Suggestions for Fourth Amendments to Patent Law in the Context of Strict Protection

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Ever since the 18th National Congress, China has made a series of major decision-making deployments for the implementation of intellectual property strategies so as to promote "strict protection" in intellectual property field, and protect various types of innovative subjects according to law. After the 19th National Congress, Chinese leaders have proposed to strengthen intellectual property protection on many important occasions so as to provide strict protection for intellectual property rights. The Chinese government has promulgated more than 150 documents related to strengthening intellectual property protection, which showed China's determination to strengthen intellectual property protection as strictly as possible.

On 18 October, 2017, President Xi Jinping highlighted in the Report of the 19th National Congress that China will "foster a culture of innovation, and strengthen the creation, protection and implementation of intellectual property rights."

On 10 April, 2018, President Xi Jinping delivered a keynote speech at the opening ceremony of the Boao Forum for Asia Annual Conference 2018, indicating that "strengthening intellectual property protection is the most important part of improving property rights protection and also the greatest incentive to promote China's economic competitiveness".

On 28 August, 2018, when meeting with WIPO Director General Francis Gurry, Premier Li Keqiang said "China will adopt a stricter IPR protection system and further improve relevant laws and regulations. Forced transfer of intellectual property rights will be punished. Acts of infringing on intellectual property rights will be severely punished."

As far as the patent system is concerned, although the international community and developed countries have constantly accused Chinese companies and individuals of squatting trademarks of luxury brands, stealing trade secrets, manufacturing and selling counterfeited goods, using pirated software and works, voices concerning low level of patent protection and weak protection in China are seldom heard.

In response to a series of major decision-making deployments and for echoing the call for strengthening intellectual property protection of the whole society, the China National Intellectual Property Administration (CNIPA) initiated the fourth amendment to the China's Patent Law. The discussion with respect to the amendment has lasted for about 10 years with an aim of promoting "strict protection" and letting infringers pay a high price, coordinating relevant departments for "large-scale protection", boosting "fast protection" for defending right quickly, and conferring "equal protection" to various innovative entities according to law.

The writer opines that from the perspective of strengthening innovation protection, attention shall be paid to the following aspects [1] when amending the China's Patent Law.

I. It is proposed to add provisions related to "correction procedures after the grant of a patent" so as to enable right holders to initiatively amend the claims in invalidation proceedings

The China's patent law imposes over-severe restrictions on patent holders. Applicants are only allowed to amend the claims before the grant of patent. After the grant or in invalidation proceedings, the patent holders are only allowed to make narrowing amendments within the scope

of protection of a claim, rather than any other clarifying amendments within the scope of protection of the description, even though it is an obvious mistake, error or loophole. Nor are there any relief measures provided for patent holders. As a result, many patents have to be invalidated. In judicial practice, no protection shall be provided for patents having claims with an unclearly-described scope of protection, which goes against the spirit of strengthened and strict patent protection. In practice, after realizing that patents have unclear scope of protection after grant, some patent holders have to invalidate their own patents so as to further clarify the scope of protection of patents, which results in waste of social resources.

In consideration of the fact that the overall quality of patent documents drafted by innovative entities in China can be improved, it is suggested by the innovative entities that, with reference to application and examination practices in foreign countries, a "correction procedure after the grant of a patent" should be added to Article 39 of the China's Patent Law, stipulating that "where, starting from the date of announcement of the grant of the patent right by the Patent Administration Department under the State Council, a patent holder finds the granted patent is defective, it or he may request the Patent Reexamination Board (PRB) to make corrections to the granted patent. The correction made to the patent documents by the patent holder shall neither broaden the scope of protection of the patent as originally filed, nor extend beyond the scope of the patent originally disclosed at the time of filing. The solution of the new claim formed after the correction has no retroactive effect on others' acts conducted before the correction." This amendment is conducive to improving the quality and stability of patents granted to domestic entities in China, and thereby enhancing the patent strength and international competitiveness of innovative entities. The reasons are listed as follows:

First of all, where a patent holder finds and is willing to overcome a defect existing in a patent, there should be a procedure established to provide the patent holder with the opportunity to make amendments and improvement.

