Comments on Drug-Related Provisions in the Fourth Revision of the Patent Law

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On 17 October 2020, the 22nd Session of the Standing Committee of the 13th National People's Congress deliberated and passed the Decision on Amending the Patent Law. One of the most eye-catching amendments of the revised Patent Law is the amendments to drug-related provisions, including: Article 42 which is added with two new paragraphs on the restoration of the term of patent, and a newly-added Article 76 relating to the mechanism for early resolution of pharmaceutical patent disputes. By far, the relevant provisions on drug-related patent protection have been finalized after years of debates.

I. Background of the promulgation of drug-related provisions in the newly revised Patent Law

1. Special attention should be paid to the balance between private rights and the public interest for protection of pharmaceutical patents

The legislative purpose of the Patent Law is to protect the legitimate rights and interests of patentees, encourage inventions and creations, stimulate the application of inventions and creations, improve innovation capabilities, and boost scientific and technological progress, as well as economic and social development. Like other intellectual property laws, seeking a balance between the protection of patent rights, as a private right, and public interest (that is, boosting scientific and technological progress, as well as economic development) is an important issue that needs to be considered in the process of patent law legislation and enforcement.

That issue becomes more significant when pharmaceutical patents are involved. Drugs are a special commodity, and closely related to people's lives and health. Protection of pharmaceutical patents is not only concerned with the private rights of patentees (usually developers of new drugs), but also with the health and social welfare of the public. Therefore, for the sake of people's health and safe, reliable, and guaranteed medication, any country that implements a patent system needs to consider the specialty and accessibility of drugs while protecting patent rights. How to seek a balance between the protection of the interests of developers to encourage them to develop more new drugs, and satisfaction of the public's medication demand, as well as drug accessibility during the protection of drug patents is a typical manifestation of seeking a balance between private rights and the public interest under the patent law, which has attracted great social attention and is also involved in a great controversy.

2. Development of the drug-related patent protection legislation in China

By looking at the legislative development of the drug-related provisions in the China's Patent Law, we can tell that starting from scratch, China's drug patent protection has gone from strength to strength.

During the formulation of the first China's Patent Law passed in 1984, drugs have never been regarded as the subject eligible for patent protection, neither in various discussions during legislation nor in the final promulgation of the formal law. The most important reason for not granting patents for "pharmaceuticals and substances obtained by chemical methods" is that monopolies over drugs are "inadvisable due to their association with the public interest and people's lives", as well as "for the sake of protection of domestic industry and market". [1] "Since pharmaceuticals are closely associated with people's health or even lives, it is inadvisable to grant patents for drugs for policy consider-

ations. China is at a relatively low level in terms of new drug research and development (R&D), but powerful in generic drugs. In order to protect people's health and pharmaceutical industry in China, it is correct to grant no patents for pharmaceuticals at present." [2]

One of the important amendments in the First Revision of the Patent Law in 1992 was to delete the provision on no grant of patents for "pharmaceuticals and substances obtained by chemical methods" from Article 25, which broadened the scope of patent protection. The reason for such deletion is that "as for pharmaceuticals and substances obtained by chemical methods, it is quite essential to provide patent protection for those products so as to change the situation that imitation dominates China's chemical industry and pharmaceutical industry, boost technological progresses of those industries, stimulate the motivation of scientific and technical personnel in these fields, and attract foreign advanced technologies. In addition, removing restrictions and broadening the scope of protection make the China's Patent Law consistent with the tendency of international patent protection and legislations of most countries in the world, which is beneficial for promoting China's status and expanding its influence in the world." [3] Of course, it can also be regarded as the response to the relevant requirements of the Memorandum of Understanding on Intellectual Property Protection signed between China and the United States. Meanwhile, the revision also involves amendments to the conditions for compulsory licensing of patents. Article 52 of the 1992 Patent Law stipulates that "where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the Patent Office may grant a compulsory license to exploit the patent for invention or utility model", wherein a compulsory license implemented "where the public interest so requires" is obviously directed to pharmaceutical patents. As explained by the drafters of the Patent Law, "in the light of this provision, there are mainly two circumstances where a compulsory license can be applied for: … Second, a compulsory license shall be granted where the public interest so requires, wherein the public interest mainly refers to national defense, national economy and public health. For instance, when a country is in urgent need of a patented drug to stop the spread of some malignant infectious disease, if the patentee neither produces or imports the drug, nor allows others to do so, it abuses its patent right, and the Patent Office is entitled to permit others to produce or import/export the drug." [4]

