Analysis on the Nature of Drug Procurement by Hospitals

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Introduction

Drugs are special commodities that play an important role in public health and even life safety. All countries set stringent review and approval procedures for their marketing. Meanwhile, in China, drug procurement by hospitals, which enables patients to get medications they need based on the doctors' prescriptions, is the most important channel for pharmaceutical sales.[1] Before the sale of approved drugs within hospitals, drugs are required to go through a series of procedures, such as application for entry into the medical insurance drug catalogue, network bidding and procurement tendering, all of which occur before the actual drug procurement by hospitals (namely, the sale of drugs), and surely before the purchase of drugs by patients. In the light of relevant provisions of the patent law, patent exploitation refers to the exclusive right to make, use, offer to sell, sell or import a patent. In case the technical solution of a generic drug falls within the scope of protection of an innovative drug, does the series of acts conducted by the generic manufacturer for the purpose of sale of drugs within hospitals constitute offering for sale or sale, which therefore results in patent infringement? This article is going to analyze the nature and legal liabilities of such acts as application for entry of generic drugs into the medical insurance drug catalogue, network bidding, procurement tendering and centralized volume-based procurement, from the perspective of patent law and in combination with judicial practice over recent years.

I. Whether the application for entry of a generic drug into the medical insurance drug catalogue constitutes offering for sale

The first step a drug should take for the sale of drugs as government-funded drugs within hospitals is to file an application for the entry of those drugs into the medical insurance drug catalogue with the National Healthcare Security Administration (NHSA). Taking the provisions of the NHSA's Working Plan for Adjusting the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022) and related documents for instance, innovative drugs, before their entry into the medical insurance catalogue, are required to go through five stages including preparation, declaration, expert review, negotiation/bidding and announcement of results. In the expert review stage, review will be jointly conducted by experts in the fields of pharmacy, clinical science, pharmacoeconomics, medical insurance administration, work-related injury, etc. in order to provide lists of recommended drugs to be added directly, to be added through negotiation/bidding, to be removed directly, and to be dealt with according to contract renewal rules. Meanwhile, such aspects as main specifications for negotiation, reference drugs and the scope of medical insurance premium payment of the drugs to be negotiated/bid, as well as general guide of the drug catalogue, names and dosages of drugs, categories of drugs (Class A and Class B), structure of catalogue classification, and remarks will be demonstrated and determined.[2]

Therefore, does the application for entry of a generic drug into the medical insurance drug catalogue constitute offering for sale or sale, thereby resulting in patent infringement?

The Guangzhou Intellectual Property Court issued the Civil Judgment No. Yue73zhiminchu 1838/2020 in *MSD (China) Investment Co., Ltd. v. Guangdong HEC Pharmaceutical Co., Ltd.*, a dispute over patent infringement, holding that, on the one hand, the application for entry of a generic drug into the medical insurance drug catalogue should not be deemed as an act of exploiting a patent as

stipulated in Article 11 of the China's Patent Law. "Although HEC's application for the entry of the accused drug into the medical insurance drug catalogue with the NHSA aims at bringing the drug into the medical insurance drug catalogue for sale after review and approval, which is qualified for production or business purpose; yet the act of application for entry the generic drug into the medical insurance drug catalogue with the NHSA by the authorized holder of the said generic drug does not constitute an act of exploiting the patent in suit. In addition, HEC's act of application terminated automatically in the course of application and HEC did not continue the application in the subsequent stages, and the medical insurance drug catalogue (2020) did not incorporate the accused product into the catalogue. Hence, the act of application for entry the generic drug into the medical insurance drug catalogue *per se* should not be deemed as an infringing act of exploiting a patent as stipulated by the patent law, …… and therefore does not constitute patent infringement."