Second, the correction procedure enables the patent holder to improve its or his patent fairly and squarely, which is more rational than the current approach that the patent holder can only make a request for invalidation of its or his own patent by itself or himself or through a straw man, and is forced to improve its or his patent through invalid proceedings.

Third, the United States, Europe, and Japan all have correction procedures after the grant of a patent. Patent holders can overcome the defects in their patents through those procedures, and prevent themselves from being attacked due to the defects of patents in the invalidation proceedings initiated by third parties.

Encouraging invention-creations is the legislative objective of the patent law. Likewise, treating innovative achievements and patent holders fairly shall also be embodied in the provisions of the patent law. Ambiguous, defective and flawed claims should not be used as the grounds for punishment if the right holders have made technical innovations; instead, they should be provided with opportunities to make corrections, which is expected to be the original intent of legislation. The purpose of patent examination and protection shall be "curing diseases and saving people's lives", rather than "throwing the baby out with the bath water", that is, as for a defective patent, the patent holder shall be given the opportunity to make corrections so that it or he can be provided with protection to an extent that is consistent with the inventive contributions it or he has made to the society. The relief opportunities should not be deprived of just because of the defects or errors in the drafting of patent documents, which will lead to the result that the creative achievements contained therein cannot be put under due protection.

II. It is proposed to add provisions related to "partial designs"

The Patent Law Amendments (Draft) extends the term of protection of designs as prescribed in Article 42 of the China's Patent Law from ten years to fifteen years, with an aim of satisfying relevant requirements for the term of protection of designs in the Hague Agreement Concerning the International Registration of Industrial Designs that China recently entered. Extension of the term of protection of design patents alone, however, cannot solve the problems existing in design protection in China. Nor can it achieve the purpose of strengthening the design protection.

Statistics showed that the average life span of China's design patents is three to five years. A great majority of design patents has lapsed due to non-payment of fees, and there are very few design patents that last for 10 years. Although the Patent Law Amendments (Draft) extends the

term of protection of designs to fifteen years, it has no significant impact on the strengthening of protection of design patents under the current circumstances.

China has become a "patent application giant", and ranked top one in the list of the number of patent filings in the world for more than ten years consecutively. The number of applications and granted design patents has increased year by year. The rise in the number of existing designs indicates the increase in the difficulty of design innovations. It is really hard to create designs that are absolutely unprecedented.

In view of the foregoing, many other countries, including the United States and Japan, have set forth provisions for protection of partial designs. China has also conducted special researches and released special reports in this regard during the third and fourth amendments to the China's Patent Law. Although there are no explicit provisions in the patent law, cases related to protection of partial design have occurred in judicial practice. As a matter of fact, providing protection to partial designs is more beneficial to the protection of innovations and designs as compared with providing no protection. Account shall be taken of incorporating relevant provisions concerning partial designs in the context that the partial design protection system in foreign countries has been adequately investigated and researched and China intends to strengthen patent protection and implement strict protection.

Those, who are against the incorporation of "partial designs", argue that China has too many junk patents, especially utility models and designs that are not required for substantive examination. If "partial designs" are protected, it will surely give rise to more junk designs. In fact, if the definition of "partial designs" and the true cause of the increase in junk patents in China have been made clear, it will be understood that there is no causal relationship between the protection of "partial designs" and the increase in junk designs. What is more, they are totally irrelevant to each other.

III. It is proposed to add relevant provisions related to "indirect patent infringement"

It is proposed that Article 11 of the China's Patent Law should be added with a third paragraph, stipulating that "where, without the permission of the patent holder, a party, clearly knowing that a relevant product is a raw material, intermediate product, component or equipment exclusively used for implementing the technical solution of a patent in suit, or a material, apparatus or special-purpose equipment exclusively used for implementing a process of a patent in suit, provides said exclusively-used product to others for production and business purposes and the others commit acts of patent infringement, or intentionally induce, instigate or abet others to commit acts of patent infringement, it or he shall bear civil liabilities."