During the third revision of the Patent Law in 2008, issues concerning drug - related patent protection also caused widespread controversy, and eventually led to the incorporation of the "Bolar exemption" provisions. As a populous country facing serious public health issues, China's incorporation of the "Bolar exemption" provisions into the Patent Law enables the public to have access to inexpensive generic drugs and medical devices in a timely manner after the expiration of term of drug and medical device patents, which is of great significance to solve the public health issues in China. [5] In addition, a new provision on compulsory licensing was added, that is, "under certain circumstances, the Patent Administration Department under the State Council may grant him or it a compulsory license to produce and export the patented drug". Through legislation, the China National Intellectual Property Administration (CNIPA) is authorized to grant compulsory licenses where the prescribed conditions are met, so as to allow Chinese enterprises to manufacture relevant patented drugs and export them to countries or regions which meet the requirements of the relevant international treaties that China joins with an aim of solving their public health issues. [6]

Furthermore, during the third revision of the Patent Law, some foreign pharmaceutical enterprises made a clear proposal to establish a patent term restoration system. In 2008, the then State Intellectual Property Office (now renamed as the CNIPA), however, stated in the explanations for the Draft of the Third Revision of the Patent Law (Draft for Public Opinions) under the item "whether public opinions are accepted: unaccepted" that governmental organizations and pharmaceutical enterprises in the United States, Japan and Europe insist that the China's patent law should be added with the provisions on patent linkage and patent term restoration, in addition to "Bolar exemption", on the grounds that "Bolar exemption" occurs in company with the patent linkage system and the patent term extension system for the purpose of balancing the interests between drug patentees and generic manufacturers, as well as between drug patentees and the public. The "Bolar exemption" alone will give rise to the imbalance of interests. But the other two systems ended up in being excluded from the Patent Law revised in 2008 because the legislative authority held that the patent linkage system is an extremely special practice adopted by the United States that fails to win unanimous recognition among other countries, there

lacks sufficient reasons for incorporating similar provisions into the China's patent law and it is not the right time for adopting the patent term restoration system.

3. Implementation of drug-related systems after 2015 owing to the change of situation

The pharmaceutical industry is a vital industry that matters a lot to the national economy and people's livelihood, and one of the battlefields for supply-side structural reforms. The key to the benign development of the pharmaceutical industry is to stimulate the balance between innovative drugs and generic drugs so as to eventually maximize the drug accessibility to provide patients (consumers) with "effective medications". But in reality, the above effect has not been achieved in China in terms of the development of the pharmaceutical industry or the protection of pharmaceutical patents. On the one hand, judging from the development of the pharmaceutical industry, the R&D of that industry in China has been deeply influenced by vertical value chain thinking for a long time and is mostly at a low and repetitive stage. The resulting issues in society are embodied as serious conflicts between doctors and patients, including inaccessibility to medications, high price for medications (especially imported medications) which are unaffordable for common patients, ineffectiveness of some medications though being available, and drug smuggling from countries and regions which are developed in terms of the generic drug industry. On the other hand, as easily seen from the aforesaid legislative development of the drug-related patent protection system in China, the legislative authorities have always been quite conservative towards the protection of drug-related patents, holding that the pharmaceutical and chemical industries in China are still at a low level and the production of generic drugs and chemicals has been dominating in China. Consequently, China, though saving a lot of time and money on pharmaceutical R&D, has lagged far behind foreign countries in a long run. In addition, poor management also leads to slow improvement of the pharmaceutical and chemical industries in China. Under such objective circumstances, the pharmaceutical and chemical industries in China will be under great pressure if the patent protection level of drugs and chemical substances is abruptly raised to be as high as that of developed countries. [7] Therefore, legislators believe that providing increasingly stronger protection for drug patents through revisions of the patent law will neither greatly impact nor seriously hinder China's pharmaceutical and chemical industries, and may provide opportunities for their development instead, but they still show preference to protection of generic manufacturers in terms of legislative formulation, and pay less attention to drug innovation. This situation had not been changed until 2015.

