Comments on Major Changes in China's Revised Implementing Regulations of the Patent Law and Guidelines for Patent Examination

CPA Research Group on Revised Implementing Regulations

The Implementing Regulations of the Patent Law and the Guidelines for Patent Examination are vital supporting administrative regulations and rules to guarantee the effective enforcement of the patent law. Since the Patent Law (hereinafter referred to as the revised Patent Law) came into effect on 1 June 2021, the revision of the Implementing Regulations of the Patent Law and the Guidelines for Patent Examination has attracted wide attention. On 21 December 2023, the State Council and the China National Intellectual Property Administration (CNIPA) announced the newly revised Implementing Regulations of the Patent Law (hereinafter referred to as the revised Implementing Regulations) and Guidelines for Patent Examination (hereinafter referred to as the revised Examination Guidelines), both of which were officially promulgated on 20 January 2024. Thereafter, the CNIPA has successively issued several supporting documents such as the Transitional Measures for Handling Examination after the Implementation of the Revised Patent Law and its Implementing Regulations (hereinafter referred to as the Transitional Measures), as well as a series of work notifications and policy interpretations, so as to clarify the specific rules for application. The revision of the Implementing Rules and the Examination Guidelines, together with the previous revision of the Patent Law, has made significant changes to China's patent practice in a number of aspects, on which patent practitioners shall conduct all-round and in-depth studies. China Patent Agent (H.K.) Ltd. organized a team to, based on its own understanding and experiences, introduce and make comments on the major changes in the revised Implementing Regulations and revised Examination Guidelines that have a substantial impact on the rights and interests of applicants or patentees, in hope of sharing our views for discussion and as a reference.

I. Patent application process

(I) Addition, correction and restoration of priority claim

The Patent Cooperation Treaty (PCT) has already provided for the addition, correction and restoration of priority claims, whereas China made reservation to the restoration of priority claims. By taking advantage of this law revision, China has cancelled the reservation as mentioned above, and the priority restoration was first introduced into the revised Implementing Regulations, thereby providing opportunities for patent applicants to overcome defects in the right of priority.

1. Addition or correction of priority claims

Before this law revision, an applicant is required to declare all the claimed priorities at the time of filing a patent application, and is not allowed to add or correct any priority claim after the filing of the patent application. By the word "correct", it means changing the claimed priority to another different one, rather than making corrections to one or two items of the filing date, application number and the original accepting authority of the earlier application. This law revision has changed this situation. Article 37 of the revised Implementing Regulations stipulates that if an applicant has claimed the priority at the time of filing a patent application, addition or correction of the priority claim can be requested within 16 months from the priority date or within 4 months from the filing date.

(1) Application conditions:

The applicant should claim at least one priority at the time of filing a patent application. It is not allowed to add, not to say correct, a priority claim if no priority has been claimed.

(2) Time limit:

Addition or correction of the priority claim can be requested within 16 months from the priority date or within 4 months from the filing date. If the time limit for addition or correction of the priority claim has expired, the applicant cannot request for restoration according to Rule 6.2 of the revised Implementing Regulations.

(3) Content:

A new priority is introduced by means of "addition" or "correction". If one or two items (not all the three items) among the filing date, application number and original accepting authority of the earlier application are missing or incorrect, amendment can be made according to Rule 34.2 of the revised Implementing Regulations, which has existed before this law revision, without referring to the provision on addition or correction of the priority claim under Rule 37 of the revised Implementing Regulations.

(4) Limitations:

(a) Addition or correction of the priority claim does not apply to a design application.

(b) The revised Examination Guidelines explicitly specify that the addition or correction of the priority claim shall not be made together with the restoration of the priority, i.e., the added or corrected priority shall not be the restored priority.

(c) The added or corrected priority shall not serve as the basis for incorporation by reference.

2. Restoration of priority rights

Before this law revision, if an applicant does not file a later application within the priority period (12 months), the priority cannot be enjoyed and no opportunity for remedy is provided. Rule 36 of the revised Implementing Regulations provides a remedial route, that is, the applicant is allowed to restore the priority.

(1) Application conditions:

The applicant shall claim the priority while submitting a later application, and file a request for restoring the priority within the time limit. If the priority is not claimed at the time of submitting the later application, the priority cannot be restored. But the applicant may re-submit an application and request for restoration of the priority within the prescribed time limit.

In the light of Rule 36 of the revised Implementing Regulations, the priority can only be restored with "justified reasons", which expression is consistent with the condition for restoration of right with "justified reasons" under Rule 6.2 of the revised Implementing Regulations. It may indicate that the examination criteria thereof are also consistent, [1] which needs to be further verified in practice.

