Studies on Issues Relating to Patent Validity under Patent Linkage System

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The patent linkage system is a system that links the marketing authorisation of generic drugs to the validity of corresponding brand-name pharmaceutical patents and the judgments on related patent infringement disputes during the drug registration and review process. This article begins with the issues and challenges to be faced in the administrative patent validity procedure after the commencement of the patent linkage system in China, in a bid to find a resolution and propose systematic adjustment based on the latest revisions of the China's Patent Law in 2020.

I. Issues raised

The patent linkage system was incorporated into Article 76 of the newly-revised China's Patent Law passed on 17 October 2020. [1] The National Medical Products Administration and the China National Intellectual Property Administration (CNIPA) jointly released, on 11 September 2020, the Implementing Measures of Early Resolution Mechanism for Drug Patent Disputes (Trial) (Draft for Comments) (hereinafter referred to as the Draft Implementing Measures), which expounds the framework given in Article 76 of the Patent Law. [2] The abovementioned latest system designs in relation to pharmaceutical patents will have a profound impact on China's pharmaceutical industry and the administrative validity procedure of related patents.

As we all know, pharmaceutical research and development (R&D) are characterized by long duration, enormous investment and high risk. Potential huge profits gained by innovative drugs are the direct incentive that stimulates companies to invest in new pharmaceutical R&D. Recovering R&D costs and obtaining subsequent R&D funds are usually realized through adequate patent protection. As the global pharmaceutical market increases continuously, on the one hand, brand-name drug companies have consistently increased their investment in new pharmaceutical R&D, and made every effort to strengthen pharmaceutical patent protection by means of, e.g., building a patent portfolio, for the purpose of obtaining exclusive market share, recovering high R&D costs and making profits; and on the other hand, generic drug companies rack their brains to challenge the validity of patents and break the patent barriers of brand-name drug companies to scramble for a slice of the action in the market. After the implementation of the patent linkage system, such provisions as "exclusivity period for the first follow-on product" will intensify the "patent war" between brand-name drug companies and generic drug companies within a certain period of time, which may in turn result in large fluctuations in the number of patent invalidation cases. Meanwhile, the introduction of the early resolution mechanism for patent disputes will also impact the examining mode and pace of patent invalidation cases. Studies on the impact of the patent linkage system on the administrative patent validity procedure are of great significance for advance preparation.

II. *Status quo* of and challenges faced by administrative patent validity procedure

The implementation of the patent linkage system may impinge on the administrative patent validity procedure in the following aspects: first, the stimulus of applications for generic drugs will raise the number of patent invalidation cases; second, the increase of associated cases will affect the conventional joinder mode; and third, the need for patent validity defense will pose a severe challenge to the patent invalidation procedure.

1. The number of patent invalidation cases will rise significantly

The number of drug-related patent invalidation cases rises on a year-over-year basis. The pharmaceutical industry in China has undergone a change from focusing on domestic development to gradually being in line with international practice, which is prominently reflected in the number of drug-related patent invalidation cases in this field.

From January 2010 to October 2020, the CNIPA accepted 452 invalidation cases in relation to chemical drug patents. The number of accepted cases rose sharply since 2017, and had been increased by 2.75 times from 2010 to 2019. The number of accepted cases in the first ten months of 2020 is substantially equal to that in the whole year of 2019.

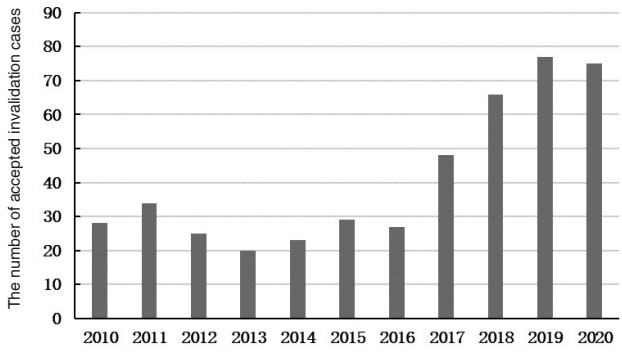

Fig. 1 The number of accepted invalidation cases in relation to chemical drug patents from 2010 to 2020 (Jan.–Oct.)

