical Crimes and Trademark Criminal Offenses

In criminal cases involving pharmaceutical products, the aforementioned two categories of offenses often overlap. As previously discussed, only when the product in question is recognized as a drug can it constitute a relevant pharmaceutical crime; otherwise, it may only be subject to charges such as the crime of counterfeiting a registered trademark. If the product is indeed a drug, further determination is required as to whether it qualifies as a counterfeit or substandard drug. If it does not meet the criteria for being counterfeit or substandard, the applicable charges remain trademark-related criminal offenses, such as the crime of counterfeiting a registered trademark. If the product is determined to be a counterfeit drug, it often constitutes an overlap of both types of offenses. The Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Specific Application of Law in Handling Criminal Cases of Producing and Selling Fake or Substandard Commodities explicitly stipulates that when an act constitutes both the crime of producing or selling fake or substandard commodities and other crimes such as intellectual property infringement or illegal business operations, the offense with the heavier penalty shall be applied for conviction and punishment.

Therefore, when a suspect sells a product that qualifies as a drug and simultaneously infringes the registered trademark of that drug, judicial authorities must apply the heavier penalty for either offense. If the suspect sells a product that qualifies as a drug but infringes a trademark that is not the registered trademark of that drug, each act must be evaluated separately, potentially resulting in combined penalties for multiple offenses.

The criminal protection of pharmaceutical trademarks involves two major categories of offenses under the Criminal Law: pharmaceutical crimes and trademark crimes. In judicial practice, it is essential to accurately determine the legal attributes of the product in question (whether it is a drug, counterfeit drug, or substandard drug) and the status of trademark infringement. In cases of overlapping offenses, the principle of "applying the heavier penalty" serves as the fundamental rule to ensure that the punishment fits the crime, thereby comprehensively safeguarding the order of the pharmaceutical market, public health and safety, and the legitimate rights and interests of trademark holders. When enforcing their rights, trademark holders should, based on

the specifics of the case, select the most advantageous legal pathway and emphasize providing key evidence during administrative investigations and criminal complaints to substantiate the product's attributes and the facts of infringement.

Due to their close association with life and health, pharmaceutical trademarks are subject to far stricter legal constraints than ordinary trademarks, including distinctiveness review, public-interest balancing, and naming conventions. This also dictates that enforcement practices for pharmaceutical trademarks must balance professionalism with complexity. Currently, China has established a multi-level protection system encompassing laws such as the Trademark Law, the Pharmaceutical Administration Law, and the Criminal Law. However, practical challenges remain in areas such as determining pharmaceutical attributes, assessing trademark similarity, and applying overlapping offenses, requiring careful consideration by law enforcement and judicial authorities in specific cases. For pharmaceutical enterprises, building an effective trademark strategy involves not only proactively mitigating registration risks and standardizing packaging and labeling, but also flexibly leveraging administrative complaints, civil litigation, and criminal reporting to build a multidimensional enforcement network when infringement occurs.

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Ms. YIN is very experienced both in trademark prosecution and enforcement aspects, particularly in handling sophisticated trademark administrative/civil litigation cases. Ms. YIN has represented many renowned international enterprises and successfully made their marks to be recognized as well-known marks. The clients she served covered different industries, which included pharmaceuticals, chemistry, food, clothing, cosmetics, international hotels, and media. One trademark administrative litigation case she represented was selected as an "Excellent Trademark Litigation Case" by the CTA in 2015. In 2016, Ms. YIN represented a Japanese client to successfully safeguard its prior copyright before the Supreme People's Court. Other meaningful cases she won covered trademark issues, such as prior trade name, trademark dilution, distinctiveness, and trademark squatting. In 2021, Ms. Yin won a civil litigation case for a famous international pharmaceutical company, where the court awarded huge damages.

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