(2) Time limit:

The request for restoration of the priority shall be made within two months from the expiration of the priority period. If this time limit is not observed, it cannot be restored under Rule 6, inclusive of paragraphs 1 and 2, of the revised Implementing Regulations.

(3) Limitations:

(a) Restoration of the priority is not applicable to design applications.

(b) As mentioned above, under the revised Examination Guidelines, the restored priority cannot be added or corrected.

(c) The restored priority shall not serve as the basis for incorporation by reference.

In the light of Rule 128 of the revised Implementing Regulations, the restoration of the priority is also applicable to international applications entering the Chinese national phase; where the priority has been restored at the international phase, the restoration of the priority is recognized at the national phase and there is no need to file a request for restoration of the priority; where the applicant claims the priority at the international phase but fails to request for the restoration of the priority, the applicant may request for the restoration of the priority within two months from the date of entering into the Chinese national phase.

(II) Incorporation by reference

"Incorporation by reference" is a remedial measure provided to the applicant where there are elements or parts missing in the application documents. The applicant can incorporate the missing elements or parts by reference to the corresponding parts of an earlier application within the prescribed time limit and the date when the application documents were first filed is regarded as the filing date. Similar to the addition, correction and restoration of the priority claim as mentioned above, the Patent Cooperation Treaty (PCT) already has provisions on incorporation by reference, whereas China made reservations on incorporation by reference and cancels said reservations through this law revision to recognize the content incorporated by reference at the international phase. In addition, Rule 45 of the revised Implementing Regulations has introduced the system into the Chinese patent application system for the first time, in hope of being in line with the international practice and providing a new remedial route for applications filed in China.

1. Application conditions:

Where the applicant intends to rectify missing or erroneously submitted application documents via incorporation by reference, the applicant shall claim the priority, together with a declaration for incorporation by reference, at the time of filing an application. [2]

2. Time limit:

The applicant shall complete the missing or erroneously submitted application documents within two months from the first filing date or the time limit prescribed by the CNIPA. If the applicant fails to do so within said time limit, restoration as specified in Rule 6.2 of the revised Implementing Regulations does not apply.

3. Content:

It is required to complete the elements or parts of the missing or erroneously submitted application documents; and the supplemented content is only limited to the content recited in the earlier application documents.

4. Limitations:

(1) The incorporation-by-reference system does not apply to design applications.

(2) The incorporation-by-reference system does not apply to divisional applications.

(3) The priority claim restored under Rule 36 of the revised Implementing Regulations shall not serve as the basis for incorporation by reference.

(4) The priority claim added or corrected under Rule 37 of the revised Implementing Regulations shall not serve as the basis for incorporation by reference.

(5) The delay as a result of incorporation by reference belongs to "unreasonable delay caused by the applicant", and the term of the patent shall not be compensated on this basis.

(III) Time and period

1. 15-day mailing period

In the light of Rule 4.7 of the revised Implementing Regulations, the date on which documents delivered in an electronic form enters the electronic system recognized by the parties concerned is regarded as the date of service. That is to say, the presumed date of receipt of electronic communications is the date of issue without adding a 15-day mailing period, which means the time limit for responding to electronic notifications and decisions is shortened by 15 days as compared with the practice before this revision.

(1) Effective date: A 15-day mailing period is not added to the time limit for responding to notifications and decisions delivered electronically after 20 January 2024.

(2) Scope: All notifications and decisions delivered electronically by the CNIPA, including those delivered electronically in the invalidation proceedings.

2. Time limit for change of inventorship and relevant provisions

The revised Examination Guidelines stipulate that if a request for change of inventorship is filed due to missing or incorrect information, a certifying document signed or sealed by all the applicants (or patentees) and all the inventors before and after the change shall be filed within one month from the date of receipt of the Notification of Acceptance, clearly indicating the reason for the change, and declaring that it has been confirmed according to Rule 14 of the revised Implementing Regulations that the inventors after change are all the personnel who have made creative contributions to the substantive features of the present invention.

(1) Time limit: Within one month from the date of receipt of the Notification of Acceptance.

(2) Content: Not only all the applicants (or patentees) and all the inventors before change but also all the inventors after change shall sign or seal the certifying document. Thus, it is necessary to check the inventors before filing a new application, and to recheck whether it is necessary to make any change to the inventors after receiving the Notification of Acceptance. If yes, the change of the inventorship shall be made as soon as possible so as to avoid missing the opportunity.