The patent linkage system will further accelerate the increase of patent invalidation cases. First, since the General Office of the Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices in 2017, both brand-name drug companies and generic drug companies have kept a close eye on the launch of relevant policies. The execution of the Phase One Economic and Trade Agreement between China and the United States in January 2020 and the official promulgation of the revised Patent Law in October 2020 further set the timeline for the implementation of the patent linkage system. Generic drug companies are obviously inclined to wait and see, and some have postponed their applications for generic drugs until the launch of the new system for the sake of the exclusivity period for the first follow-on product, and also postponed their requests for patent invalidation against corresponding patents. Second, a generic drug applicant may challenge a brand-name drug patent, but as a countermeasure, the holder of the brand-name drug patent may also challenge the patent (such as a dependent patent or a surrounding patent) of the generic drug applicant. Competing generic drug applicants may also try every means to expel counterparts from the market in order to gain market share. These all contribute to an increase in the number of patent invalidation cases. Third, the competition for the exclusivity period for the first follow-on product among generic drug companies will also lead to the growth of requests for invalidation against brand-name drug patents to a considerable extent.

In the first year in which the patent linkage system was fully implemented in South Korea, the number of patent invalidation cases was doubled. After the official implementation of the patent linkage system in March 2015, the Korean Intellectual Property Office accepted, from March 2015 to February 2016, 1,909 cases concerning patent linkage, most of which are patent invalidation cases (1622) (see Table 1 on the next page). [3]

Since it is stipulated in the China's Patent Law that anyone can file a request for invalidation against a granted patent, in view of the annual marketing of new drugs and generic drugs, it is conservatively estimated that the number of drug-related patent invalidation cases may increase by at least 50% annually in the coming years from 2021. This will pose a great challenge to CNIPA's examination of patent validity cases in the pharmaceutical field in terms of examining mode, quality control and manpower.

2. The increase of associated cases will greatly affect the conventional examining mode

Joinder of cases is currently the primary mode of handling several invalidation cases filed against the same pat-

ent. The current Guidelines for Patent Examination only set forth the provisions on "rolled-up hearing", and there is no explicit definition of "joinder of cases". However, in practice, the same collegial panel will usually hold a rolled-up hearing for associated cases (either in terms of facts or parties concerned) filed within a certain period of time and make a joinder decision depending on the specific situation. Joinder of cases is conducive to improving the efficiency of examination, unifying trial standards, and offering convenience to parties concerned, and more importantly, avoiding multiple invalidation decisions with conflicting conclusions issued successively.

After the implementation of the patent linkage system, the likelihood that several generic drug applicants file requests for invalidation directed to the same patent within the same period of time will increase. Meanwhile, according to Article 46 of the China's Patent Law, any entity or individual considering the grant of the patent not in line with the relevant provision of the Patent Law may file a request to declare the patent invalid. In practice, in addition to invalidation requests filed by generic drug applicants, there are also other invalidation requests filed for the sake of interests other than the marketing authorisation of generic drugs. These invalidation cases require quite differently from those filed by generic drug applicants in terms of the trial cycle. Their intertwining will make the examination more complicated.

Then, a patent invalidation case may be intertwined with administrative adjudication or litigation proceedings for deciding whether a technical solution falls within the scope of a patent. On the one hand, the determination of the scope of protection in administrative adjudication proceedings is often based on the conclusion of a patent invalidation case. On the other hand, two case types are also interrelated to each other in terms of the interpretation of the scope of protection of claims, and thus the examination of an invalidation case may be restricted and influenced by the administrative adjudication proceedings.