Article 11 of the current China's Patent Law stipulates direct infringement, but not indirect infringement. During the previous amendments, drafts and suggestions for incorporating indirect infringement have been proposed, but they all went to nowhere due to some controversies. Nevertheless, in judicial practice, there were a few indirect infringement-related cases heard in courts all over China as early as a dozen of years ago, such as the "magnetic mirror arc circuit" case [2], the "novel weeding composition" case [3], the "*Alpha Laval Corporate AB v. Hengli Co.*" case [4]. At present, the absence of indirect infringement in the patent law is inconsistent with judicial demands and practical judgments.

During the third amendment to the China's Patent Law, three special research projects were established for "indirect infringement" and three special reports were eventually completed. After adequate studies and argumentation, the research groups which accomplished the three special reports reached substantively the same conclusions, that is, the "indirect infringement" system should be introduced, and the provisions related to "indirect infringement" have been drafted. The relevant provisions, however, were not adopted into the law in the third amendments to the China's Patent Law in 2008. The CNIPA particularly made an explanation in the Interpretation on the Draft Amendment of the Patent Law of the PRC, stating that "about indirect infringement — during the opinion solicitation process, many foreign companies, and some domestic enterprises and experts and scholars proposed adding the provisions on indirect infringement. Indirect infringement refers to the acts of providing special components or apparatuses (which are not patented) exclusively used for committing infringement of a patent by the one who clearly knows that the others intend to commit patent infringement. The incorporation of provisions on prohibiting indirect infringement into the patent law essentially intends to expand the scope of protection to non-patented products which are, however, relevant

to patented technologies. Therefore, the issue related to indirect infringement has fallen within a sensitive grey area between the interests of patentees and of the public interest. If the formulation or application of relevant rules is slightly inappropriate, it may impair the public's right to use the prior art freely. In consideration of the above factors and the fact that the patent holder can seek for protection by asserting rights against direct infringers and hold them jointly and severally liable according to the provisions on joint infringement of the General Principles of the Civil Law of the PRC, the CNIPA believes that it is not a right time to adopt the provisions on indirect infringement into the patent law."

The fourth amendment to the China's Patent Law was carried out a decade later after the third amendments to the China's Patent Law. Things have been tremendously changed compared to ten years ago. In particular, the number of software patents and business method patents has sharply risen in China. The lack of clear provisions on indirect infringement leads to chaos that "different judgments are made for the same case" in judicial practice: some courts determined "joint infringement" occurred, some concluded "non-infringement" as neither constituent elements of direct infringement nor the constituent elements of joint infringement are satisfied, and some determined "indirect infringement". The inconsistency of judicial judgements is not good for patent holders to exercise their own rights or to protect their patents, and is disadvantageous to the protection of software patents, business method patents and business model patents, let alone strict and strengthened protection.

The incorporation of the provisions concerning indirect infringement is the embodiment of "implementing intellectual property strategies and strengthening intellectual property protection" at the legislative level. There are indeed urgent needs for the protection of industrial innovations. In the era of distributed network and cloud computing, as for the methods for communication, use and processing and the method patents for using the products on specific users, it is really hard to provide effective protection for patents owned by patent holders and stimulate innovations merely by way of direct infringement remedies stipulated in the existing laws, which is not conducive to the realization of the ambitious goal of building a strong intellectual property country.

