Patent Linkage System Under Judicial and Administrative Procedures

— Comments on Article 76 of the Patent Law

Tao Guandong

Numerous legal debates over the patent linkage system in China during its establishment had been settled as Article 76 of the China's Patent Law clarifies its structure. This also indicated that the patent linkage system has been endorsed by the legislature in China, hoping to "enhance the innovative capability of the pharmaceutical industry". As the birthplace of the patent linkage system, "the U.S. has implemented the patent linkage system. Ever since, both patented drugs and generic drugs in the U.S. have undergone great development, the interests between brand-name companies and generic companies have been well balanced and generic drug prescriptions accounted for about 90% of the prescriptions nationwide." [1] According to the reply to the representatives of the National Committee of the Chinese People's Political Consultative Conference from the National Medical Products Administration, it can be seen that China has adopted relatively lenient policies towards the patent linkage system, and affirmed the function of the system to promote the innovation of China's pharmaceutical industry. The patent linkage system is quite complicated as it involves many aspects such as platform construction and information disclosure, patent listing, generic drug certification, judicial and administrative linkages, stay period, and exclusivity period for first follow-on applicants. [2] However, Article 76 of the China's Patent Law generally sets forth the requirements on the party concerned, the exercise of rights, the competent authorities and the results, etc. How to solve specific issues on a case-by-case basis still needs to be clarified by specific judicial interpretations and relevant link-up measures stipulated by the competent authorities. In order to better promote the implementation of the patent linkage system, the Supreme People's Court issued, on 5 July 2021, the Provisions on Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration (hereinafter referred to as the "Drug Provisions"). Just one day before, the State Drug Administration and the China National Intellectual Property Administration jointly promulgated and implemented the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (Trial) (hereinafter referred to as the "Drug Measures").

I. Judicial and administrative dispute resolution mechanisms

1."Dual-track" dispute resolution mechanisms

China currently adopts a "dual-track", i.e. judicial and administrative, mechanism to solve patent infringement disputes. As for a dispute over whether a marketed drug falls within the scope of protection of a patent, a patentee or interested party may either file a lawsuit with the people's court (the judicial track) or a request with the patent administration department (the administrative track). Article 65 of the China's Patent Law reads "where a dispute arises as a result of the exploitation of a patent without the authorization of the patentee, that is, the infringement of the patent right of the patentee, it shall be settled through consultation by the parties. Where the parties are not willing to consult with each other or where the consultation fails, the patentee or any interested party may institute legal proceedings in the people's court, or request the administrative authority for patent affairs to handle the matter……" [3] It is the own right of the patentee or any interested party to decide which proceedings to select. The Patent Law, the Drug Provisions

and the Drug Measures do not set any restrictions on it. In order to prevent patentees or interested parties from exploiting the dual-track mechanism by repeatedly initiating judicial or administrative proceedings that may prolong the stay period, the Drug Measures stipulate that if the party concerned has selected to request the patent administration department under the State Council to make an administrative ruling and later file an administrative lawsuit with the people's court due to dissatisfaction with the administrative ruling, the stay period will not be extended. That is to say, as far as the term of the stay period is concerned, administrative or judicial proceedings will not be different for patentees or interested parties.

A patentee or interested party has the right to decide whether to initiate an action and select which proceedings to safeguard its legitimate rights and interests. The selection between judicial proceedings and administrative proceedings needs to be rationally made based on the nature of the judicial and administrative proceedings and in consideration of the stability of the patent in suit, the technical solution of the drug applied for registration, the situation of the generic pharmaceutical company, etc. On the one hand, from the perspective of procedural effect, the result of judicial proceedings will be final. Resolving disputes over infringement resulting from drug marketing review and approval between brand-name companies and generic companies via judicial proceedings can reduce the burden of litigation on both parties and avoid further costs in manpower, financial, technical and other resources due to the uncertainty of conclusions or in pursuit of a more favorable outcome. On the other hand, from the perspective of substantive effect, the early resolution of patent disputes is not necessarily more beneficial to the parties concerned, especially to the generic companies. In comparison with brand-name companies, which have more comprehensive understanding of patent-related technology, such as the background, technical solution and examination procedures of the patents in suit, generic companies are generally in a disadvantageous position. Since some issues can be found and clarified only through the invalidation proceedings or patent litigation procedures, generic companies may have difficulty in evidence collection and technology understanding. Thus, it is not easy for them to succeed in challenging patents.