Furthermore, the exclusivity period for the first follow-on product will pose new challenges to the conventional joinder of cases. The exclusivity period for the first follow-on product is a privilege given to the first generic drug applicant who successfully challenges patent validity. The difference in the definition of the first generic drug applicant "who successfully challenges patent validity" will result in different examining modes for invalidation cases. Up to now, the Draft Implementing Measures cannot provide a final definition of the first generic drug applicant "who successfully challenges patent validity" in spite of several rounds of opinion solicitation,[5] which poses a severer challenge to the conventional joinder of cases to some extent.

3. The need for patent validity defense poses a severe challenge to the patent invalidation proceedings

Introducing patent validity defense into the civil proceedings is a hot topic that has attracted wide concerns in recent years. During the "Two Sessions" in 2019, a representative of the People's Congress once suggested reforming and improving the patent invalidation proceedings, wherein one specific proposal is to "explicitly set forth a provision on patent validity defense" in the patent law. [6] Al-

Case types	Jan. 2013 - Feb. 2015	2015										2016		Total
		Mar.	Apr.	May	June	July	Aug.	Sep.	Oct.	Nov.	Dec.	Jan.	Feb.	
Negative scope confirmation	132	103	57	23	2	16	1	4	7	40	25	2	7	419
Positive scope confirmation	11												3	14
Patent invalidation	181	515	563	22	1	1	1		3	8	1	2		1,298
PTE invalidation	0	162	332	10				1						505
Total	324	780	952	55	3	17	2	5	10	48	26	4	10	2,236

Table 1 Case types after the implementation of patent linkage system in South Korea [4]

though the legislature did not adopt the above suggestion in the fourth revision of the patent law, the launch of the patent linkage system raked up the issues concerning the patent validity defense. According to Article 6 of the Draft Implementing Measures, the fourth type of declaration made by a generic drug applicant is that the patent registered for the brand-name drug should be declared invalid, or the generic drug is not covered by a claim of the said patent. As regards the fourth type of declaration, both the generic drug applicant and the patentee may initiate a dispute resolution mechanism, which is theoretically aimed to solve the above two issues. Therefore, some scholar once opined that "it is necessary to delve into a trial mode for resolving an administrative dispute over patent invalidation in a civil case. Where the patent validity is challenged, that is to say, a generic drug applicant files a counterclaim for invalidating the patent right, the people's court can directly make a decision on patent validity and the plaintiff's (patent infringement) claim, and there is no need to require the generic drug applicant to file a separate invalidation request with the Patent Reexamination Board according to the general procedure requirement." [7] As a matter of fact, the Supreme People's Court released, on 29 October 2020, the Provisions on Several Issues Concerning Application of Law to the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval (Draft for Comments), wherein Article 9.2 stipulates that "where the applicant for drug marketing authorisation claims that the relevant patent obviously falls under the circumstance that it should be declared invalid, after ascertaining the facts, the people's court may decide to dismiss the claims of the patent holder or interested party, or declare the drug-related technical solution applied for registration does not fall within the scope of protection of the relevant patent at the request of the applicant for drug marketing authorisation." Although the judicial interpretation is still at the stage of opinion solicitation, sufficient attention should be paid to the patent validity defense with the launch of the patent linkage system even though such a defense was not incorporated into the patent law during its fourth revision.

In summary, the implementation of the patent linkage system makes the administrative patent validity examination to confront both internal and external difficulties. On the one hand, the patent linkage system provides an opportunity to introduce the patent validity defense into the civil infringement proceedings, and will re-trigger discussion on the reform of the binary (administrative and civil) patent system; and on the other hand, the increase in the number of invalidation cases, especially those associated with other proceedings, will lay heavy pressure on the existing examination and management mechanism of the administrative patent validity procedure. The competent authority must cope with both issues well.

III. Countermeasures and optimization of administrative patent validity examination

In face of the above situations and challenges, the following countermeasures are recommended: one is to set up a mechanism to guarantee fast filing and prioritized examination of patent invalidation cases so as to meet the practical demands for the decision or examination on patent validity in actions for confirmation or administrative adjudication proceedings; second is to classify and select cases for fast-track examination; and third is to set up an examining mode adapted to the needs of patent linkage.