3. Time limit for restoring the request for reexamination

Rule 6.2 of the revised Implementing Regulations relates to the restoration of the request for reexamination in the event of missing the time limit. It is added to the previous provision that: "if the time limit for requesting reexamination has expired, the applicant may request to restore the right with the patent administration department under the State Council within two months from the date of expiration of the time limit for requesting reexamination". Similar provision is also added to the revised Examination Guidelines. This provision offers a clear legal basis for the restoration of the request for reexamination where the time limit for requesting reexamination is not observed by a party concerned, and clarifies the time for requesting such restoration.

4. Time for issuing the Notification of Termination of Patent Right

In the revised Examination Guidelines, the time for issuing the Notification of Termination of Patent Right is revised to the time when the surcharge period of annual fee expires, i.e., "where, at the expiration of surcharge period of annual fee, the patentee still fails to pay or pay in full the annual fee or the surcharge, a Notification of Termination of Patent Right shall be made by examiner", which means a Notification of Termination of Patent Right is issued immediately at the expiration of surcharge period of annual fee, rather than two months after the expiration of surcharge period of annual fee as stipulated in the previous Examination Guidelines. The time provided for the patentee to restore the patent right is shortened by two months.

(IV) Non-prejudicial disclosures

1. Disclosure for the first time for the purpose of public interest when a state emergency or an extraordinary situation occurs in China

Regarding the non-prejudicial disclosures, Article 24 of the revised Patent Law is added with the provision "where it was made public for the first time for the purpose of public interest when a state emergency or an extraordinary situation occurred in the country" under item (1), which means that an invention-creation, for which a patent is applied, does not lose its novelty due to earlier disclosure where, within six months before the date of filing, it was disclosed for the first time for the purpose of public interest when a state emergency or an extraordinary situation occurred in China. As for a certifying document in this regard, the revised Examination Guidelines require that the certifying document should be issued by "a competent authority" of the government at or above the provincial level. The certifying document shall indicate the reason for and date of disclosure for the purpose of public interest, and the date, form and content of the disclosure of the invention-creation, and be stamped with an official seal.

2. The circumstances where it was first made public at a prescribed academic or technological conference includes publication at an international conference

As for the applicable scope of non-prejudicial disclosures, Rule 33.2 of the revised Implementing Regulations extends the scope of "academic or technological conference" as mentioned in Article 24 of the revised Patent Law from "any academic or technological conference organized by a competent department under the State Council or by a national academic or technological association" to further include "any academic or technological conference organized by an international organization that is recognized by a competent department under the State Council", which means the scope of academic and technological conferences is expanded from domestic conferences to international conferences that comply with the relevant provision.

3. Certifying documents regarding exhibitions or conferences

As for a certifying document, a mandatory requirement for the certifying document "issued by the entity which organized the international exhibition or academic or technological conference" is deleted from Rule 33.3 of the revised Implementing Regulations. In practice, it is extremely difficult to obtain a certifying document issued by the organizer of an exhibition or conference, especially when the organizer is aboard and the exhibition or conference has ended. This law revision eliminates the mandatory requirement for a certifying document issued by the organizer, which facilitates the application of the provision on non-prejudicial disclosures.

As for the certifying documents stipulated in the revised Examination Guidelines, in addition to the "organizer of the international exhibition", the "organizing committee of the exhibition" can issue the document certifying the international exhibition. But there is no amendment to the documents certifying the academic or technological conference, which should still be issued by "the competent authority under the State Council or national academic organizations organizing the meeting". Judging from the literal expression, the requirements for certifying documents are still stringent. A close eye shall be kept on the application of said provision in practice.

4. Knowledge of disclosure after the filing date

According to Rules 33.3 & 33.4 of the revised Implementing Regulations, in the event of "disclosure at exhibitions" (Article 24(2) of the revised Patent Law) or "disclosure at conferences" (Article 24(3) of the revised Patent Law), the applicant shall make a declaration at the time of filing the patent application, and submit certifying documents within two months from the filing date. In the event of "disclosure for the sake of the public interest" (Article 24 (1) of the revised Patent Law) and "disclosure by others without the consent of the applicant" (Article 24(4) of the revised Patent Law), the patent administration department under the State Council may require the applicant to submit a certifying document within a specified time limit when necessary.