On the other hand, the application for entry the generic drug into the medical insurance drug catalogue does not constitute offering for sale. "Offering for sale refers to the declaration of will to sell goods by means of e.g. advertisement, shop window display or exhibition. Offering for sale is a legal act, and the declaration of will is the essence of a legal act. The declaration of will, as a concept in private law, is an expression of will to establish, alter and terminate civil rights and obligations for the purpose of achieving the effect of private law. The pursuit of the purpose of private law is its ultimate goal, so offering for sale is a legal act performed for the sake of pursuing the effect of private law. The accused infringement involves the application with a particular administrative authority, which is neither an act of exhibition nor of display for selling goods. Although the application of a pharmaceutical company for the entry of a generic drug into the medical insurance drug catalogue with the administrative authority aims at production or business purpose, the application is filed with the administrative authority in charge of national medical insurance, and cannot therefore be deemed as offering for sale…… Even though the generic drug successfully goes through those procedures set by the NHSA and enters into the medical insurance drug catalogue after several rounds of selection, as long as the pharmaceutical company does not take such further actions as applying for network bidding for the sale of the generic drug to the public, it is hard to concluded that such act as application for entry into the medical insurance drug catalogue constitutes offering for sale under the patent law."

The court also indicated in the judgment that "the act of HEC's application for entering the accused generic drug into the medical insurance drug catalogue with the NHSA, i. e., application for entering the generic drug, which has been approved for manufacture, into the medical insurance drug catalogue with an administrative authority, is in essence an act of applying for an administrative license with a national administrative authority."[3] According to the NHSA's Interim Measures for Administration of Drugs for Basic Medical Insurance, only after NHSA's review and approval can drugs be permitted to enter into the medical insurance drug catalogue, and furtherly be brought into the scope of medical insurance and entitled to be paid by medical insurance funds, which indicates the administrative license attribute of the entry of drugs into the medical insurance drug catalogue to some extent. There is a view that in addition to the administrative license attribute, the entry of drugs into the medical insurance drug catalogue also has the private law attribute. In the negotiation/bidding stage, when the NHSA, on behalf of medical institutions, conducts negotiation with pharmaceutical companies which files applications regarding the procurement of drugs to be added to the catalogue, it also has the identity as a counterparty to a contract. It is therefore concluded that the above judgment may be worthy of discussion since the above judgment concludes that the application for entry into the medical insurance drug catalogue does not constitute offering for sale without taking account of the private law attribute of the medical insurance drug catalogue and the "dual" identities of the NHSA, but simply based on the grounds that the permission of entry into the medical insurance drug catalogue is an administrative license, the application is submitted with an administrative authority, rather than pharmaceutical consumers, and there is no declaration of will to sell products to unspecified persons, and that only when a generic company further applies network bidding for the sale of generic drug online can such an act constitute offering for sale. The application for entry of a generic drug into the medical insurance drug catalogue has the effect of declaring a will to sell drugs to some extent, and thus may constitute offering for sale. [4]

The authors, however, hold that although the application for entry of a generic drug into the medical insurance drug catalogue has the effect of declaring a will to sell

drugs, the entry of drugs into the medical insurance drug catalogue should be regarded as a preparation for network bidding. As a matter of fact, after an innovative drug is added to the medical insurance drug catalogue, a generic drug simply needs to be proved to have the same active ingredients as the innovative drug. Once the medical insurance code is generated, the generic drug will be able to be recorded into the medical insurance e-system and therefore complete its entry into the medical insurance drug catalogue. A generic company is also entitled to decide whether to withdraw from the medical insurance drug catalogue or not at its own discretion. As a relatively independent step in the marketing of generic drugs, the act of application for entry of a generic drug into the medical insurance drug catalogue is somewhat different from such a typical act of offering for sale as invitation to offer for an unspecified majority of people. At this stage after all, the NHSA merely negotiates price rather than signs an agreement with companies applying for bringing their generic drugs into the medical insurance drug catalogue. In fact, it is medical institutions (i.e., hospitals) that actually sign an agreement with generic companies. Therefore, the act of application for entry of a generic drug into the medical insurance drug catalogue should not be regarded as an act of offering for sale.

II. Whether generic drug network bidding constitutes offering for sale

1. What is "drug network bidding"?

There is no clear definition of drug network bidding. It generally refers to "drug network bidding and procurement", which is a special act in the course of centralized procurement of drugs. Drug companies bid within the price limit range set by the bidding office on the online procurement information platform. High-priced drugs are eliminated, and low-priced drugs are shortlisted on the basis of price priority. Drug manufacturers sign a supply contract with hospitals on the information platform.

