



2022.04

QUARTERLY

NEWSLETTER

PANAWELL INTELLECTUAL PROPERTY



Cover: Interior of office block where Panawell locates

TABLE OF CONTENTS



Panawell Intellectual Property, consisting of Panawell & Partners, LLC and Panawell & Partners Law Firm, provide full spectrum of services in all fields of intellectual property rights, such as patent, trademark, copyright, computer software, anti-unfair competition, trade secrets, custom protection, domain name, license, assignment, enforcement, administrative and civil litigation, IP consulting and management.

03 INSIGHT

- 2022 World Intellectual Property Day Is Coming
- Statistics of Patent Grants and Trademark Registrations in 2021 in China
- China's Supreme Court Issued Judicial Interpretation of Anti-Unfair Competition Law
- CNIPA Stopped Issuing Paper Patent Certificates
- China Officially Joined the Hague System and Marrakesh Treaty

07 SOLUTION

- An Overview of Pharmaceutical Patent Link System in China

11 TIPS

- What are the Formality Requirements for Chinese Patent Applications Related to Biological Material Sample Deposit?

12 FIRM

- Panawell to Set up Branch in Ningbo

2022 World Intellectual Property Day Is Coming

Since 2001, the World Intellectual Property Organization has designated every April 26 as the World Intellectual Property Day, to learn about the role that intellectual property rights play in encouraging innovation and creativity.

According to WIPO, the World Intellectual Property 2022 recognizes the huge potential of young people to find new and better solutions that support the transition to a sustainable future. Across the globe, young people are stepping up to innovation challenges, using their energy and ingenuity, curiosity and creativity to steer a course towards a better future. Innovative, energetic and creative minds are helping to drive the changes we need to move to a more sustainable future. Discover how intellectual property rights can support the youth of tomorrow to create a better future. This year the theme of World Intellectual Property Day is "IP and Youth: Innovating for a Better Future" and celebrates youth-led innovation and creativity. The youth of today are an incredible and largely untapped source of ingenuity and creativity. Their fresh perspectives, energy, curiosity and "can do" attitude, not to mention their hunger for a better future, are already reshaping approaches and driving action for innovation and change. World Intellectual Property Day 2022 is an opportunity for young people to find out how IP rights can support their goals, help transform their ideas into reality, generate income, create jobs

and make a positive impact on the world around them. With IP rights, young people have access to some of the key tools they need to advance their ambitions. Throughout the campaign, young people will be able to gain a better understanding of how the tools of the IP system – trademarks, design rights, copyright, patents, plant variety rights, geographical indications, trade secrets and more – can support their ambitions to build a better future. WIPO also review their role in supporting national and regional efforts to create a legal and policy environment for young inventors, creators and entrepreneurs to thrive. The engagement in World Intellectual Property Day last year was at record levels, and it is expected that World Intellectual Property Day 2022 will reach new heights. Young people are the innovators, the creators and the entrepreneurs of tomorrow. Through their creativity and ingenuity, young people in all regions are driving change and carving pathways to a better future. World Intellectual Property Day 2022 celebrates this exciting generation of change-makers .

(Source: official website of WIPO)

Statistics of Patent Grants and Trademark Registrations in 2021 in China

In January 2022, the China National Intellectual Property Administration (CNIPA) released the statistical data on patents granted by and trademarks registered with the CNIPA in 2021.

Number of Chinese Patents Granted in 2021

	Invention	Utility Model	Design
Total	695,946	3,119,990	785,521
Chinese Applicants	585,910	3,112,795	768,460
Foreign Applicants	110,036	7,195	17,061

Number of Valid Patents till December 2021

	Invention	Utility Model	Design
Total	3,596,901	9,243,443	2,580,532
Chinese Applicants	2,773,287	9,190,633	2,453,506
Foreign Applicants	823,614	52,810	127,026

Number of PCT International Applications Received by CNIPA in 2021

Total	73,434
Chinese Applicants	68,338
Foreign Applicants	5,096

Number of Trademark Registration in 2021

	Registered Trademark	Valid Registered Trademarks till Dec. 2021
Total	7,738,947	37,239,520
Chinese Applicants	7,545,358	35,322,797
Foreign Applicants	193,589	1,916,723

In this regard, it is particularly notable that in order to heavily crackdown on the abnormal patent

applications, ensure the delivery of the legislative purpose of the Patent Law to encourage genuine innovation activities, and comprehensively improve the quality of patents, the CNIPA would no longer publish statistical data on the number of patent filings from the end of 2021, with an effect of curbing blind pursuit the amount of patent filings by the administrative regions and applicants. To this effect, enhanced IP governance by virtual of introduction of a variety of laws and regulations has brought good initial results.