2. Initiation of proceedings under patent linkage system

Litigation as mentioned in Article 76 of the China's Patent Law is a brand-new type. The Drug Provisions clarify that the cause of action is to "affirm whether a technical solution falls within the scope of protection of the patent". Judging from the type of litigation, this cause of action belongs to action of affirmation without explicit claim for performance [4]. The action can be initiated either by the patentee or interested party for affirming that the technical solution falls within the scope of protection of the patent or by the generic applicant for affirming that the technical solution does not fall within the scope of protection of the patent.

Although the patent linkage system provides the patentee or interested party with an opportunity to early resolve its dispute with generic companies, it does not mean that the patentee or interested party must initiate legal proceedings against generic companies within the objection period after receiving the notice. The right to litigation is a basic right of a natural person, a legal person and other organizations. Whether and when to exercise this right, as well as what to claim, are own choices of the patentee or interested party made based on objective facts with no interference from any organization or individual. In the Drug Measures, it is clearly stated that "where a patent dispute cannot be early resolved, if the patentee, after the marketing approval of the related drug, believes that the drug infringes its patent right and therefore causes a dispute, the resulting dispute shall be resolved according to the provisions of the China's Patent Law and other laws and regulations." [5] If the patentee or interested party renounces to file a lawsuit against a generic company within the objection period, it can still exercise its right to litigation subsequently, but may be faced with the risks of expiration of the statute of limitation or losing market share to the generic company.

Whether to initiate the dispute resolution procedure during the marketing approval of generic drugs is out of legal and economic concerns as well. From a legal perspective, the patentee or generic company should file a lawsuit or request within the objection period in a bid to resolve the infringement dispute as early as possible so as to protect its own legitimate rights and interests. From an economic perspective, litigation will inevitably be costly in terms of manpower, technology and capital. If the patentee, though clearly knowing that the marketing of the generic drug may infringe its patent, does not enforce its right but waits until the generic company has developed to a certain scale and gained certain profits, and, at that time, files a lawsuit,[6] the monetary compensation can be comparable with the profits through its own operation. In order to minimize the risk of in-

fringement facing the generic company in the case that the patentee or interested party does not file a lawsuit or request for a ruling, Article 4 of the Drug Provisions stipulates that "if a patentee or interested party fails to file a lawsuit before the people's court within the time limit specified by the link-up measures (for the drug marketing authorization and the resolution of patent disputes during the stage of drug marketing authorization application), the applicant for a drug marketing authorization can file a lawsuit before the people's court to request the court to affirm that the drug applied for registration does not fall within the scope of protection of the patent." [7]

3. Identity of both parties concerned

Different from most patent infringement disputes, under the patent linkage system, the parties are clear, and those common difficulties in, e.g., identifying the defendant and collecting information on the accused technical solution, have been largely solved. Article 13 of the Drug Provisions stipulates that "services made by the people's court to the contact person, correspondence address, email, etc. published by the parties on the platform [8] established by the relevant administration department under the State Council in accordance with the link-up measures shall be deemed as valid services." [9] The contact information published on the platform is generally that of the generic company itself. During litigation, the parties concerned may change the above information to that of their agents *ad litem* in order to facilitate direct contact and process management in the trial. Further, "after the party concerned submits a confirmation of the address for service to the people's court, the people's court may also deliver relevant documents to the address stated in the confirmation." [10]

As for the subjects, one party in the lawsuit under the patent linkage system is the applicant, namely the applicant for the generic drug marketing authorization, and the opposite party is the patentee or interested party. Regarding the applicant, the Drug Measures classify the applicants for chemical generic drugs into four types according to their certifications, wherein type I is that there is no listed patent information on the platform; type II is that the listed patent on the patent platform has expired or was declared invalid, or the generic drug applicant has obtained the necessary patent license; type III is that the generic applicant undertakes not to market the generic drug until the expiration of the corresponding patent; and type IV is that the listed patent on the platform should be declared invalid, or the generic drug does not fall within its scope of protection. [11] Judging from their contents, the first three types do not involve the stability of the patent rights, or substantively affect the economic interests of the patentees or interested parties. It is not likely that legal disputes will arise between the parties in these situations. With a type IV certification, however, the applicant denies the validity of the patent or infringement, which will undoubtedly have a direct impact on the interests of the patentee or interested party. Patent challenges as normally called are often raised by the type IV applicants. As to the interested party, the Drug Provisions define its scope as including patent licensees and drug marketing authorization holders [12]: (1) Licensees includes the licensees of exclusive license, of sole license or of non-exclusive license. As for the licensees' right to litigation, Article 2 of the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in Cases Involving the Review of Act Preservation in Intellectual Property Disputes has provided well-thought-out and highly practicable provision, which has been widely recognized in judicial practice. Thus, no other specific provisions are necessary for the Drug Provisions. [13] (2) Drug marketing authorization holders refer to the drug patents holders who apply for and obtain the marketing authorization and shall bear the main responsibility for the quality of the drug within its life cycle. Marketing authorization holders and product license holders are not necessarily the same. The former may produce products by themselves or by authorizing other companies. [14]