1. Adhering to the binary examining mode and giving full play to the prioritized examination for invalidation cases

Judgment on patent validity goes hand in hand with judgment on whether a technical solution falls within the scope of protection of the patent, which is not unique in drug-related patent disputes. Breaking the barrier of the binary system is not the only way to substantively resolve the disputes. Under the binary system, it is surely possible to find a way that fits China's conditions by designing a smooth workflow and bringing respective advantages into full play.

Adhering to the binary system is the basic requirement of lawful administration. The binary (administrative and civil) patent system is explicitly stipulated in the patent law and is a historical choice of the patent law for compliance with China's national conditions. It plays a unique role at present. In the context of patent linkage, generic drugs and brand-name drugs are so special that under some circumstances, disputes cannot be substantively resolved and the purpose of the patent linkage system cannot be realized by purely judging whether a generic drug falls within the scope of a patent without considering patent validity. After all, the patent linkage system works under the framework of the patent law and thus should be consistent with its general infrastruc-

ture. In the case that the patent law does not explicitly introduce the patent validity defense into the civil procedure, in principle, such defense raised by a generic drug applicant should not be considered in either administrative adjudication proceedings or actions for confirmation as to whether the generic drug falls within the scope of the patent. Moreover, patent validity defense is not the only way towards an early and rapid dispute resolution.

Issues concerning patent validity in the administrative adjudication proceedings or actions for confirmation may be solved by a system ensuring fast filing and prioritized examination of patent invalidation cases. First, the fundamental goal of the patent linkage system is to make full use of limited resources to rapidly resolve patent disputes at minimum cost and with optimum quality. In comparison with judgment on whether a technical solution falls within the scope of a patent, judgment on validity of a pharmaceutical patent sets higher requirements on technical backgrounds and professionalism. Setting up a team of specialized technical investigators to solve technical problems in litigation instead of utilizing mature patent invalidation proceedings and professional examiners is not a reasonable method for allocation of resources. Second, as for patent validity disputes in the administrative adjudication proceedings or actions for confirmation, the patent administration department under the State Council may, at the request of the generic drug applicant, accept the case and examine in accordance with the Administrative Measures for Prioritized Examination of Patents. Statistics show that the patent office usually finishes prioritized examination on validity within five months. Such a period may be shortened by another one or two months if coupled with a flexible delivery mechanism. In doing so, the patent administration department under the State Council can bring its "professional" advantages into full play, saving social resources to the maximum extent.

Together with a "green channel" in administrative litigation, it is possible to consolidate second-instance civil and administrative procedures and obtain an effective judgment within the stay period for marketing authorisation. Solving a dispute at minimum cost in exchange for maximum social benefits is the basic requirement of law and economics. Good communication and coordination between administrative and judicial procedures will enable the professionals to exert their function. Irrespective of whether it is an action for confirmation or an administrative adjudication proceeding, if the fourth type of declaration made by a generic drug applicant is that the patent registered for the brand-name drug should be declared invalid, the decision on invalidation can be made as quickly as possible by means of fast-track filing and prioritized examination in the invalidation proceedings, and it is very likely that the first-instance administrative litigation on validity coincides with the first-instance action for confirmation in terms of time so as to enable the joinder of cases at least in the second instance as long as the people's court cooperates with the administrative authority to provide a "green channel" for prioritized examination of such an invalidation case. This workflow design will help administrative authorities and people's courts to exert their advantages respectively to escort the implementation of the patent linkage system and provide better services for the parties concerned.

2. Setting up a classification mechanism to select cases for fast-track examination

In the near future, the contradiction between limited examining resources and rapid increase in case number, as well as the contradiction between examination quality and efficiency, will continue to exist. Only by improving efficient management and implementing different policies for different types of cases can the requirements of various sectors of the society for patent validity proceedings be satisfied.