(Source: official website of CNIPA)

China's Supreme Court Issued Judicial Interpretation of Anti-Unfair Competition Law

On March 17, the Interpretation of the Supreme Court on Several Issues Concerning the Application of the Anti-Unfair Competition Law of the People's Republic of China (hereinafter referred to as "the Interpretation") was released, which has come into force since March 20, 2022. The Interpretation has a total of 29 articles. In the revised Anti-Unfair Competition Law have been set forth detailed provisions on issues, such as Article 2 of the Law, counterfeiting and confusion, false publicity, and online unfair competition.

The Interpretation is an important measure taken by the Supreme Court to give full play to the role of intellectual property adjudication and respond to the judicial needs imposed by new fields and new business forms in a timely manner. Implementation

of the Interpretation is of great significance for strengthening the anti-unfair competition judiciary, enhancing the basic position of the competition policies, and promoting the formation of a domestic unified market with high efficiency, standardization and fair competition.

(Source: the Intellectual Property Tribunal of the Supreme Court)

CNIPA Stopped Issuing Paper Patent Certificates

On February 9, 2022, the China National Intellectual Property Administration released the Announcement No. 472 on the Adjustment of the Way of Issuing Patent Certificates for Electronic Patent Application, which notified that from March 1, 2022, the CNIPA would stop receiving requests for paper patent certificate of electronic patent applications, and would only issue electronic patent certificates through the electronic patent application system.

Before March 1, 2022, for electronic patent applications with a grant announcement date between March 3, 2020 and February 25, 2022, the applicant, if needed, could submit a request and obtain a paper patent certificate through the CNIPA's patent electronic filing website (<http://cponline.cnipa.gov.cn>).

The implementation of this announcement shows that the Chinese patent certificates have fully entered the electronic age.

(Source: official website of CNIPA)

China Officially Joined the Hague System and Marrakesh Treaty

On February 5, 2022, China officially joined two key treaties of the World Intellectual Property Organization, the Hague System and the Marrakesh Treaty, both of which will officially enter into force in China on May 5, 2022.

While attending the opening ceremony of 2022 Beijing Winter Olympic Games, WIPO Director General Daren Tang received China's accession document to the 1999 Geneva Act of the Hague Agreement from Changyu Shen, the Commissioner of China National Intellectual Property Administration. It is noted that Chinese residents filed a total of 795,504 designs in 2020, representing some 55% of the worldwide total. China's entry into the Hague System will make it easier and cheaper for these designers to protect and promote their works overseas.

At the same time, Mr. Tang also received China's accession document to the Marrakesh Treaty from Jianchun Zhang, Vice Minister of National Copyright Administration of China. The Marrakesh Treaty is the only human rights treaty in the copyright field in the world so far, and will further guarantee the equal access to culture and education for people with blindness or visual impairments. With China's entry into the Marrakesh Treaty, people who are blind or have other visual impairments will benefit from having greater access to China's old and rich continuing literary and cultural traditions.

Background

About the Hague System

The Hague System provides a straightforward solution to international design protection. Applicants file one online international application and pay one set of fees to register up to 100 designs in more than 90 countries, which eliminates the need to file separate and multiple applications in individual countries or regions.

China's accession to the Hague System provides Chinese applicants with a flexible and convenient approach to international design protection, which greatly saves the applicants' cost and time. In fact, before China joined the Hague System, some Chinese enterprises such as Xiaomi and Lenovo have already used the Hague system to submit many international design applications, which shows that the Hague system can better meet their demand for an easier and faster way to operate internationally. The increasing demand from Chinese enterprises to apply for design patents overseas is the fundamental reason why China decides to join the Hague System.