It should be noted that advantageous institutional attempts for indirect infringement have been conducted in years-long judicial practice, and it is now the ripe time for incorporating indirect infringement into law. At first, the provisions on abetting and assisting infringement were first seen in Article 148 of the Opinions on Several Issues Concerning the Implementation of the General Principles of the Civil Law of the PRC (Trial) issued by the Supreme People's Court (SPC). Similar provisions are seen in Article 9 of the existing Tort Liability Law. As early as 2001, the Beijing High People's Court (BHPC) issued the Opinions on Several Issues Concerning Patent Infringement Determination (Trial) (the 2001 Opinions), wherein Articles 73 to 80 explicitly set forth the standards for determining "indirect infringement", which was an advantageous attempt to officially launch the system. In view that the concept "indirect infringement" is groundless in such a higher-level law as the Patent Law, the BHPC released the Guidelines for Patent Infringement Determination (2013) in September 2013, in which the wording "indirect infringement" was deleted from the 2001 Opinions. On 20 April, 2017, the BHPC released the Guidelines for Patent Infringement Determination (2017), wherein the contents related to indirect infringement were remained in "Part V. (II) Acts of Joint Infringement". Moreover, foreign countries, such as the United States, Japan, Germany, and the United Kingdom, also have relevant provisions on indirect infringement.

Therefore, the timing of incorporating indirect infringement into law is ripe from the perspective of institutional attempts made by the SPC and local courts in judicial practice for many years and demonstrations of laws of major foreign countries.

IV. It is proposed to cancel the fixed order of the methods for calculating damages, and the right holders should be entitled to choose the method for calculating damages on their own

The Patent Law Amendments (Draft) proposes the following provision into Article 65 of the China's Patent Law: "for willful patent infringement with serious circumstances, the damages may be one to five times the current damages"; meanwhile, the statutory damages are raised to no less than RMB 100,000 and no more than RMB 5,000,000. Literally speaking, it seems that the amount of damages has

been greatly increased, and the provision on punitive damages has been added so as to be more stringent on the issue of damages. It is really worthy of discussion as to whether such amendments can crack down on infringement and strengthen patent protection.

During the third amendment to the Trademark Law in 2013, the upper limit of the statutory damages was raised to RMB 3,000,000. But in practice, the damages awarded by the courts in trademark infringement cases are not apparently higher than those prior to the amendments to the Trademark Law. It can thus be seen that the increase in damages merely by amending the provisions does not solve the problem at all.

The patent law stipulates four methods for calculating damages, namely, damages shall be calculated according to the loss of the plaintiff, the profits gained by the defendant, the multiplier of patent royalties and statutory damages. In the meantime, pursuant to relevant provisions in the patent law, the four methods for calculating damages are applied in a fixed order, and when instituting an action, the patent holder has to make its decision on which method shall be used. Such provisions greatly limit the parties' right to choose the method for calculating damages, affect the calculation of damages on the part of patent holders, and pose huge obstacles to patent holders' relief-seeking. As a matter of fact, in patent infringement lawsuits, selecting the methods for calculating damages in a fixed order is not only unrealistic, but also infeasible. Nor will anyone do so in that way. It is proved by the fact that statutory damage calculation is applicable in a large number of patent infringement cases.

As for how to truly increase the amount of damages for the sake of strengthened and strict protection of patent rights, it is suggested to cancel the current fixed order of the methods for calculating damages caused by patent infringement and allow patent holders to freely select the applicable method according to actual conditions when filing lawsuits. Only when the amount of basic damages is increased can the amount of punitive damages (if any) be raised subsequently.

It shall also be noted that the provision proposed in the Patent Law Amendments (Draft) is related to "willful infringement of patent rights". In practice, there is no definition to willful infringement. The term "willful" in the Civil Law or Tort Liability Law may be summarized as hoping or doing nothing to the occurrence of infringement with the clear knowledge of harmful results (infringement results). The essence of the patent system is viewed as disclosure in exchange for monopoly, that is, to encourage patent holders to disclose their patented technologies in exchange for granting a monopoly for a certain period of time with the ultimate goal of boosting social progresses and scientific and technological development. Any patented technical solution is made through R&D and improvement on the basis of previous technical solutions and with the help of others' achievements, which is unavoidable. If the disclosure of patented technologies is regarded as the acquaintance with the patented technology by the whole society, the exploitation of the patented technology or the R&D or improvement based on the patented technology (which in most cases constitutes equivalent infringement) will constitute willful infringement, which is apparently opposite to the legislative intent of the patent system. Therefore, it is inappropriate to take "willful" as a constituent element of patent infringement and as the ground for determining the amount of damages.