(1) Distinguishing the types of invalidation petitioners and setting different targets

Petitioners in drug-related patent invalidation cases are characterized by diversity, and different types of petitioners have different demands on examination cycle. After the implementation of the patent linkage system, in addition to invalidation requests filed by generic drug applicants on the basis of the fourth type of declaration, generic companies will also try their utmost to remove patent barriers before investment or application for marketing authorisation due to huge cost, high risk and heavy dependence on patents in the field of pharmaceutical production. The most common way is to file an invalidation request in the name of a generic drug applicant itself or a "straw man". Meanwhile, non-market entities may also constantly file requests for invalidation directed to some blockbuster drugs. Since invalidation decisions are not urgently awaited for solving pending infringement disputes under the above two circumstances, there is usually no urgent need to have petitioners' invalidation requests closed in a relatively short period of time. This is different from the requirements of generic drug applicants for examination cycle under the patent linkage sys-

tem.

It is suggested to reasonably adjust the targets according to different needs on the premise of maintaining the overall average examination cycle. To be specific, by refining management, cases can be closed in a shorter time or examination thereof can be prolonged depending on the parties concerned. A shorter examination cycle may be set for invalidation cases concerning patent linkage than other invalidation cases, so as to close such cases as soon as possible and provide the examination conclusions for judicial or administrative proceedings within nine months. This not only is the basic requirement of invalidation cases concerning patent linkage, but also ensures that the invalidation proceedings can be brought into full play in the operation of the patent linkage system.

(2) Coordinating with the fast-track examination mechanism to meet the target

On 1 August 2017, the then State Intellectual Property Office implemented the Administrative Measures for Prioritized Examination of Patents (Order No. 76), stating that at the request of a party concerned, prioritized examination can be conducted in patent invalidation cases related to patent infringement. In comparison with common infringement disputes, invalidation cases concerning patent linkage set up a stricter time limit for examination. For instance, even though the petitioner supplements reasons and evidence or the patentee amends a claim by ways other than deletion, high examination efficiency should still be maintained. For this reason, the current provisions on prioritized examination cannot fully meet the cycle and procedural requirements of invalidation cases concerning patent linkage.

A fast-track examination mechanism can be set up based on prioritized examination on the premise of following the basic principles such as compliance with the law, impartiality and hearing. To be specific, in comparison with the existing normal examination procedure, the fast-track examination may be characterized by, among other things, flexible document submission and delivery (e.g., delivery by e-mail so as to reduce the time spent on transportation), flexible time limit for evidence adduction and response (e.g., appropriately setting the time limit for transferring documents or making a response according to the type and amount of evidence), flexible process management and flexible oral hearing notification.

A fast-track examination with simplified and flexible procedure will provide convenience for the parties concerned, facilitate the reasonable allocation of examination resources and sound operation of the patent validity proceedings, and meanwhile resolve drug-related patent disputes in a quick and timely manner. Invalidation of improperly granted patents will be conducive to early marketing of generic drugs and drug availability. On the contrary, valid patents should be maintained timely in an effort to protect the legitimate interests of brand-name drug companies. In addition, a fast-track examination mechanism will not seriously impinge on the current examining mode. On the one hand, there is no technical obstacle for adapting to the electronic examination system; and on the other hand, during the coronavirus outbreak, documents have been forwarded through emails in some cases with remote oral hearings, which greatly shortens the delivery time and improves the oral hearing efficiency.

To sum up, the requirements for the implementation of the patent linkage system can be substantially met by setting different targets for drug-marketing-related patent invalidation cases and other cases and by establishing a fast-track examination mechanism.

3. Establishing a special examining mode in line with the patent linkage system so as to provide support for the exclusivity period for the first follow-on product

Joinder of cases is currently common for examining multiple invalidation cases concerning the same patent right. Generally speaking, the same collegial panel will hold a rolled-up hearing for related cases (either in terms of facts or parties concerned) within the same period of time and make a joinder invalidation decisions on a case-by-case basis. Three examining modes are possible for invalidation cases concerning patent linkage.