Prior to 1993, hospitals independently purchased medicines they needed. Such an opaque and undisclosed decentralized procurement model gave rise to quite a few problems. In August 1999, the former State Council Office for Restructuring the Economic System proposed the concept of "centralized bidding and procurement of medicines" for the first time in the Report on Issues Relating to Centralized Bidding and Procurement of Medicines. In November 2001, six ministries, including the former Ministry of Health, jointly published the Work Practice of Medical Institutions Concerning Centralized Bidding and Procurement of Drugs (Trial), marking the official and full-scale centralized bidding and procurement of medicines by state-owned medical institutions at or above the county level nationwide. In February 2015, the General Office of the State Council released the Guidance Opinion on the Improvement of the Centralized Drug Procurement Work of State-Owned Hospitals, which is a milestone for the centralized bidding and procurement of drugs at the provincial level. In March 2018, the NHSA was founded for, among other things, guiding the formulation of rules for centralized drug procurement and the establishment of a centralized procurement platform. However, drug network bidding, as a part of the centralized drug procurement, is policy-oriented, administrative and complicated. [5]

2. Whether generic drug network bidding constitutes offering for sale

In practice, most patentees of innovative drugs will, when generic companies applying for network bidding on the procurement platforms, choose to bring a patent infringement lawsuit with court or file a complaint with the patent administration department on the grounds that the application constitutes offering for sale, seeking for cessation of such an application. The judicial and administrative departments in China are inclined to determine such an act constitutes offering for sale. For instance, in a dispute over patent infringement between Jiangsu Hansoh Pharmaceutical Co. and Jiangsu Sandoz Co., Sandoz asserted that Hansoh's participation in the centralized drug procurement constituted offering for sale, but Hansoh insisted that it did not has the declaration of will to sell the accused products to unspecific medical institutions in Fujian Province. In the Civil Ruling No. Zuigaofazhiminxiazhong 290/2020, the Supreme People's Court held that Hansoh's network bidding of the accused product constituted a declaration of will to sell the accused product to medical institutions in Fujian Province. Given that the accused infringement occurred in Fuzhou, Fujian Province, according to the relevant reply of the Supreme People's Court that the civil intellectual property cases at first instance which relate to patents and occur in Fujian Province is under the jurisdiction of the Fuzhou Intermediate People's Court, the court of first instance has the jurisdiction over the said case. In this case, the Supreme People's Court refrained from commenting on the issue of of-

fering for sale in its ruling, deeming that whether said act constituted offering for sale under Article 11 of the Patent Law should be determined by the court of first instance after substantive trial. However, the determination of jurisdiction by the Supreme People's Court actually showed its inclination to rule that the Hansoh's act of network bidding constituted infringement, specifically offering for sale. [6]

There is a view that drug network bidding involves complex factors in various aspects, so it is not appropriate to determine any act relating to drug network bidding as offering for sale in a simple and one-size-fits-all approach. For instance, the declaration of qualification is a relatively independent step in the course of drug network bidding. If it is deemed as offering for sale, it means that generic companies cannot declare their qualification for bidding even on the last day of the patent term, and can start to apply for network bidding and subsequent steps such as bidding, tendering and sale only when the patent term expires, which will lead to an extension of the patent term in disguise. Furthermore, if the drug network bidding is simply determined as offering for sale, it will have a direct impact on drug availability. Therefore, a detailed legal analysis and demonstration on whether drug network bidding constitutes offering for sale shall be conducted on the basis of China's national conditions and basic factual findings. [7]