Turning to trademarks, the trademark law does not protect the logo *per se*, but the goodwill conveyed by the trademark. In order to prevent others from free-riding and taking advantage of others' goodwill, the trademark law requires trademark applicants to avoid collision with existed trademarks in terms of trademark design, application and use. The China's Trademark Law stipulates "where an infringer maliciously infringes upon another party's exclusive right to use a trademark and falls under serious circumstances, the amount of damages may be determined as not less than one time but not more than three times the amount that is determined according to the aforesaid methods." That provision takes into account the subjective state of mind of the trademark infringer, which is in line with the practice of the trademark law.

Accordingly, it is suggested that Article 65 of the China's Patent Law should be amended as follows: "the amount of damages for patent infringement shall be reasonably determined according to the patentee's actual losses caused by the infringement, the profits gained by the infringer from infringement, and the multiplier of patent royalties; and the patentee or any interested party may select the method for calculating damages and provide corresponding evidence. If it is hard to determine the actual losses of the patentee, the profits acquired by the infringer or the patent royalties, the people's court may award the damages of no more than RMB 5,000,000 according to the type

of the patent right, and the nature and circumstances of the infringing act.

The amount of damages shall cover the reasonable expenses paid by the right holder for stopping the infringing act.

Where the right holder has exhausted its efforts in discharging the obligation of burden of proof, but the account books and materials related to the infringing acts are mainly controlled by the infringer, the people's court may, for the purpose of determining the amount of damages, order the infringer to submit account books and materials related to the infringing acts. Where the infringer fails to provide such account books or materials or provides false account books or materials, the people's court may render a judgment on the amount of damages in reference to the claims of the right holder and the evidence furnished thereby."

V. It is proposed to cancel the provisions on "the principle of good faith"

The Patent Law Amendments (Draft) newly proposes that "applying for a patent and exercising a patent right shall follow the principle of good faith", which is suggested to be deleted for the reasons as follows:

First, a patent right is different from a trademark right in nature. A patent right intends to protect innovations and achievements made through intelligent labor. When applying for patents, patent applicants are required to submit a complete technical solution and pay an annual fee on a yearly basis, that is, patent applicants have to pay considerable time, energy and financial resources (considerable costs) to obtain and maintain the patent rights. In contrast, the trademark right seemingly protects the logo *per se*, but in fact the goodwill conveyed by the trademark. Only in the use of the trademark can it exert its function to indicate the source of goods or services. Patents and trademarks are essentially different, so it is inappropriate to simply transplant the principle of good faith in the civil law and the trademark law into the patent law.

Second, since any patented technology is achieved as a result of R&D and improvement of the prior art, it is really difficult, in practice, to judge whether a patent applicant or holder exercises the right to the patent dishonestly, which renders the provision nonsense.

Third, it can be understood that the above provision is intended to solve the current problem that there exist a large number of junk applications and patents. Yet it is foreseeable that said provision cannot solve the problem, but poses a threat to right holders. Enterprises are, in essence, profit-seeking. The root cause of the proliferation of junk patents lies in incorrect policy orientation, such as patent filing appraisal, and tax incentives, rewards and bonuses for enterprises that satisfy certain requirements (which includes, among other things, the ownership of a certain number of patent filings). Hence, the fundamental solution to the issue of junk patents is to correct policy orientation and guidance so as to encourage enterprises to create innovations in a more scientific way. The provision requiring patent applicants and holders to follow the principle of good faith cannot solve the problem at all.