In August 2015, to address the current issues in the pharmaceutical industry, China launched all-round pharmaceutical and medical reforms, with the focus mainly on the following three aspects: (1) To be quality-oriented and conduct a generic drug quality and efficacy conformity assessment: in August 2015, the State Council issued the "Opinions on Reforming the System for Reviewing and Approving Drugs and Medical Devices" (No. Guo Fa [2015] 44) (hereinafter referred to as "the Opinions"), which propose to engage on assessment of generic drug quality and efficacy conformity, in order to promote the overall pharmaceutical industry level, make sure the validity, safety and quality controllability of products that have been approved for marketing can reach or get close to advanced world levels, better satisfy the public needs for medications, and promote the upgrading and structural adjustment of the pharmaceutical industry. The Opinions marked the full launch of China's medical reforms. (2) To accelerate the examination and approval work and reduce the backlog: the Opinions propose to take measures to solve the backlog of applications for registration, strictly control the review and approval of drugs that are oversupplied at the marketplace, strive to eliminate the backlog by the end of 2016, realize the annual balance between the number of accepted applications for registration and the number of reviewed and evaluated applications for registration as early as possible, and realize the review and approval of the applications for registration within the prescribed time limit by 2018. (3) To encourage innovation: researches were conducted on "the patent linkage system", "regulatory data protection" and "the patent term compensation system", and finally on 8 October 2017, the General Office of the Central Committee and the General Office of the State Council jointly issued a master plan guiding the medical reforms, i.e., "the Opinions on Deepening the Reform of the Review and Approval Systems and Encouraging Innovation on Drugs and Medical Devices", which clarifies the aims to "establish the Catalogue of China's Marketed Drugs", "explore the establishment of the patent linkage system", "carry out pilot trials for patent term restoration system" and "improve and implement the regulatory data protection system". In November 2019, the Gen-

eral Office of the Central Committee and the General Office of the State Council jointly issued the Opinions on Strengthening the Protection of Intellectual Property Rights, which mentions again the contents in relation to the protection of drug-related intellectual property rights, such as "to explore the establishment of the patent linkage system and the patent term restoration system".

In addition to the aforementioned reform measures in the pharmaceutical industry to achieve the balance between innovative drugs and generic drugs, China also links the development of the pharmaceutical industry with "health for all" and "prosperity for all" and confirms the importance of the pharmaceutical industry development at the macro level. At the National Health Conference held in August 2016, Chinese President Xi Jinping made a speech to profoundly elaborate on the significance of health for all, clarify the guidelines and goals of hygiene and health work under the new situation, and require the acceleration of the "Healthy China" initiative, which is a master plan guiding the development of hygiene and health industries in China. [8] The "Healthy China" initiative is also an important part of President Xi's report delivered at the 19th National Congress. "We shall carry out the 'Healthy China' initiative. A healthy population is a key mark of a prosperous nation and a strong country. We will improve the national health policy, and ensure the delivery of comprehensive lifecycle health services for our people. We will deepen reform of the medicine and healthcare system, establish distinctively Chinese systems for providing basic healthcare, medical insurance, and quality and efficient healthcare services, and develop a sound modern hospital management system." The Outline of the "Healthy China 2030" Plan emphasized that health is a prerequisite for people's all-round development and a precondition for economic and social development. To this end, we need to "promote science and technology innovation in health care, stimulate drug innovation, boost the marketing of generic drugs after the patented drugs for major diseases expire, vigorously develop new varieties of biological and chemical drugs. By 2030, quality standards of drug and medical devices will fully meet international standards." To achieve the two centenary goals and national rejuvenation, China should, on the one hand, take measures based on reality, regard people's health as a strategic priority to accelerate the process of building a healthy China, and on the other hand, build a vital and competitive pharmaceutical innovation industry to occupy a place in the future international competition.

In January 2020, China and the United States signed a "Phase One" trade deal, touching upon issues concerning the establishment of an effective mechanism for early resolution of drug-related patent disputes and patent term extension. The fourth revision of the China's Patent Law should make a response to the relevant contents of the "Phase One" trade deal. The "COVID-19" pandemic has aroused people's unprecedented attention to health, medications and the pharmaceutical industry. In face of new diseases, we need to first encourage the R&D of new medications to find "effective medications" and then achieve the drug accessibility to ensure that "medications are available". Therefore, the implementation of the patent term extension system that encourages drug innovation and the patent linkage system that realizes the balance between innovative drugs and generic drugs is in line with the current situation.