The initial protection term for a design patent under Hague System is 5 years, after which the design can be renewed twice, to ensure at least 15 years protection. Where the national law of the designated country allows a longer design patent term, it will also apply to the international design under the Hague system. China's Patent Law revised in 2020 has extended the protection term

of design patents to 15 years, making preparation for joining the Hague System.

(Note: The instrument of accession also specified that the 1999 Act will not be applied in the Hong Kong Special Administrative Region or the Macao Special Administrative Region of the People's Republic of China until otherwise notified by the Government of the People's Republic of China.)

About the Marrakesh Treaty

The WIPO-administered Marrakesh Treaty makes the production and international transfer of specially-adapted books for people with blindness or visual impairments easier, by establishing a set of limitations and exceptions to traditional copyright law. It is WIPO's fastest growing treaty and includes 84 contracting parties before China's accession comes into force on May 5, 2022.

(Source: official website of WIPO)

An Overview of Pharmaceutical Patent Link System in China

Source: Official Website of CNIPA

By pharmaceutical patent link is meant a link of pharmaceutical approval with patents for the purpose of resolving patent disputes and addressing infringement risks before pharmaceuticals are launched in the marketplace. On July 4, 2021, China National Medical Products Administration and National Intellectual Property Administration jointly issued the *Measures for the Implementation of the Mechanism for Early Settlement of Drug Patent Disputes (interim)* (hereinafter referred to as "the Measures"), and the Patent Information Registration Platform for Marketed Drugs was formally put into operation on the same day. On July 5, the CNIPA released the *Measures for Administrative Adjudication of Early Settlement Mechanism on Drug Patent Disputes*, and on the same day the Supreme Court released the *Provisions on Several Issues Concerning the Application of Law to the Trial of Civil Cases of Patent Disputes Related to Drugs for Registration*. The implementation of series of measures and rules shows that the pharmaceutical patent link system has been officially launched in China.

The main contents of the Measures include, among other things, the platform construction and information disclosure system, patent right registration system, generic pharmaceutical patent declaration system, judicial link and administrative link system, approval waiting period

system, pharmaceutical review and approval categorizing system, and first generic pharmaceutical market exclusivity system.

Following is an overview of the main parts of the pharmaceutical patent link system.

I. Pharmaceutical Marketing Authorization Holders to Register Patents

The pharmaceutical marketing authorization holders, usually original pharmaceutical development businesses or companies, shall register their registered patent-related pharmaceuticals or drugs with the CNMPA's Patent Information Registration Platform for Marketed Drugs within 30 days upon obtaining their pharmaceutical registration certificates, and update information within 30 days after any change in the patent information takes effect. In particular, the patent link system does not apply to registered pharmaceuticals with their patent information not registered on the patent information registration platform. Therefore, the original pharmaceutical development businesses with approved registration are advised to register all patent information of their registered pharmaceuticals or drugs at the earliest possible date.

The specific pharmaceutical patents registrable on the marketed pharmaceutical patent information registration platform include pharmaceutical active ingredient compound patents of chemical pharmaceuticals (excluding APIs), pharmaceutical composition patents containing active ingredients,

and pharmaceutical use patents; traditional Chinese medicine compositions of traditional Chinese medicine patents, Chinese medicine extract patents, and drug use patents; serial structure patents, and medical use patents of active ingredients of biological products. The relevant patents do not include patents relating to intermediates, metabolites, crystal forms, preparation methods, and detection methods.

II. Generic Pharmaceutical Applicants' Declarations

On the basis of the completed relevant patent registration of registered pharmaceuticals, a generic pharmaceutical applicant, when filing an application for a generic pharmaceutical marketing authorization, is required to make a declaration on the patent of the original pharmaceutical (that is, the originally developed pharmaceutical) registered on the NMPA's patent information registration platform. The declarations are of the following four types:

Type One Declaration: There is no patent information relating to the generic pharmaceutical on the patent information registration platform.

Type Two Declaration: The patent relating to the generic pharmaceutical included in the patent information registration platform has been terminated or declared invalid, or the generic pharmaceutical applicant has been licensed by the patentee to exploit the relevant patent.

Type Three Declaration: The patent information

registration platform enlists a patent relating to generic pharmaceutical, and the generic pharmaceutical applicant is committed not to launching the generic pharmaceutical in the marketplace before the expiry of the corresponding patent.