(1) Pros and cons of different examining modes

First, cases are examined in strict accordance with the order in which the invalidation requests are filed. According to Article 11 of the Draft Implementing Measures, the first generic drug applicant who successfully challenges patent validity will enjoy a 12-month exclusivity period if it is also the first applicant obtaining the marketing authorisation. When multiple generic drug applicants file invalidation requests successively and their grounds and evidence are all sufficient to invalidate the patent, the order of examination of invalidation cases will, to some extent, affect who will be entitled to the exclusivity period for the first follow-on product. Under such circumstances, it appears to be fair that the invalidation cases are examined in strict accordance

with the order in which the invalidation requests are filed, and invalidation decisions are made for different invalidation requests respectively. However, the examination efficiency will be lower than that of the joinder of cases. It is also likely that invalidation decisions made within a certain period of time are completely different, thereby causing confusion among the public.

Second, pending cases shall be examined in a joinder trial. Where generic drug applicants file invalidation requests successively, as long as the earlier requests are still pending, they will be examined together with the subsequent requests, and only one invalidation decision will be made for all the requests. By adopting this mode, the likelihood of making conflicting invalidation decisions within a certain period of time can be greatly reduced. However, on the one hand, some cases may last for a longer time, and on the other hand, some generic drug companies may be prone to taking a "free ride".

Third, with reference to the practice in South Korea, cases which are filed and accepted within a grace period (e.g., 14 days or a month) will be examined in a joinder trial with one invalidation decision issued. If the patent is invalidated, all invalidation petitioners who have filed invalidation requests within that period are deemed to have successfully challenged the patent. Such a mode is highly efficient and can help the collegial panel make an invalidation decision based on the most solid grounds and evidence and avoid conflicting decisions as much as possible. But it is prone to resulting in "free riding", leading to inflated increase of invalidation cases.

(2) Optimization for the mode of examining invalidation cases involving patent linkage

Different examining modes have their own pros and cons, and against the same drug patent, the invalidation petitioner may or may not be the applicant for the generic drug under the patent linkage system. Therefore, as for the optimization and adjustment of the examining mode, account shall be taken of the needs of the party concerned under the patent linkage system, and efforts be made to prevent too much impact on the existing examining mode. In view of various factors and needs, the authors make the following suggestions.

First, invalidation cases concerning patent linkage should, in principle, be examined in strict accordance with their order. In principle, invalidation cases concerning patent linkage all relate to the competition for the exclusivity period for the first follow-on product, which is a reward or favor offered to generic drug applicants for their initiatives and success in challenging patent rights. Thus, an invalidation decision shall embody the "initiatives" to file an invalidation request as early as possible, as well as the substantive efforts to "invalidate a patent based on grounds and evidence". For the sake of just and fair, and timely and efficient examination, invalidation cases concerning patent linkage should, in principle, be examined in strict accordance with their order. The "order" shall be in conformity with the "filing dates of the invalidation requests", rather than the "dates when they are accepted", so as to avoid the effect of different examination speeds on the order.

Oral hearings for invalidation cases filed within a certain period of time can be examined in a joinder trial as long as it is possible, and examination decisions shall, in principle, be issued separately. "Issuing separate decisions" is to respond to the substantive contribution made by each petitioner, and it is not necessary that one invalidation decision is made in response to each invalidation request. In order to avoid confusion caused among the public by multiple different invalidation decisions, it is preferable to make only one invalidation decision for multiple invalidation requests; however, comments shall be given on each petitioner's invalidation grounds and evidence to reflect its substantive contribution to patent challenge. "A certain period of time" can be set on a case-by-case basis. It is recommended to take the oral hearing as a cut-off point, which means, in principle, invalidation cases filed after the oral hearing shall not be examined in a joinder trial so as to prevent prolonged delay.