The authors opine that the aforesaid view is worthy of discussion. The determination of offering for sale has also undergone changes in China's judicial practice. It is stipulated in Article 24 of the Several Provisions of the Supreme People's Court on Issues Relating to Application of Law to Adjudication of Cases of Patent Disputes promulgated in 2001 that "the offering for sale referred to in Articles 11 and 63 of the Patent Law means the declaration of will for sale by way of advertisement, shop window display or exhibition." With the development of society, Article 107 of the Guidelines for Patent Infringement Determination (2017) issued by the Beijing High People's Court and the Guidelines for Case Handling of Administrative Adjudication for Patent Infringement Disputes published by the China National Intellectual Property Administration in 2019 further enumerate similar acts that occur "on the Internet" as common acts of offering for sale. Thus, the declaration of will on the Internet to sell a product constitutes offering for sale and thereby patent infringement once the product falls within the scope of protection of other's patent. Network bidding by generic companies on the centralized procurement platforms at the provincial level, indicating their possession of the drugs, the price of drugs, as well as their declaration of will to invite medical institutions to purchase their drugs, is an act of invitation of offer. Generally speaking, state-owned hospitals will make an option among drugs listed in the catalogue on the procurement platform according to their own needs, and eventually determine what drugs to purchase after going through the relevant procurement processes required, such as the evaluation of the Pharmaceutical Affairs Committee. That is to say, drug network bidding on a procurement platform can be considered as the declaration of will to sell drugs to unspecific medical institutions planning to procure drugs on the procurement platform. Furthermore, drugs participating in network bidding should be those that have been approved of marketing, which completely meet the requirements for production and sale. Hence, the act of drug network bidding constitutes offering for sale in the sense of the patent law.

There is a view that network bidding involves intricate steps, including, e.g., the declaration of qualification, review and publicity, bidding and tendering, winning the bid, procurement and delivery, after all of which drugs can finally be sold to hospitals. Therefore, different steps of network bidding should be distinguished. [8] The authors think that on the one hand, the steps of procurement and delivery are acts of performing a contract after a hospital purchases drugs and executes a contract. Those steps have actually constituted act of sale, and do not fall within the scope of network bidding. Network bidding, however, should be treated as a whole, rather than be divided into different steps respectively for determination, which is not in line with the conventional practice relating to patent infringement determination. On the other hand, various local governments try to take measures to simplify and expedite the process of network bidding so as to promote the drug availability, which greatly accelerates the process of network bidding. Innovative companies try every means to stop generic companies from network bidding on the grounds that once network bidding is done, numerous hospitals may sign procurement contracts with the generic companies. The innovative companies will then be put into a difficult situation to deal with how to prevent the generic drugs from being sold in numerous hospitals, which is hard to be achieved from the aspect of neither the cost nor the effect. That is also why the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) explicitly identifies the act of offer-

ing for sale as patent infringement and requires for its cessation, that is to say, the prohibition of the act of offering for sale in the patent law is aimed to nip infringement in the bud in an effort to prevent the issue of negative externalities such as more loss on the part of patentees and further increase in administrative and judicial costs caused by the diffusion of infringing products. [9]

3. Whether the entry of generic drugs into the medical insurance drug catalogue will affect the determination of network bidding as offering for sale

In practice, whether the entry of generic drugs into the medical insurance drug catalogue is not an essential condition for network bidding. In other words, not all drugs participating in network bidding are added to the medical insurance drug catalogue. The excluded drugs if purchased by hospitals will be sold as self-paid medicines and the cost thereof shall be borne by the patients themselves. The drug price is the major factor that affects the decision on whether the drug will enter into the medical insurance drug catalogue, i.e., medical insurance negotiations are primarily negotiations about drug price from economic and clinical perspectives, and the price determined after negotiations is usually lower than that on the international market. It can be seen that the entry of generic drugs into the medical insurance drug catalogue will not affect the determination of network bidding as offering for sale.

III. Whether the participation of generic drugs in tendering and procurement constitutes offering for sale

Offering for sale is the declaration of will to sell a patented product (including a product directly obtained by a patented process) or provide a patented process for a specific or unspecific subject. In judicial precedents, offering for sale is generally analyzed and determined on the basis of whether a product is circulated on the market and whether the product is sold by a dealer. Generally speaking, offering for sale occurs prior to actual sale and is aimed for actual sale. In practice, actual sale may refer to direct expression of will to sell, such as sending a price list, participating in an auction, or participating in tendering, or indirect expression of future sale, such as display in exhibitions, or public demonstration.

As stated above, network bidding is actually an essential step in drug bidding procurement and is in close association with drug tendering and bidding. If the act of network bidding indicates the will of generic companies to sell generic drugs in a region and constitutes offering for sale, the participation in bidding procurement thereafter shall also be determined as offering for sale.