Type Four Declaration: The patent relating to the generic pharmaceutical enlisted or included in the patent information registration platform shall be declared invalid, or the generic pharmaceutical does not fall within the scope of protection of the relevant patent.

Regarding a generic pharmaceutical applicant's declaration, the NMPA will disclose the application information and corresponding declaration to the public on the information platform within 10 working days after the application is accepted, and the generic pharmaceutical applicant will notify the generic pharmaceutical marketing authorization holder. If the marketing authorization holder is not the patentee, the marketing authorization holder shall notify the patentee.

III. Dispute Resolution: Civil Litigation or Administrative Adjudication

If any patentee or interested party has objection to the four patent declarations, he or it may, within 45 days from the date when the NMPA publishes the application for pharmaceutical marketing authorization. They may file a lawsuit with the court or request the CNIPA for administrative adjudication on whether the relevant technical

solution of the pharmaceutical applied for marketing falls within the scope of protection of the relevant patent. An interested party, if dissatisfied with the CNIPA's administrative decision, may file a lawsuit in the court under the law after receiving the administrative decision. If the lawsuit involving the same patent dispute is docketed with the court, the CNIPA will not accept the request filed by the interested party for the administrative adjudication. Where a party files a request for invalidation of the patent involved during the court proceedings of the case, the CNIPA may not suspend the handling of the case. Administrative adjudication does not deal with issues of patent validity.

IV. Waiting Period for Initiation

For a generic pharmaceutical application, the NMPA will set a 9-month waiting period (calculated from the date of docketing or acceptance) for the registration application upon receiving a copy of notification on docketing by the court or acceptance in connection with the administrative adjudication. The waiting period is set only once, within which technical review is not suspended. In respect of the four types of declarations regarding traditional Chinese medicines and biological products, patentees and interested parties can also resolve disputes through civil litigation or administrative adjudication, but there is no waiting period set for approval.

V. Categorized Approvals

Applications for registration of pharmaceuticals

that have passed the technical review shall be dealt with by the NMPA in connection with the effective court or administrative decision:

(1) Falling into the scope of protection of relevant patents: Applications for registration of the relevant generic pharmaceuticals are transferred to the administrative examination and approval cycle before expiry of the term of the patent.

(2) Not falling into the scope of protection of the relevant patents or in case of settlement reached between the two parties: They are transferred to the administrative examination and approval cycle.

(3) The patent is invalidated: They are transferred to the administrative examination and approval cycle.

(4) With the waiting period exceeded and the effective court decision or mediation letter, or the CNIPA's administrative decision not received: They are transferred to the administrative examination and approval cycle.

(5) Where the effective court or the CNIPA's administrative decision is received, determining that it falls within the scope of protection of the relevant patent: Applications for registration of the relevant generic pharmaceuticals are transferred to the administrative examination and approval cycle before expiry of the term of the patent.

VI. Market Exclusivity Period

Regarding the first generic pharmaceutical having succeeded in challenging the patent (that is, the

Type Four Declaration is submitted and the relevant patent is declared invalid at request) and approved for marketing, the NMPA shall, within 12 months from the date of approval of the generic pharmaceutical, not approve any same generic pharmaceutical for marketing. But, the 12-month market exclusivity period system does not exist for traditional Chinese medicines and biological products.

The above is an overview of the pharmaceutical patent link system in China, which will tremendously change the market for the pharmaceutical businesses. All original pharmaceutical development and generic pharmaceutical businesses should fully study the new system, and utilize it to seek a favorable market position.

What are the Formality Requirements for Chinese Patent Applications Related to Biological Material Sample Deposit?

Under the Chinese patent rules, where an invention for which a patent is applied concerns a new biological material which is not available to the public and which cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant shall, no later than the date of filing (or the priority date where priority is claimed), deposit a sample of the biological material with a depositary institution designated by the China National Intellectual Property Administration, namely the International Depositary Authorities (IDA) under the Budapest Treaty. There are three IDAs located in China, i.e. China General Microbiological Culture Collection Center (CGMCC) in Beijing, China Center for Type Culture Collection (CCTCC) in Wuhan, and Guangdong Microbial Culture Collection Center (GDMCC) in Guangzhou.