II. Characteristics of drug-related provisions in the newly revised Patent Law

As stated above, in the newly revised Patent Law, there are mainly two drug-related provisions:

First, Article 42 is newly added with the second paragraph concerning "patent term adjustment (PTA)", i.e., "the Patent Administration Department under the State Council may, at the request of the patentee, adjust the term of an invention patent to compensate for unreasonable delays in the patent grant proceedings, except those caused by the applicant. Such an adjustment is available only when the patent is granted after at least four years from the filing date, and at least three years after the request for substantive examination was filed." Article 42 is also newly added with the third paragraph concerning "patent term extension (PTE)", i.e., "to compensate for the delays caused by regulatory review and approval of a new drug, the Patent Administration Department under the State Council may, at the request of the patentee, grant a compensation term for patents covering a new drug that has been approved for marketing in China. The compensation term shall not exceed five years, and the total effective patent term after the approval for the marketing of the new drug shall not exceed 14 years. "

Second, there is added a new Article 76 concerning

"the mechanism for early resolution of pharmaceutical patent disputes", i.e., "in the process of review and approval of a drug applied for marketing, if a dispute over the patent right related to the drug applied for registration arises between the applicant for marketing of the drug and the relevant patentee or interested party, any relevant party may file a lawsuit before a people's court, requesting a judgment on whether the relevant technical solution of the drug applied for registration falls within the scope of protection of other's drug patent. The drug supervision and administration department under the State Council may, within the prescribed time limit, decide whether to suspend the marketing of the relevant drug according to the effective judgment of the people's court. The applicant for marketing of the drug and the relevant patentee or interested party may also request an administrative ruling from the Patent Administration Department under the State Council for disputes over any patent related to the drug applied for registration. The drug supervision and administration department under the State Council and the Patent Administration Department under the State Council formulate a specific linkage method for handling drug patent disputes during the review and approval stage and the application stage for drug marketing, which will be implemented after it is reported to and approved by the State Council."

The patent term restoration and the mechanism for early resolution of pharmaceutical patent disputes stipulated in the China's Patent Law are aimed to respect and protect innovation, encourage imitation, strive to resolve disputes in advance of the marketing of generic drugs, and ultimately achieve drug accessibility to benefit consumers. That is the common goal for all countries and regions where the patent linkage system and the patent term restoration system are implemented. When formulating, selecting and designing specific provisions, various countries must bear in mind their own national conditions, industrial development status and goals to be achieved before making a localized design. Take the patent linkage system for example. The system originated in the United States. But later, the patent linkage system established in Canada was once in the dilemma of double jeopardy, and is still different from that of the United States, for example, there is no market exclusivity for first follow-on applicant and the first follow-on applicant who successfully challenges an innovator's patent is entitled to claim for compensation. In the South Korea's patent linkage system, the drug supervision department plays a very important leading role, and the entire system is more advantageous for generic drugs. In addition to the invalidity and non-infringement declarations, a request for a trial to determine on whether an application falls within the scope of a drug-related patent, which is unique in the South Korea, is also incorporated into the patent linkage system.

China should also take its national conditions into consideration when protecting drug patents. China is the most populous country in the world, which means it is second to none in terms of the number of drug users and the amount of drugs consumed. For historical and technological reasons, production of generic drugs is still the mainstream in the China's pharmaceutical industry. Although many generic manufacturers are making great efforts in drug R&D and innovation in tandem with advantageous policies, the dominating position of generic drugs in China's pharmaceutical industry will not change a lot in the next few years. Thus, as for policy design and selection, China may have to show preference to generic manufacturers just like the South Korea. As a matter of fact, reference has been made to South Korea's rules when stipulating the relevant provisions in Article 76 of the newly revised Patent Law. Due to the differences in the system between China and South Korea, it is necessary to scientifically design specific provisions based on China's system to realize the original intention of establishing the system. Moreover, in view that the China's patent law adopts a "dual-track system" for patent protection, the mechanism for early resolution of drug patent disputes is provided with an administrative route for resolving disputes, which conforms with the current practice in China. Of course, in comparison with Article 75 in the Second Draft of the Patent Law (draft for deliberation), Article 76 of the newly revised Patent Law is a more general and principled provision. Specific regulations cannot be implemented until relevant supporting measures are promulgated.

III. Recommendations for practitioners

Although medications are in close association with the public's health and lives, it seems that the public is not quite familiar with medications and the pharmaceutical industry. China has issued a series of policies to encourage innovation and development of the pharmaceutical industry since 2015, which shows that the pharmaceutical industry is prioritized and a new growth point for China's future development.