In a dispute over patent infringement between Qilu Pharmaceutical Co. and Beijing Sihuan Pharmaceutical Co., the plaintiff at first instance, Sihuan, filed a lawsuit against the defendant at first instance, Qilu, for the latter's participation in the centralized bidding procurement of drugs within the jurisdiction of the court of first instance constituted offering for sale, and Qilu raised an objection to the jurisdiction, which was overruled by the court of first instance. As being unsatisfied with the decision, Qilu appealed to the Inner Mongolia High Court, which issued the Civil Ruling No. Neiminxiazhong 16/2016, holding that offering for sale means that a product complies with all the requirements for circulation on the market, and a dealer gives an explicit declaration of will to sell the product to the public. In this case, the injection product in suit has obtained the GMP certificate, and the approval number given by the State Food and Drug Administration, which means the product is qualified for marketing. In addition, Qilu's participation in Hohhot (the capital of Inner Mongolia Autonomous Region) in the centralized bidding procurement of drugs for Inner Mongolia Autonomous Region indicates its will to sell the product in suit on Hohhot's market, and shall be deemed as offering for sale in the sense of patent law. [10]

The centralized bidding procurement of drugs refers to the way of procurement that multiple medical institutions procure the drugs they need in the form of tendering and bidding through a centralized bidding procurement organization, which is to ensure the smooth implementation of the basic medical insurance system for urban employees, regulate the drug procurement and sale of medical institutions fundamentally, and alleviate the burden of medical expenses on the society. On 14 November 2018, the fifth session of the Central Committee for Comprehensively Deepening Reform deliberated and passed the Pilot Program of the Centralized Procurement of Drugs Organized by the State, which clarifies the overall idea of national institutions, alliance procurement and platform operation. On 15 November 2018, with the approval of the Central Committee for Comprehensively Deepening Reform, China organized the pilot program for centralized drug procurement, which was

carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing and Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi'an (hereinafter referred to as the "4+7 Cities"). The pilot cities assigned representatives to form a Joint Procurement Office as the working organization on behalf of public medical institutions in pilot cities to carry out the centralized procurement of drugs. Daily work and specific implementation of the pilot program was undertaken by the Shanghai Pharmaceutical Centralized Bidding Procurement Affairs Management Office. The Joint Procurement Office published the Papers on Drug Centralized Procurement in "4+7 Cities", which indicates the volume for procurement during the procurement of chemical drugs. On 26 November 2019, the NHSA issued the Opinions on Current Drug Price Control, which clarified the deepening of the reform of the volume-based centralized drug procurement system, adhered to the principle of "volume-based procurement, volume-price linkage, and bidding-procurement integration", in order to promote the drug price to reasonable level.

Offering for sale is a statutory and independent infringement, whose assumption of civil liabilities is not premised on actual sale; however, where a sale agreement is reached, it falls within the scope of sale, rather than offering for sale. [11] Hence, if a generic drug falls within the scope of protection of an innovative drug, all the acts of participation of generic companies in tendering and bidding, including centralized procurement and volume-based procurement, constitute offering for sale. And if the generic company finally executes any procurement contract, it constitutes sale.

IV. Legal liabilities for offering for sale

In China's judicial practice, the legal liabilities an infringer should bear for his act of offering for sale have undergone a transition from no compensation as there are no damages caused by the act of offering for sale, to separate compensation as the act of offering for sale may result in reasonably presumed damages.

In the Strophanate case, regarding the defendant's infringing act of offering for sale on the 14th National Pesticide Exchange Conference and Agricultural & Chemical Products Exhibition held at Shanghai World Expo Exhibition & Convention Center, the Shanghai Intellectual Property Court issued the Civil Judgment No. Huzhiminchuzi 213/2015, in which the claim of the plaintiff (BASF Corporation) for infringement damages was dismissed and only reasonable expenses for right protection was supported on the grounds that "as for the amount of damages, since the act of offering for sale performed by the defendant did not lead to the decrease in the market share of the plaintiff's patented product or cause any actual loss, the court did not support the plaintiff's claim for the compensation for economic loss." In a dispute over design patent infringement between Beijing Huajiesheng Electromechanical Equipment Co., Ltd. and Shenzhen Dingsheng Door Control Technology Co., Ltd., the Supreme People's Court issued the Civil Judgment No. Zuigaofaminzai 8/2018, holding that "as for the offering for sale performed by the respondent, the retrial petitioner did not adduce evidence to prove that the act of offering for sale had caused actual loss, or that the respondent had gained profits from infringement. In comprehensive consideration of the nature and characteristics of the accused infringement, the court would not support Huajiesheng's claim for the compensation of economic loss. As for reasonable expenses, the retrial petitioner did not provide sufficient evidence to support its claim of RMB 20,000; however, given that the retrial petitioner entrusted a lawyer to participate in the lawsuit, the court supported the claim of the retrial petitioner for reasonable expenses at its discretion."