Second, invalidation cases concerning patent linkage shall be examined with priority, on the premise of causing no excessive impact on other cases. Early and quick resolution of patent disputes is the basic requirement of the patent linkage system. The twelve-month exclusivity period for the first follow-on product is crucial to generic drug applicants. Thus, for dispute resolution, speed and quality are equally important. Prioritized examination of invalidation cases concerning patent linkage is essential to fast resolution of disputes. As invalidation petitioners, generic drug applicants and other entities are equal before the law. Even invalidation cases concerning patent linkage call for faster examination due to the need for early dispute resolution, different petitioners should be treated equally in terms of basic procedures and substantive issues. Therefore, if prior to the

filing of an invalidation request concerning patent linkage, a patent can be invalidated based on another pending invalidation request, an invalidation decision shall be issued based on said previous request according to Rule 72 of the Implementing Regulations of the Patent Law.

Third, where an earlier decision has declared a patent invalid or partially invalid, a later filed invalidation case can be handled in different ways. Where prior to a new invalidation case, there is an earlier decision to be in effect or undergoing administrative litigation, according to the current practice, if the earlier decision maintains the validity of the patent, the examination on the later filed invalidation request will proceed; and if the earlier decision declares the patent invalid or partially invalid, the later invalidation request will be suspended and the earlier decision shall take effect.

In principle, invalidation cases concerning patent linkage can be handled in the above manners. However, in order to resolve patent disputes timely and promptly, the authors suggest handling invalidation cases concerning patent linkage on a case-by-case analysis: (1) if the earlier decision declares the patent partially invalid, and maintains the validity of the patent based on the amended claims filed by the patentee, examination of a later invalidation request can proceed based on the amended documents; and (2) except the above situation, if the earlier decision declares the patent invalid or partially invalid, the later-filed invalidation request shall be suspended until the administrative lawsuit is concluded. In comprehensive consideration of various factors, especially the low chances to lose invalidation cases in the chemical drug field, such a scheme can minimize the impact on the current examining mode on the premise of meeting the demands of the party concerned.

IV. Conclusion

As a new system, the patent linkage system will not only affect the administrative patent validity procedures by heavier workload, but also pose a challenge to the conventional examining mode. New issues will be solved with limited examination resources by way of making adjustment according to the needs of new situations, optimizing case-filing and examination methods, as well as resource allocation, and introducing a coordination mechanism that works well with the judicial procedure and the drug marketing review and approval procedure. ■

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[1] In the process of drug marketing review and approval, if a dispute arises between the applicant for marketing authorisation and the relevant patentee or interested party over the patent right relating to the drug under review, a relevant party may file a lawsuit with a people's court and request the court to make a judgment as to whether the technical solution of the drug applied for registration falls within the scope of protection of other party's patent. The drug supervision and administration department under the State Council may decide whether to suspend the drug marketing authorisation according to an effective judgment issued by the people's court.

[2] Article 11 of the Draft Implementing Measures stipulates that: if the market exclusivity period is granted for the first chemical generic drug that successfully challenges a patent and is approved of marketing (hereinafter referred to as the "exclusivity period for the first follow-on product"), the drug supervision and administration department under the State Council shall not approve of the marketing of a similar generic drug within twelve months from the date of approval of the drug, and the exclusivity period shall not exceed the patent term of the challenged drug.

[3] The reason why the number of invalidation cases in South Korea rose sharply in a short period may be closely associated with the rule for determining the "first" generic drug applicant who successfully challenges patent validity in the provision concerning the exclusivity period for the first follow-on product. Specifically, invalidation requests filed within fourteen days from the filing date of the first invalidation request are regarded as the same batch of requests. If any one of the invalidation requests successfully challenges patent validity, the batch of requests shall be considered as successful in challenging patent validity. As a consequence, many generic drug companies submit subsequent invalidation requests in hope of obtaining the exclusivity period by "free-riding".

[4] Qiu Enfu (2019). Introduction to patent linkage system in South Korea and inspiration for that in China. *Electronics Intellectual Property, 3*.