Statistics showed that China's export of pharmaceutical products totaled 73.83 billion U.S. dollars, up 224% over 2010. According to the data provided by the China Customs, there were 1,390 Chinese preparation export companies in 2010, among which 1,145 are Chinese-funded, and 34 preparation export companies, including 10 Chinese-funded ones, gained an export value of over 10 million U.S. dollars; and there were 1,501 Chinese preparation export companies in 2019, among which 1,282 are Chinese-funded, and 58 preparation export companies, including 34 Chinese-funded ones, gained an export value of over 10 million U.S. dollars. It can be seen that the export of preparations is on the steady increase, and the export trade which mainly involves active pharmaceutical ingredients (API) has undergone substantial changes. In 2019, Chinese-funded companies exported preparations worth of 2.005 billion U.S. dollars, accounting for 48.8% of the total export. In 2019, the export of 29 Chinese pharmaceutical companies reached more than one million U.S. dollars. Among the top 20 companies in terms of exports to the U.S., 18 are domestic companies, and the top 12 are local companies, wherein the export of Humanwell Healthcare and CSPC Pharmaceutical Group grew by over 30% . Companies, such as Nanjing Kingfriend Biochemical Pharmaceutical Co., Ltd., Sinotherapeutics Inc., Changzhou Pharmaceutical Co., Ltd., and Yiling Pharmaceutical Co., Ltd., have made breakthroughs in commercialization in the United States, and their export value has achieved a triple-digit growth. The export of preparations of western medicine to the United States reached 0.421 billion U.S. dollars, accounting for 10.24% of the total export value with an increase of 8.78% year on year and an increase of nearly 5% over 2010. China has accelerated its export of preparations of western medicine in recent years, the compound annual growth rate (CAGR) of the export value of the preparations of western medicine from 2010 to 2019 was 11.43%, and the export value thereof surged from 1.551 billion U.S. dollars in 2010 to 4.109 billion U.S. dollars in 2019, with its proportion in the export value of the western medicines increasing from 7.36% to 10%. [9]

As for the patent linkage system that may be unfamiliar to the IP industry in China, on the one hand, the drug supervision and administration department and the Patent Administration Department should formulate specific implementing rules, and the judicial authority should issue relevant judicial interpretations, for the purpose of specifing and interpreting those rules, which shall be constantly supplemented and improved with the development of pracctice, making it in line with China's national conditions, in hope that the localized rules can achieve the goal of the system; and on the other hand, practitioners in various fields shall make efforts to understand and utilize the rules to their advantage based on their own needs. To be specific, the innovative companies need to increase efforts and investment on R&D constantly and maintain the validity of the related patents as much as possible; the generic companies need to enhance their own capabilities in terms of innovation and imitation so as to enhance their strength in capabilities, rather than in numbers; since drug-related issues are quite professional, lawyers and attorneys providing legal services shall be not only acquainted with related technical knowledge, systems and rules, but also have an international perspective and vision, understand international rules to cope with foreign-related disputes, and assist pharmaceutical companies in making a plan to enter into the international market; and relevant personnel of the patent administration and judicial authorities need to accelerate the speed of patent examination, case trial and judgment so as to complete work within the prescribed time limit as much as possible and further promote the early and effective resolution of drug patent disputes. ■

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[1] Duan Ruilin (February 1981). Introduction to Knowledge of Patent Law (p19). Patent Literature Publishing House.

[2] Tang Zongshun (June 1988). A Course in Patent Law (p. 66). Law Press·China.

[3] Wen Xikai (editor-in-chief) (March 1994). Interpretation of the Patent Law (p. 80). Patent Literature Publishing House.

[4] See *ibid*, pp. 155-156.

[5] The Treaty and Law Department of the CNIPA (compiler) (March 2009). Introduction to the Third Revision of the Patent Law (pp.88-89). Intellectual Property Publishing House.

[6] See *ibid*, pp. 66-67.

[7] Hu Zuochao (editor-in-chief) (March 1994). Patent Foundation (pp. 91-92). Patent Literature Publishing House.

[8] Retrieved from http://cpc.people.com.cn/pinglun/n1/2016/0821/c78779-28652227.html.

[9] Retrieved from https://cj.sina.com.cn/articles/view/5115326071/130e5ae77020014w3x.