In a dispute over infringement of a utility model patent between Tsingtao Tsingke Heavy Industry Co., Ltd. and Tsingtao Chenyuan Machinery Equipment Co., Ltd., the Supreme People's Court held that "although the act of offering for sale is aimed for sale, it is a statutory and independent infringement, and the assumption of civil liabilities therefor is not premised on actual sale. Once offering for sale occurs, as the offering price set by the accused infringer is usually lower than that of the patented product, it will give a psychological suggestion to potential consumers, which may affect the reasonable pricing of the patented product, or make consumers give up purchasing the patented product and consider contacting the accused infringer, which may give rise to purchase delay or even affect the normal sale of the patented product. In addition, the act of offering for sale of the accused infringer may have an adverse impact on the advertising effect of the patented product. It can be seen that offering for sale will cause harm to the patentee. For instance, it may lead to price erosion, or reduction or delay of business opportunities on the part of the patentee, which are reasonably presumed results.

Where there is a wrong, there is a remedy. Unless otherwise specified in law, the remedy shall at least include the assumption of two basic civil liabilities for infringement (cessation of infringement and compensation for loss), rather than one of them …… Where it is difficult for the patentee to adduce evidence to prove the specific loss suffered by him due to the offering for sale, the amount of damages will be determined on the basis of statutory damages." In this case, Chenyuan's claim, i.e., it only has to compensate for the reasonable expenses of the right holder for right protection in the event that the loss or profits resulting from the offering for sale cannot be proved, is untenable. Where the infringer only performs the act of offering for sale, the consequences of infringement may be less severe than that of actual sale. Thus, when determining the civil liabilities, especially the amount of damages, that the accused infringer should assume for offering for sale, the malice and details of infringement reflected in the evidence on file should be paid more attention to and a distinction should be made based on the merits of the case. [12] A similar view can be found in cases such as an appeal from a dispute over infringement of a utility model patent between Dongguan Lietu Silicone Technology Co., Ltd. and Shenzhen Kean Silicone Product Co., Ltd. [13]

The authors hold that offering for sale happens prior to actual sale, and the actual loss caused to the patentee usually has not occurred yet. According to the principle of full compensation for civil damages, although the patent law explicitly stipulates that the legal liabilities for patent infringement include the cessation of infringement and compensation for damages, since it is often hard to prove the actual loss suffered by the patentee due to offering for sale, the court generally will not order the infringer, who provides an offering for sale, to assume the liability for compensation, but will support the patentee's claim for compensation for reasonable expenses. Nevertheless, in some disputes, if a patentee can prove that the act of offering for sale has resulted in actual loss, the infringer should compensate for such loss. Detailed analysis and determination shall be made on a case-by-case basis. What is worthy of discussion is the view that the patent law does not exclude the application of legal liabilities for damages to the act of "offering for sale", and the infringer should be liable for compensation once conducting the act of offering for sale, in which, even if there is no actual loss caused, the provision of statutory damages can be applied. However, in case of drugs, the specialty of drugs must be taken into consideration. Once a generic company conducts network bidding and participates in the bidding procurement, especially the volume-based procurement, it may cause irreparable loss to the market share and price of the innovative drugs. Under such circumstances, it is not improper to order the generic company to compensate for the patentee's damages based on the actual circumstances of the case.

V. To achieve the balance between generic drugs and innovative drugs and protection of the public interest, attention should not be paid only to the interests of generic companies

At present, when discussing drug-related policies, some people place emphasis on the protection of the public interest; even when discussing how to strike a balance between generic drugs and innovative drugs, they actually pay more attention to the protection of the interests of generic companies. Drugs affect the life and health of the public, so drug-related policies have strong public attributes. However, the realization of drug availability requires more attention for the balance between generic drugs and innovative drugs. Without innovative drugs, generic drugs can imitate nothing. It is the interests of patients that are ultimately harmed.