II. Patent rights and stay period under the patent linkage system

1. Scope of patents under the system

Article 76 of the China's Patent Law clarifies the parties concerned, procedures and relevant authorities under the patent linkage system. Patents to which Article 76 applies, i.e., the scope of listed patents, are specified in the link-up Drug Measures formulated by the drug administration department and the patent administration department. The Drug Provisions of the Supreme People's Court do not mention this issue, but were explained in a press conference that since the Drug Measures has specified the patents to which the patent linkage system applies, the Drug Provisions keep consistent therewith. In other words, both the judicial and administrative proceedings cover the same scope of patents.

As for the number of patents, theoretically speaking, the more patents listed on the platform, the more options the patentees have in initiating patent linkage procedures, and accordingly the more obstacles the generic companies will encounter when applying for drug marketing authorization, and the lower likelihood that the public timely access to low-price drugs as a result of entry of generic drugs into the competitive market. In view of categories, chemical drug patents, for example, include compound patents, crystal form patents, preparation patents, method patents, medical use patents, and device patents, and some device patents may even be design patents. A considerable number of these patents are only weakly associated with the effectiveness and safety of drugs. [15] By reviewing the evolution of the patent linkage system, we can find that in its early stage the United States failed to restrict or to systematically define the scope of patents because of defects in the system and mechanism, as well as conflict of interests of parties, thereby resulting in severe abuse of patent linkage. It was not rare that patentees listed false patents or expired patents, or even patents for intermediates, metabolites, crystal forms, preparation methods or detection methods. Although these patents are peripheral to the patented innovator drugs, they legally play substantially the same role as core patents in the patent linkage system. [16]

Therefore, to clarify the scope of patents so as to effectively curb abuse of the patent linkage system is fundamental for its proper operation. In China, drugs are divided into three groups, i.e., chemical drugs, traditional Chinese medicines and biological products. The Drug Measures correspondingly specify different scopes of patents to be listed: (1) for chemical drugs (excluding active pharmaceutical ingredients), patents can be granted for active ingredient compounds, pharmaceutical compositions comprising active ingredient(s), and medical uses; (2) for traditional Chinese medicines, patents can be granted for compositions of traditional Chinese medicine, extracts of traditional Chinese medicine, and medical use; and (3) for biological products, patents can be granted for a sequence structure of active ingredient(s) or medical use. [17] In order to prevent abuse, the Drug Measures also exclude patents for intermediates, metabolites, crystal forms, preparation methods and detection methods from the scope. Clearly-defined scope of listed patents protects generic companies from being unfairly obstructed in acquiring marketing authorization and prevents improper delay in drug marketing due to abuse of the patent linkage system. Legally, scientifically and reasonably listing patent information and making full advantage of legitimate rights conferred by the system are both rights and obligations of patentees. The Drug Measures clearly stipulate information that needs to be provided for a listed patent in Article 4 and the legal liabilities for abuse in Article 15.