VI. The provision on "patent term restoration" shall be improved

On 8 October, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council released "Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices" (hereinafter referred to as the "Opinions"), wherein Part III "Promoting Pharmaceutical Innovation and Generic Drug Development" clarifies that (17) Carrying out Pilot Trials for Patent Term Restoration System. Some new drugs are selected for trials, so as to compensate a duly patent term for delayed marketing time caused by clinical experiments, as well as drug review and approval procedures. The incorporation of the provision concerning extending the patent term of drugs in the Patent Law Amendments (Draft) complies with both the practical requirements for protection of pharmaceutical patents and the provision concerning pharmaceutical patent protection in most countries. That provision will provide great support and encouragement for the development of R&D of innovative drugs.

However, according to the Patent Law Amendment (Draft), pharmaceutical patents qualified for patent term restoration under Article 42.2 of the China's Patent Law are only limited to "invention patents related to innovative drugs simultaneously applying for marketing within and out of the territory of China". Based on the provision, invention patents related to innovative drugs applying for marketing only

within the territory of China are not eligible for patent term restoration, which will definitely dampen the enthusiasm of Chinese innovative pharmaceutical companies for innovations, and be harmful to encourage the domestic innovative companies to apply for marketing of innovative drugs domestically, which will ultimately harm the interests of consumers (patients).

In view of the above, it is suggested that the provision should be amended as follows: "in order to make up for the review and approval time required for the marketing of innovative drugs, the State Council may decide to extend the term of patents for invention of innovative drugs initially applying for marketing within the territory of China or simultaneously applying for marketing within and out of territory of China. The extended term shall be no more than five years, and the total effective patent term after the marketing of the innovative drugs shall not exceed 14 years." Such a provision will make sure that innovative drugs initially applying for marketing within the territory of China are eligible for an extended patent term. Due to different review and approval requirements, speed and time limits at drug supervision and administration authorities in various countries, judicial interpretations or more specific rules stipulated by the drug supervision and administration department in China are required to further specify the simultaneous marketing within and out of the territory of China, namely, whether it refers to simultaneous application, approval or marketing.

VII. It is proposed to add the provisions regarding "artificial infringement" so as to lay a foundation for the "patent linkage system"

Protection of pharmaceutical patents involves four aspects: Bolar exception, patent term restoration, patent linkage system and compulsory licensing. Among them, the provisions on compulsory licensing have been adopted in the China's Patent Law at an early stage; Bolar exception has been introduced into the current China's Patent Law in 2008. The provision concerning the patent term restoration has been added in the Patent Law Amendment (Draft) this time. However, the provisions on the "patent linkage system" are still missing.

The implementation of the "patent linkage system" is premised on "the act of artificial infringement" in the China's Patent Law. In view of the foregoing, it is suggested to introduce a provision concerning "artificial infringement" into Article 11 of the China's Patent Law, i.e., Article 11.2 stipulates that "where a generic drug applicant submits an application for drug registration to the drug supervision and administration authority, if the drug application contains a drug involved in a valid pharmaceutical patent or pharmaceutical process patent, it is deemed as patent infringement". It is also suggested to clarify the liabilities of infringement. Once artificial infringement is established, the infringer shall withdraw the application for drug registration; and if the infringer does not withdraw the application, the provisions of the Drug Administration Law shall be applied to deal with this situation.

The reasons for making the proposed amendments are listed as follows:

First, drugs are special as they are necessities for human beings to maintain their lives and dignity. For the sake of drug accessibility, consideration shall be given to both the promotion of new drug R&D and the decrease of drug prices. Therefore, the protection of pharmaceutical patents under the China's Patent Law has gone through a process from not providing protection to providing weak protection and then to increasingly strengthening the protection. Ever since 2006, China has released a series of policies as incentives for encouraging drug innovations and promoting the development of the pharmaceutical industry. Currently, there have been some essential elements of patent linkage system in the China's drug administration system. It is necessary to introduce the relevant contents of the patent linkage system into the China's Patent Law in an effort to improving the patent linkage system on the basis of the current system.

