

Pharmaceutical-Related Intellectual Property Protection



Intellectual property (IP) refers to creations of human intelligence. According to the World Intellectual Property Organization (WIPO), IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create. Literally, people have extended substantial efforts to strike the right balance between the interests of innovators and the wider public interest, the IP system aims to foster an environment in which creativity and innovation can flourish.

With the development of technology, some new industries are getting prosperous within the information society. The online economy is going to rise on a large scale in the future which means knowledge economy will be continuously developed. It is known to us

that intellectual property is an intangible right which is going to be explored and further protected as the economic trade grows. Pharmaceutical-related intellectual property is a comprehensive project which may involve many kinds of approaches to protect the owners' rights.

On January 16, 2020, China and the United States signed the first phase of the Economic and Trade Agreement between the Government of the People's Republic of China and the Government of the United States of America ("the Agreement"). Chapter I of the Agreement Provides for the 11 specific provisions of China-U.S. Intellectual Property Cooperation, and section 3 and 4 are pharmaceutical-related intellectual property rights provisions.

Undoubtedly, the United States has been very successful in Western medication. Whereas, China is the “Root” of Chinese medicines and has been putting great efforts in the advancement of medication by combining Chinese and Western medication. Pharmaceuticals are a matter concerning people's life and health, and there continues to be a need for finding new treatments and cures. At present, Wuhan coronavirus outbreak which makes the society and the whole country to pay highly attention to health protection. China and the United States will continuously cooperate in medication innovation and health care.

The agreement mainly focuses on three basic aspects of pharmaceutical-related intellectual property rights. It contains consideration of supplemental data, effective mechanism for early resolution of patent disputes and effective patent term extension.

Firstly, both countries should accept supplemental data as a method for pharmaceutical patent applicants to satisfy relevant requirements including sufficiency of disclosure and inventive step for patentability during patent examination proceedings, patent review proceedings, and judicial proceedings. It is likely for China and the United States to meet national requirements and standards easier for their products during patent application, pharmaceutical patent examination, patent review and even judicial proceedings. The easier to meet the relevant requirements for patentability, the more successful for the patents to bloom in both countries.

Secondly, the agreement provides an effective mechanism for early resolution of patent disputes. This regulation is closely tied to the market ingress with medication. Since pharmaceutical marketing takes some time, before the drug is listed, there may be others relying on previously disclosed information. In case of patent infringement, both countries should establish a stable system to notify the patentee, licensee or listing licensee about the situation which may make a bad influence during their drug marketing assessment. Furthermore, both

parties should set sufficient time and opportunities for the patentee to seek proper ways to save their products. Besides, the establishment of judicial or administrative procedures and expedited relief between the two countries. These would also help to resolve disputes timely and effectively. At the same time, China will establish a nationwide pharmaceutical-related system to ensure pharmaceutical patent owners are able to sue even before the permission of the drug's marketing. The Chinese government allows people to seek judicial procedures, administrative procedures and quick relief for the validity of the patent or any other dispute resolutions for the infringement.

Thirdly, the Agreement issues effective pharmaceutical patent term extension. Both China and the United States need to make some convenience for an extension of the patent validity to compensate for unreasonable delays in the patent licensing or drug market approval process. It defines an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in China, or three years after a request for examination of the application, whichever is later. In addition, with respect to patents covering a new pharmaceutical product that is approved for marketing in China and methods of making or using a new pharmaceutical product that is approved for marketing in China, China, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a

patent covering a new product, its approved method of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that product in China.

According to the article two of the Pharmaceutical Administration Law of the People's Republic of China, medicines are substances used to prevent, treat and diagnose human diseases, purposefully regulate a person's physiological function and provide for indications or functional treatment, usage and dosage, including Traditional Chinese medicine, chemical sages, and biological products. Pharmaceutical-related intellectual property protection is extremely important because people have to spend a lot of time and money to develop new drugs while it is much easier for others to copy it. Also, it has high potential profits which may attract many competent to go for it. Both China and the United States are highly concerned about the early resolution of drug patent disputes, which relies strongly on the technical support of the drug patent database. China and the United States should promptly notify the patentee, inform the potential infringer of the status quo of patent applications, encourage the rights holders to defend their rights, in order to protect the independent innovation and research and development of the pharmaceutical industry hard-earned rights and interests are not infringed. The



development of this database requires the government to take the lead, and at the same time introduce professional academy and experienced medical professions to contribute to the database of pharmaceutical-related intellectual property. Government, courts should jointly devote themselves to support it.

In short, pharmaceutical-Related Intellectual protection matters people's livelihood and has a great impact on daily life. Only when the government, courts and the whole society jointly make efforts can we make the medication industry intellectual property protection get better and supportive.