2. On the number of stay periods

The stay period lasts for nine months. Considering the time required for patent examination in China and particularly for concluding a patent infringement case in the Beijing Intellectual Property Court,[18] in comparison with that in the United States, the stay period in China is not long and generic companies will not be significantly affected. However, in view of the history of the patent linkage system, although the duration of the stay period is defined, its number also greatly impact on the respective interests of the parties. Although the Drug Measures define the scope of patents to be listed, a drug is often covered by multiple patents, and thus, theoretically speaking, the stay period would last indefinitely if the patentee keeps filing lawsuits based on different patents within the current stay period. Under the patent linkage system in the United States, in the disputes between GlaxoSmithKline Pharmaceutical Company (GSK) and Apotex Inc. over a generic version of Paxil (paroxetine), after the grant of a 30-month stay period, GSK successively listed nine patents, filed infringement lawsuits against Apotex based on four of them and obtained 30-month stay period respectively. This litigation strategy finally gave GSK a stay period of up to 65 months. [19]

How shall we understand the number of stay periods in the China's patent linkage system? Article 8 of the Drug Measures reads "the stay period, starting from the date of accepting the case by the people's court or by the patent administration department under the State Council, shall be provided only once". Literally speaking, "once" in a normal context means "one single time" or "one time and no more". [20] However, we should not just read a term literally, but also consider its context such as the system, value orientation and social significance, to avoid drawing a conclusion that does not comply with the legislative purpose of the patent linkage system, or confuses and baffles generic companies, the public and patentees or interested parties.

On 8 October 2017, the general office of the CPC Central Committee and the general office of the State Council released and enacted the 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) "for the purposes of promoting structural adjustment and technology innovation in drug and medical device industries, improving competitiveness, and meeting the clinical need of the general public……" It is in the Opinions that the blueprint for establishing the patent linkage system in China was proposed. According to the goals of the Opinions, the China's patent linkage system is established to promote technology innovation in drug industry, and ensure that the public has access to the drugs necessary for treatment. The public requires not only drug accessibility, but also drug affordability. The China's patent linkage system intends to allow the early entry of generic drugs into the market and coexistence with patented drugs, so as to promote the competition and therefore enable the public to have better access to low-price drugs. Article 1 of the Drug Measures also emphasizes the legislative purposes thereof, i.e., "to protect the legitimate rights and interests of patentees of drag-related patents, encourage the innovation of new drugs, promote the development of high-level generic drugs, and establish the early resolution mechanism for drug patent disputes". Therefore, the patent linkage system in China is to provide patentees or interested parties with a route to early notice potential infringement and settle disputes with generic companies, and meanwhile to promote the development of generic drugs and contribute to earlier accessibility to high-level generic drugs by the public. Bearing this in mind, we will better understand the number of stay periods stipulated in the Drug Measures.

When patent linkage is triggered, factors that affect the number of stay periods generally include subject, drug, patent, act and term. (1) Subject, i.e. the parties. The process can be initiated either by the patentee or interested party, or by one or more generic companies. (2) Drug. Although multiple subjects or patents may be involved, they are linked to only one drug. It is the drug itself that is to be marketed by generic companies and examined by the drug evaluation agency. (3) Patent. The number of disputed patent(s) can be one or more. (4) Act. Patentee or interested party may file a lawsuit or request for a ruling under the patent linkage system based on multiple patents, and there may also be multiple companies certifying generic drugs. The number of patents and generic applicants may lead to multiple stay periods. (5) Term. This factor is closely associated with the number of patents, and more closely with the patentee or interested party. Among the above-mentioned factors, subject, drug, patent and act are all centered on the drug itself. When taking the drug as the standard for determining the number of stay periods, where the patentee or interested party, or the generic company initiates the judicial or administrative proceedings to confirm whether patent infringement occurs, the stay period shall be provided only once in any proceedings irrespective of the number of patents involved. This will prevent the patentee or interested party from abusing the patent registration system by filing lawsuits repeatedly so as to extend the stay period, and will not impede other patentees or interested parties who plan to enforce their rights against other generic companies, or impair any subsequent rights of those generic companies. The determination of the number of stay periods based on the drug is more in line with the current development of the China's pharmaceutical industry, and would prevent the delay in the marketing of generic drugs due to the existence of multiple patents, which may hinder the public from enjoying the competitive benefits resulting from the patent linkage system. It can be seen that the duration and number of stay periods have certain impact on the patentees or interested parties, making them more cautious in deciding which patent to enforce.