Second, on 8 October, 2017, the third part "Promoting Drug Innovation and Generic Drug Development" of the Opinions clarified: (16) Exploring the Establishment of Patent linkage System. The exploration on the establishment of the linkage system between the drug review and approval system and drug-related patents shall be carried out in order to protect the legitimate rights and interests of patent owners, reduce the risk of patent infringement of generics, and encourage the development of generic industry. When a drug applicant submits the application, it shall clarify the relevant patent and the ownership thereof, and notify the relevant patent holder within the statutory period. If there is a dispute over the patent right, the parties may file a lawsuit

with the court, but the technical review on drug shall not be stopped during the lawsuit. For drugs passing technical review, the food and drug regulatory authority shall make decisions on whether or not to approve the applications for marketing based on the court's judgments, decisions, or mediation agreements. If no effective judgment, decision or mediation agreement is made when the statutory period expires, the food and drug regulatory authority may approve the follow-on application. Without provisions concerning "artificial infringement" in the China's Patent Law, the exploration of the entire patent linkage system cannot be carried out due to lack of legal support.

Third, on the basis of the Opinions, the National Medical Products Administration is engaged in making amendments to the Drug Administration Law, which surely includes the introduction of the patent linkage system. In view that the patent linkage system involves the functional linking and coordination between the drug supervision and administration department and the patent administration department, it is necessary to incorporate the corresponding part of the patent linkage system into the patent law from the perspective of uniformity of legislation and law enforcement, which lays the institutional foundation for the coordination between the two departments in the future.

Fourth, judging from the more-than-thirty-year practical effects of the patent linkage system, which is originated in the United States, it has not only boosted the development of innovative drugs but also greatly promoted the development of generic drugs. Currently in China, generic companies are in the dominant position in the pharmaceutical industry. The incorporation of the relevant contents of the patent linkage system in the patent law to improve the construction of related systems is conducive to enhancing the innovative capabilities of both generic and innovative companies, thereby strengthening the protection of drug patents and stimulating the development of the pharmaceutical industry.

As far as the anticipated effect is concerned, the incorporation of the relevant contents of the patent linkage system is conducive to reducing the risk of the drug administration department as an infringing defendant, lowering the number of lawsuits after the approved drugs enter into the market, decreasing the impact of lawsuits and the loss suffered by relevant enterprises, and beneficial for unifying the relevant standards for pharmaceutical patent cases in the invalidation proceedings.

VIII. Concerning Articles 41 and 46 of the Patent Law, which clarify the nature of patent invalidation cases and empower the courts to determine the patent validity

It is suggested that Article 41 of the China's Patent Law should be added with a third paragraph, stipulating that "after trial, the people's court shall make a judgment to maintain or partially maintain the patent, or remand the case to the patent administrative department to re-make a judgment."

It is suggested that Article 46.2 of the China's Patent Law should be amended as follows: "If the party is dissatisfied with the PRB's decision to invalidate or maintain the patent right, it or he may file a lawsuit with the people's court within three months from the date of receipt of the notice, and cite the other party in the invalidation proceedings as the defendant, and the PRB may be cited as a third party."

It is suggested that Article 46 of the China's Patent Law should be added with a third paragraph, stipulating that "after trial, the people's court shall make a judgment to declare the patent valid, partially valid, or invalid and revoked."

The specific grounds for amendment are listed as follows:

According to the China's overall process for deepening of reform and opening up, the China's patent system and judicial mechanism have undergone significant changes. The establishment and operation of the IP Court of the Supreme People's Court (SPC) and the local IP tribunals are the best proof. The Chinese government approved of the establishment of the IP Court of the SPC, which was a major measure of the patent system to reduce the level of dispute resolution, and also laid a solid foundation for ending repeated litigation by the judicial final ruling. Therefore, we should strive to use the optimal patent dispute resolution mechanism to deal with the challenges brought about by innovative reforms and the scientific and technological revolution.