[5] Article 18 of the Implementing Plan of Patent Linkage System (Interim) (Draft for Internal Comments) issued on 12 April 2018 stipulates that the drug review and approval department can grant a twelve-month exclusivity period for the first generic drug that successfully challenges a patent and is approved of marketing. A similar generic drug shall not be approved of marketing within the exclusivity period. Where the patentee is not informed of the date of application timely,

no exclusivity period shall be granted. The applicant's act of requesting the Patent Reexamination Board (PRB) to declare a patent invalid due to incompliance with the provision of the Patent Law shall be deemed as challenging the patent.

Article 16 (exclusivity period) of the Draft Measures for the Administration of Patent Linkage (Trial) (Draft for Internal Comments) issued in July 2018 stipulates that the drug review and approval department can grant a twelve-month exclusivity period for the generic drug meeting the following requirements, and a similar generic drug shall not be approved of marketing within the exclusivity period: (1) the generic drug is the first one approved of marketing; and (2) the PRB has declared the patent invalid based on the invalidation request of the generic drug applicant or the people's court has decided that the generic drug applicant does not commit infringement.

Article 9 (prioritized review and approval) of the Draft Measures for the Administration of Patent Linkage (Trial) (Draft for Internal Comments) issued on 13 February 2019 stipulates that where the patent administration department under the State Council declares the patent invalid at the request of the generic drug applicant, the drug supervision and administration department under the State Council will conduct prioritized review and approval of the application for generic drug marketing.

[6] Luo Dongchuan. Amending and improving patent invalidation proceedings. WeChat Account: China Trial, posted on 15 March 2019.

[7] Cheng Yongshun. Issues to be considered and solved by the judicature during the implementation of the patent linkage system. WeChat Account: Zhichanli, posted on 4 April 2020. The author opined that the advantages of the system lie in that (1) in consideration of the specialization of patent challenging cases, the Intellectual Property Court of Beijing, in which the National Medical Products Administration is located, not only has the jurisdiction over such cases but also the exclusive jurisdiction over administrative patent invalidation cases. That is to say, it has the jurisdiction over both types of cases. (2) By hearing whether the patent right should be invalidated or has been infringed in the same case by the same court, it is possible to avoid inconsistency of judgements made in administrative and civil proceedings heard by different courts or by different tribunals of the same court, lower the uncertainty in the results of patent challenging cases, and thereby prevent improper damage suffered by the generic drug patentee, or inappropriate deprivation of the exclusivity period granted to the generic drug applicant. (3) Trying these two different types of cases by the same court can improve efficiency, avoid repeated litigation and accelerate the trial process so as to be consistent with the stay period for the marketing authorisation of a generic drug, and reduce the litigation burden on the parties and waste of social resources.

SPC's Intellectual Property Court Releases Annual Report and Typical Cases

The national-level Intellectual Property Court in Beijing has accepted 5,121 cases, with 4,220 of them concluded since its establishment in 2019, according to a report released by the IP Court on 26 February 2021.

The report also said that the cases accepted by the IP Court last year increased as much as 63 percent compared to 2019 due to the continued rise in intellectual property disputes.

As a standing judicial organ under China's Supreme People's Court, the IP Court was set up to hear civil and administrative appeals on technology-related intellectual property disputes and anti-monopoly disputes, and it aims to help prevent inconsistency of legal application and improve the quality and efficiency of the trials related to IPR.

Since the cases handled by the IP Court are complicated and demand specific knowledge and skills in the sector, the IP Court has selected 39 professional judges across the country, and 36 percent of them have technical and legal interdisciplinary backgrounds to better fit the job.

According to the report, the IP Court had held 114 series of Judges Conference in the past two years to study difficult legal issues related to IPR and established a talent pool with more than 450 technical investigators covering more than 30 technical fields.

"It took about a year for a technology-related IP appeal to be settled by High Courts before the IP Court was established. But now the IP Court only takes an average of 123 days in 2020 for one case to conclude", said He Zhonglin, first deputy chief judge of the IP Court.

In 2020, the IP Court also heard 376 technology-related IP cases involving parties from Hong Kong, Macao, Taiwan and foreign countries, with 281 of them concluded.

Source: China Daily