III. Analysis of influential factors under the "dual-track" mechanism

1. Influence of invalidation proceedings

No matter whether the parties choose to resolve their infringement dispute under the patent linkage system through judicial or administrative proceedings, they need to appraise the effect of patent invalidation proceedings. According to the China's Patent Law and the Guidelines for Patent Examination, among the three patent types (invention, utility model and design), utility model and design patents are granted without substantive examination. Therefore, according to judicial interpretations of the China's Patent Law, if the accused infringer files a request for invalidation in a dispute over patent infringement, the judicial proceedings are likely to be suspended. While, because invention patents have been substantially examined, it is not necessary to suspend the legal proceedings. [21] However, in practice, the likelihood of invention patents being invalidated is not significantly lower than that of utility model or design patents. [22] As for listed patents under the patent linkage system, although it is still a possible that a utility model or design pat-

ent covering a drug will be listed on the platform, they are predominately invention patents. In other words, the invalidation generally will not hinder the trial under patent linkage. In order to facilitate the early settlement of dispute, Article 6 of the Drug Provisions further stipulates that when a lawsuit has been filed in accordance with Article 76 of the China's Patent Law, the people's court generally will not suspend the trial on the grounds that the patent administration department under the State Council has accepted an invalidation request against the patent in suit. In practice, to accelerate the trial and to reduce the impact on infringement disputes due to the uncertainty brought by the invalidation, the parties can actually expedite the invalidation proceedings and obtain the invalidation decision earlier in virtue of the case acceptance notice, subpoenas or other documents issued by the court.

To better achieve the goal of the patent linkage system, that is, the early settlement of disputes between both parties as much as possible, both the Drug Provisions for judicial proceedings and the Drug Measures for administrative proceedings set forth special provisions on detailed issues such as the jurisdiction, the parties concerned, the service, the handling authority, the time limit for concluding the case and the procedures: (1) as for the jurisdiction, the Beijing Intellectual Property Court has sole jurisdiction, which prevents the extension of trial time due to jurisdictional objection, and meanwhile the Beijing Intellectual Property Court, as the court trying administrative patent lawsuits, effectively guarantees the progress of the trial in terms of, e.g., litigation procedure, staffing and technical resources; (2) as for the parties, the inclusion of the interested parties is compliant with the actual needs of the right holder; (3) as for the service, since it is clearly indicated that the service to the contact person, correspondence address, email, etc. registered by the parties on the platform shall be deemed as valid services, difficulties in services that are rather common in judicial practice have been directly eliminated at the regulation level; and (4) as for the procedure, the Drug Provisions reiterate the provisions concerning the suspension by emphasizing that it is normally unnecessary. All these specific designs show the legislator's sincerity in implementation of the patent linkage system.

Although the Drug Provisions provide that in disputes under patent linkage system, a party's request for suspension will "generally" not be granted, in view of the likelihood of drug patents being invalidated and the substantive fairness, the trial will be inevitably affected by the invalidation procedure to some extent. Drug patents, like other patents, may be invalidated. Although the patent linkage system is aimed to expeditiously solve the infringement disputes between patentees or interested parties and generic companies, fairness is as crucial as efficiency under this system. If a party provides a negative patent evaluation report showing that the patent in suit is unstable or belongs to prior art, or there exist other circumstances where the trial shall be suspended, the case can still be suspended.

2. Impact of patent technology appraisal

Drug patents are generally related to chemical invention. Different from utility model patents or design patents that are directly observable, drug patents often require qualitative analysis of compounds, traditional Chinese medicine ingredients or biological products, or quantitative analysis of pharmaceutical components such as elements, chemical structures or compounds. Both qualitative analysis and quantitative analysis require special instruments and devices, and professionals. The judicial and administrative authorities have been provided with technical investigators or professional technology examiners or can invite technical experts, and those hearing the case have technical backgrounds and capabilities, but their judgments are mainly based on intuitive understanding of documents which cannot replace scientific and objective laboratory analyses. Under the patent linkage system, among the four types of certifications, that the patent is unstable and that the generic drug does not fall within the scope of the patent will unavoidably give rise to technical appraisal.

Technical appraisal is regulated with strict procedural rules. In judicial proceedings, technical appraisal is requested by a party concerned, usually by the patentee or interested party. But in patent linkage related lawsuits initiated by generic companies, they may also request for appraisal. Theoretically speaking, it is possible that both parties reach an agreement on the appraisal agency. In judicial practice, however, this is rather rare. In most cases, the judicial authority designates the appraisal agency, and the latter then proposes some appraisers as candidates. Based on the technical expertise, experiences and background of the candidates, both parties decide whether to challenge or request to replace an appraiser. After the agency and the appraisers are determined, the appraisal agency will suggest an appraisal plan, based on which the court will hold a hearing, and then the appraisal may pro-

ceed. During the appraisal, both parties need to pay close attention to the selection of appraised materials since drugs due to their own characteristics are prone to deterioration if stored improperly, which in turn alters their chemical properties, molecular activity and efficacy and may further affect the result of the trial. If a sample is damaged, the parties have to struggle to select a new one for appraisal.