At present, the litigation procedure for patent invalidation disputes in China is unscientific, and the invalidation proceedings are so complicated that the trial of patent infringement cases and that of patent invalidation cases are

mutually affected each other. On the one hand, the nature of the administrative litigation of patent invalidation disputes is unscientific. In the patent invalidation cases, the confrontation between the invalidation requester and the respondent is the one between both parties. In practice, patent invalidation proceedings are generally treated as special procedures, and patent administrative review authorities are not treated as litigation defendants. The PRB makes a judgment by acting as the judge of disputes, which is not a unilateral act of the administrative authority. The patent invalidation decision is obviously different from the typical administrative acts such as administrative punishment, and is also different from the reexamination decision concerning whether a patent right shall be granted. However, the litigation procedures for patent invalidation cases in China are exactly the same as the administrative litigation procedures. The PRB must appear as a defendant in every invalidation case, which leads to a huge waste of public resources and renders the position of the PRB awkward in litigation. If related cases cannot be settled, the people's court can do nothing but uphold or revoke the PRB's decision, rather than directly deciding the validity of the patent, which leads to many *de facto* tricky issues like repeated litigation, redundant procedures and high cost of right safeguarding in the link between patent reexamination procedures and patent administrative litigation procedures, as well as civil patent infringement lawsuits and administrative patent invalidation and litigation proceedings.

The reform achievements shall be ultimately implemented in the form of law. In the existing patent invalidation system, the defects in the linking process between administrative review and litigation have existed for many years, and those issues can only be solved in legislation, i.e. through explicitly worded provisions of the patent law so as to avoid "excessive flexibility" of law enforcement by administrative and judicial authorities and "wrangling" therebetween as seen in the past practice, so as to protect the legitimate rights and interests and litigation rights of innovators and relevant practitioners, and make sure disputes can be resolved fairly.

The patent invalidation proceedings are reformed in an effort to achieve two basic objectives: one is to simplify relief procedures and promote the substantive resolution of disputes; and the other is to ensure the uniformity of law enforcement standards. [5] On 1 January, 2019, the IP Court of the SPC was officially unveiled to try all the second-instance invalidation cases and infringement cases in a centralized manner, which will thereby realize the consistency of judgments on patent validity at the highest judicial level. From the perspective of legislative technologies, it shall be clarified that the people's court has the judicial power to modify administrative acts or the PRB should re-make the decision as substantively required by the judgment of the people's court, instead of simply stating "filing a case with the people's court" in the legislation. This is a consensus reached on how to resolve the "repeated litigation" issue, i.e., Articles 41 and 46 in the Patent Law Amendment (Draft) shall be slightly modified to clarify that the PRB may appear in the patent invalidation lawsuit as a third party, rather than a defendant, and judicial interpretation may be made to further clarify the specific procedures thereof.

Of course, in the context of strengthened and strict protection of intellectual property rights, providing strengthened and strict protection for patent rights is not only a matter of legislation (i.e., law amendment), but also involves judicial interpretation, judicial practice, law enforcement, and accurate understanding and application of relevant rules by judges and law enforcers in individual cases. A good institutional design is the basis for all the foregoing matters. For the purpose of improving the patent system and implementing the innovation-driven development strategy, we suggest modifying relevant provisions of the Patent Law Amendment (Draft) to truly confer strengthened and strict protection to patent rights. ■

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[1] Reference shall be made to the Patent Law Amendment (Draft) on 23 December, 2018.

[2] The Civil Judgment No. Jinjingzhongzi 152/1993. The defendant did not commit infringement directly, but manufactured and sold the key components of the patented product without permission.

[3] The Civil Judgment No. Suminsanzhongzi 014/2005. The defendant manufactured the key components of the patented product exclusively used for producing a composition.

[4] The Civil Judgment No. Huerzhongminwu(zhi)chuzi 156/2005. The defendent provided the mould exclusively used for manufacturing the infringing product.

[5] Luo Dongchuan. Modification and Improvement of Patent Invalidation Proceedings. Retrieved from http://www.chinatrial.net.cn/news/26204.html.