Patent Developments in the China Biotech/Pharma Sector

With a large number of overseas biomedical talents returned to China for development in the past decade, China's strong support for innovation in recent years, together with the introduction of a series of favorable policies by China Food and Drug Administration (CFDA) since 2015, China has now become a hot land for global pharmaceutical research and development.

As a critical factor in fostering the pharma and biotech innovation, patent protection is closely related to the pharma company's business strategy and its corporate valuation. What new developments in pharmaceutical IP protection in China require relevant companies, investors and IP practitioners to pay attention to, and what are the main differences from biotech/pharma IP protection in Europe and the United States?

In this Whitepaper and companion Webinar Ms. WANG Ying, a patent lawyer and partner of AnJie Law Firm will introduce (1) the outline of IP development in China, including the revised draft of the patent law, changes in IP litigation and the latest judicial interpretation on patent; (2) recent progress of China's patent linkage and data protection system; (3) introduction of typical litigation cases in the field of biomedicine, and (4) summarize the key issues and challenges that pharmaceutical company need to pay attention to.

(1) The Outline Of IP Development In China

Since the Specialized IP courts established in Beijing, Shanghai and Guangzhou in 2014, tremendous changes have been taken place in the IP judicial system. For examples, technology investigation officers are now widely used in patent or trade secret litigation cases to help with the technical facts finding. Although China is not a common law country, China now emphasizes more on the use of "guiding cases" or "leading cases" to improve the consistency of judgments and to guide local court to deal with controversial issues. There are more other changes, like damage increase, establishment of fifteen IP tribunals in China, the IP appellate court system under discussing, etc.

What's more, the revised draft of the patent law and the latest proposed Judicial Interpretation on Patent Grant and Invalidation Administrative Litigation are pending for discussion.

(2) Recent Progress Of China's Patent Linkage And Data Protection System

With the reform in drugs and medical device review and approval system since 2015, lots of new policies and regulations have been introduced by CFDA, to solve the

problem of backlog of drug review applications, to improve the quality of generic drug, to support innovation in drug and medical device, etc. One of the hot topics under discussion is the patent linkage and data protection system.

Patent linkage, data protection and patent term extension policies have been mentioned in a series of CFDA announcement and government opinions. For data protection, an Implementation Measures has been issued for public comments in April this year. Without doubt, patent linkage is a very comprehensive work which involves the coordination of CFDA, China National Intellectual Property Administration (CNIPA) and the court. Further, many other factors such as the social medical insurance system will also impact the effectiveness of patent linkage system. The timeline for all such patent linkage related reforms is uncertain.

(3) Typical Litigation Cases In The Field Of Biomedicine

CNIPA is quite strict in accepting supplementation of post-filing data, in evaluating inventive step and granting broad claim scope, etc. When evaluating the pharmaceutical related IP in China, the investors or pharma companies should adopt different standards taking into consideration of the development in the IP legislation and judicial activities. Four typical pharma cases will be introduced in this Whitepaper and companion Webinar.

The first case is about the amendment of Markush claim. The Supreme Court in its latest decision this year, reversed the Beijing High Court's judgement of allowing the patentee to delete some definitions of the groups in a Markush claim during the invalidation procedure, which supported the Patent Reexamination Board's (PRB) practice of rejecting amendments made to a Markush claim during an invalidation procedure. Such judgement implies, to make the patent more stable, when drafting or prosecuting the application, the applicant should add more dependent claims to cover any possibly valuable intermediate scopes based on the optimal compound.

The second case is about the scope of protein sequence. Biotech and Pharma companies were disappointed for a long time since CNIPA will only allow pretty narrow claims scope for protecting new gene or protein generally. In this case, the Supreme Court supports the PRB’s decision of allowing protein sequence claims to be limited by species and 99% identity together with the functional limitation. Although such claim scope is still narrow, it is much better than the scope of one specific sequence.

The third case discusses the principle of accepting supplementation of post-filing data during prosecution, invalidation or administrative litigation proceedings. CNIPA adopts a quite stricter rule in accepting post-filing data than patent offices in the U.S., Europe and Japan.

So far, the PRB and courts have the similar attitude of not allowing the patentee to submit post-filing data to prove the merely alleged technical effect in the specification. The applicant pursuing global patent protection shall understand such differences in China and try to disclose the data in the application document in a sufficient way when filing the application.

The fourth case is about the inventive step. In this case, the PRB and courts held the same opinion that although the patentee had provided the comparative data in the specification to show the inventive step, such data was not convincing and could not be concluded as an unexpected technical effect. Since Chinese government is now emphasizing more on the quality of the patent rather the quantity, the chemical companies should be even more careful in designing comparative examples in a more scientific and convincing way.

This Whitepaper and companion Webinar will be helpful to pharmaceutical companies, especially those multinational pharmaceutical companies, investors and IP practitioners.

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