At the filing of an application related to the deposit of a sample of the biological material, the applicant shall indicate in the request and the description the scientific name of the biological material (with its Latin name), the title and address of the depositary institution, the date on which the sample of the biological material was deposited and the accession number of the deposit and also submit the certificate of deposit and that of viability from the

depository institution (where the certificates are in foreign languages, a Chinese translation will be also needed). In case the applicant fails to provide such information and certificates at the time of filing, he can make rectification within four months from the filing date.

In respect of the Chinese national phase of PCT international applications, the applicant shall furnish indications to the International Bureau for the deposit of sample of biological material before the technical preparations for international publication have been completed, make such indications in the entering statement, and submit the certificate of deposit and the certificate of viability of the biological material (and Chinese translation thereof). Where the particulars of the deposit are included in the description in a way other than the form, the applicant shall indicate, in the entering statement under the specified items, the location, i.e., the page number and number of lines of the content concerning the deposit in the Chinese description. Where the particulars of the deposit are indicated in the Indications Relating to Deposited Microorganism or Other Biological Material (i.e. Form PCT/RO/134) or other separate sheet, such form or sheet shall be included in the international publication document, and be translated into Chinese as part of the international application at the time of entry into the national phase. In case the applicant fails to provide such information and certificates at the filing of Chinese national phase application, he can make rectification within four months from the date of entry.

Panawell to Set up Branch in Ningbo

Panawell is to set up a branch in Ningbo City, Zhejiang Province to meet the rapidly growing needs of our customers there for international intellectual property-related prosecution and legal services, especially to address the needs of the Ningbo-based enterprises which are top in single industry in the world for global patent technology circumvention and strategic distribution, the needs for the intellectual property rights protection in cross-border e-commerce, and the needs of would-be listed businesses for early intellectual property warning solutions, with an effect of providing better, more timely and efficient services to our clients in the Yangtze River Delta region.

Ningbo, China's giant industry-centered or oriented city with well-developed comprehensive industrial and manufacturing sectors, is an advanced manufacturing base and hub of petrochemical, auto and components, electrical appliance, textile and clothing industries, where the nation's many champion manufacturing centers are based. It is also one of the key metropolitan centers where an approved national independent innovation demonstration zone, and a national technological achievements transformation demonstration zone are situated. Besides, it is a pilot city offering nation-level intellectual property dispute mediation, and a key city for the construction of a national intellectual property operation service system, housing the China (Ningbo) Intellectual Property Protection Center, a Pilot Unit for Construction of the National Technical

Support System for IP Infringement Dispute Inspection and Appraisal, and the local sub-center of the National Guiding Center for Overseas Intellectual Property Dispute Response. The Supreme Court has approved the establishment of Ningbo Intellectual Property Court, with cross-regional jurisdiction over major IP cases in Ningbo, Wenzhou, Shaoxing, Taizhou and Zhoushan cities. Panawell's Ningbo Branch will be located on the 14th floor of Fengting Tower, Hefeng Creative Square near Sanjiangkou, the core urban center of Ningbo. The Hefeng Creative Square, now an important innovation platform built by the Ningbo government to build a new innovative city, upgrade the service industry, and optimize the industrial structure, has been turned into a hub of the city's industrial design industry, where 126 industrial design and cultural creation facilities are set up by well-known organizations from the Netherlands, Italy, Germany, the United Kingdom, Luxembourg and Spain, as well as those by renowned domestic institutions from Beijing, Shanghai, Guangzhou and Shenzhen.

Panawell, an intellectual property firm committed to providing professional IP services, has an outstanding team composed of dedicated professionals who, graduated from top universities with master or doctoral degrees in science and engineering, are competent of providing enterprises in Ningbo and the regions beyond with their quality professional services in the fields including electronics, communication, computer science, physics, material science, mechanics, chemistry, pharmaceuticals and biology.

PANAWELL & PARTNERS LLC

Addr: 1002-1005, 10th Floor, China Life Tower
16 Chao Yang Men Wai Street, Chaoyang District

Beijing 100020, China

Tel: (86 10)85253778

Fax: (86 10)85253671

Code: 100020

E-mail: mail@panawell.com

Website: www.panawell.com



Editor: Jane Wang
Lan Wang
Shute XU
Translator: Jane Wang
Yujing Zhang
Yazhi Zhao
Dan Jin
Layout: Shunshun Dong