It should be noted that innovative drugs bear almost all the risks in the whole process of marketing of generic drugs. Regardless of the R&D investment on innovative drugs, even after the innovative drugs have accomplished the whole process of R&D and filed the application for the approval of marketing, and eventually been approved for marketing, the innovative drugs still play a role in clearing obstacles for entry into the medical insurance drug catalogue and the networking bidding for generic drugs. As stated above, after an innovative drug is added to the medical insurance drug catalogue through negotiations, a generic drug simply needs to be proved to have the same active ingredients as the innovative drug. Once the medical insurance code is generated, the generic drug will be able to be recorded into the medical insurance e-system and therefore complete its entry into the medical insurance drug catalogue. During the bidding procurement, the generic drugs

can keep the track of what is going on with innovative drugs to accomplish the network bidding at all times. In fact, the innovative company basically undertakes the time cost, economic cost and uncertainty of the entire medical insurance negotiation and drug biding procurement. Under such circumstances, the innovative company surely hopes to occupy certain market share for drugs, in order to recover R&D investment and gain profits.

Once the generic drug accomplishes network bidding, it will enter into the bidding procurement stage, especially the volume-based procurement stage, which may cause irreparable loss to the innovative drug. On the one hand, not all innovative companies would like to participate in the volume-based procurement in consideration of the cost benefit. Once the generic drug successfully enters into the volume-based procurement stage, the established drug price system of the innovative drug will be destroyed, and the market share thereof will be extremely reduced. On the other hand, after the network bidding of the generic drug, the unspecific majority of medical institutions are all potential buyers, and the innovative company has to spend enormous energy, time and money on right protection, the effect of which is usually unsatisfying. That is why most innovative companies try to prevent generic drugs at the network bidding stage.

Drug availability involves laws, regulations and policies of various departments. Thus, as far as the balance between innovative and generic drugs is concerned, attention shall be paid to both industries. Patent system is in essence a system for protecting innovations, which involves several rules relating to drugs; however, it is improper to require all the systems to take into account the interests of generic companies and the public interest during the construction. Only conferring full protection on innovative drugs is it possible to motivate innovative companies to research and develop new drugs, based on which multiple systems and policies should work jointly so as to promote the development of innovative and generic drugs, and eventually achieve drug availability. ■

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[1] Of course, drugs can be sold directly on the shelves of pharmacies, instead of hospitals. However, the direct sale of drugs within pharmacies will not be discussed herein for the reasons that it is not the main channel and source of profits of drug sale in China and that it does not involve the acts before the drug sale within hospitals as mentioned herein.

[2] Part III: Working Procedures of the Work Plan for Adjusting the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2022).

[3] The Civil Judgment No. Yue73zhiminchu 1838/2020.

[4] Sun Xi. Case studies: Does the application for entry into the medical insurance drug catalogue constitute offering for sale in the sense of patent law? WeChat Account: IP ForeFront, posted on 2 June 2022 and last visit on 31 July 2022.

[5] Xu Bo (2021). Distinguishing different situations and balancing the interests of all parties---A brief analysis of the basis for judging whether drug network bidding constitutes offering for sale (I). Chinese Pharmaceutical News, posted on 25 January 2021.

[6] Li Zhanke. Injunctive reliefs and countermeasures for infringement of drug-related patents. WeChat Account: IP ForeFront, posted on 13 October 2021 and last visit on 31 July 2022.

[7] See supra note 5.

[8] *Ibid*.

[9] Tang Tiejun and Wang Yuming. Changes in judicial practice concerning regulation of infringing act of the offering for sale as viewed from the Rivaroxaban case. WeChat Account: IP ForeFront, posted on 21 July 2022 and last visit on 31 July 2022.

[10] See supra note 6.

[11] The Civil Judgments Nos. Zuigaofazhixingzhong 451/2021 and 702/2021.

[12] The Civil Judgments Nos. Zuigaofazhiminzhong 1658/2020 and 1659/2020.

[13] The Civil Judgments Nos. Zuigaofazhiminzhong 470/2021 and 511/2021.