Conclusion

The patent linkage system was formally proposed with a preliminary framework in China in 2017, and was finally implemented with the China's Patent Law, the Drug Provisions and the Drug Measures enacted in 2021 after extensive discussion and opinion solicitation among the drug evaluation authorities, the patent office, the judicial authorities, experts, scholars, and the public. In order to effectively safeguard the legitimate rights and interests of right holders and the interested parties, China has established a "dual-track", i.e., judicial and administrative, mechanism to resolve patent infringement disputes in the drug marketing review process, providing the parties with more flexibility. Meanwhile, the detailed designs in terms of jurisdiction, time limit, service and procedure are also in the interests of the parties. Consideration is given to not only the demands of right holders or interested parties for early resolution of infringement disputes, but also the needs to encourage generic companies and make drugs available to the public. A 12-month market exclusivity period provided to the first chemical generic drug applicant who successfully challenged the patent and was approved for marketing further contributes to the development of generic drugs. In comparison with the preliminary framework, the current system has been much enriched and improved. ■

The author's affiliation: Shanghai Intellectual Property Court

[1] Letter in response to the Proposal No. 3372 (Science and Technology 139) at the 5th Session of the 12th National Committee of the Chinese People's Political Consultative Conference.

[2] Item 2 of the Policy Interpretation of the Drug Measures.

[3] Article 65 of the China's Patent Law.

[4] Chief Judge of the Third Civil Division of the Supreme People's Court answered the reporters' questions about the Several Issues Concerning the Application of Law in the Trial of Civil Cases of Patent Disputes Related to Drugs Applied for Registration. An answer to question 3.

[5] Article 7 of the Drug Measures.

[6] This litigation strategy is commonly seen in online infringement disputes. The right holder begins to collect evidence much earlier than filing a lawsuit. After noticing the infringement, the right holder does not sue immediately but waits until the infringer scales up its business in order to obtain higher monetary compensation.

[7] Article 4 of the Drug Provisions.

[8] The platform refers to the patent information listing platform of marketed drugs, which was officially launched on 4 July 2021.

[9] See supra note 7, Article 13.

[10] *Ibid*.

[11] Article 6 of the Drug Measures.

[12] See supra note 7, Article 2.2.

[13] Article 2.2 of the Provisions on Several Issues Concerning the Application of Law in Cases Involving the Review of Act Preservation in Intellectual Property Disputes.

[14] Articles 33 to 40 of the Drug Administration Law.

[15] Wang Xiaolin and Li Jian (2017). Patent law issues related to patent linkage system in China. *Patent Agency, 4, 5*.

[16] Liang Zhiwen (2017). Transplantation and creation of patent linkage system. *Political Science and Law, 8, 106*.

[17] See supra note 5, Articles 2 and 6; and supra note 2, Item 4.

[18] See supra note 7, Article 1, which stipulates that first-instance cases filed by the parties in accordance with Article 76 of the Patent Law to confirm whether a solution falls within the scope of a patent shall be within the jurisdiction of the Beijing Intellectual Property Court.

[19] Chen Jing and Shi Luwen (2012). Studies on U.S. patent linkage system. *Chinese Journal of New Drugs, 22, 2592*.

[20] Modern Chinese Dictionary (6th edition, p. 1521). The Commercial Press.

[21] Article 9 of Several Provisions of the Supreme People's Court on Issues Concerning Application of Law in the Trial of Disputes over Patent Infringement reads "where the defendant files a request for invalidation of the patent right when making its or his defense in the dispute received by the people's court and arising from the infringement of the patent right for utility model or design, the people's court shall suspend the legal proceedings." Four circumstances where the legal proceedings may not be suspended are also presented.

[22] Upon the requests for invalidation, 47.04% of the challenged invention patents were invalidated or partially invalidated, while 46.47% of the utility model patents were invalidated or partially invalidated in the same period. Dong Tao and He Hui (2015). China patent quality report—Studies on implementation of utility model and design patent system. *Science Technology and Law, 2, 275*.