Accordingly, the revised Examination Guidelines provide that where the applicant knows after the filing date or after receiving the notification from the Patent Office the "disclosure for the sake of the public interest" and "disclosure by others without the consent of the applicant", the applicant shall make a declaration for the grace period for non-prejudicial disclosure and submit the certifying document within two months after knowing said disclosure or within the time limit for response specified in the notification respectively. However, no provision is set forth for the knowledge of "disclosure at exhibitions" or "disclosure at conferences" after the filing date. Under these two circumstances, the applicant shall still make a declaration in the request at the time of filing an application, and submit a certifying document within two months from the filing date.

(V) Patent Evaluation Report

Before this law revision, only the patentee or any interested party can request the CNIPA to issue a patent evaluation report for utility models or designs, and said report can only be furnished at the request of the people's court or the patent administration department. Article 66 of the revised Patent Law clarifies that the patentee, the interested party and the accused infringer can all furnish and even voluntarily furnish a patent evaluation report. On the basis of the revised Patent Law, the revised Implementing Regulations further specify that when going through the patent registration formalities, the applicant may also request the CNIPA to issue a patent evaluation report.

The revised Examination Guidelines further make clear the subjects who can request a patent evaluation report through this law revision: where a patent is owned by multiple patentees, a part of the patentees may request for a patent evaluation report. The "accused infringer" includes any entity or individual receiving lawyer's letters from the patentees, complaint notices from an e-commerce platform, and the like. Although the revised Examination Guidelines have no definite provisions, according to *argumentum a minore ad maius*, the accused infringer can also request the CNIPA to issue a patent evaluation report in litigation or administrative proceedings.

II. Standards for patent examination

(I) The principle of good faith

The revised Patent Law is added through law revision with Article 20.1 which requires that the application for patents and the exercise of patent rights shall follow the principle of good faith. Rule 11 of the revised Implementing Regulations further clarifies the principle of good faith in the process of patent application, specifying that "all types of patent applications shall be based on real invention-creation activities and shall not be falsified", and is incorporated into the grounds for rejection at the preliminary and substantive examination stages and the grounds for invalidation in Rules 50, 59 and 69, respectively, thereby rendering the preliminary examination, substantive examination and invalidation proceedings under the principle of good faith.

The revised Examination Guidelines stipulate in Part I, Chapter One, Section 7.9 that the examination as to whether a patent application complies with Rule 11 of the revised Implementing Regulations is subject to the Provisions on Regulating Patent Application Activities. Activities in violation of Rule 11 of the revised Implementing Regulations are called "abnormal patent application activities" in Article 2 of the Provisions on Regulating Patent Application Activities, and eight types of abnormal patent application activities are listed in Article 3:

"(1) The invention-creation contents of multiple patent applications submitted are obviously the same, or essentially formed by the simple combination of different invention-creation features and elements;

(2) The submitted patent application involves fabrication, forgery, alteration of invention-creation contents, experimental data or technical effects, or plagiarism, simple replacement, patchwork of prior technologies or prior designs, etc.;

(3) The invention-creation content of the submitted patent application is mainly generated at random by using computer technologies and the like;

(4) The invention-creation of the submitted patent application obviously does not conform to the common sense of

technological improvements or designs, or is inferior or piled up, or unnecessarily narrows down the scope of protection;

(5) The applicant submits multiple patent applications without conducting actual R&D activities and cannot make reasonable explanations;

(6) The multiple patent applications substantially associated with specific entities, individuals or addresses are submitted respectively, successively, or in different places for malicious purposes;

(7) Transfer or accept the right to apply for a patent for improper purposes, or change the inventor or designer falsely;

(8) Other abnormal patent application activities that violate the principle of good faith and disrupt the normal order of patent work."

In comparison with the practice that the violation of the duty of candor renders a patent unenforceable in the U.S. laws, [3] the violation of the principle of good faith in China directly renders a patent application rejected or invalidated, which is however applicable in a wider scope. As a matter of fact, prior to this law revision, the CNIPA has been regulating the "abnormal patent application activities". But it was through this law revision that the regulation of the "abnormal patent application activities" is incorporated into the legal framework. However, the "principle of good faith" is still interpreted according to the previous basic rationale of the "abnormal patent application activities". A close eye shall be kept on whether the interpretation of the principle of good faith will affect some normal patent applications for invention-creations in practice, and what are the standards for proving the violation of the principle of good faith and relevant grounds therefor during examination.

According to Article 9 of the Transitional Measures, the examination according to the principle of good faith has a retrospective effect, and patent applications filed before the promulgation of the revised Patent Law, revised Implementing Regulations and revised Examination Guidelines can be examined under the above provision.

(II) Examination as to whether utility model and design applications obviously do not comply with the requirements on inventive step

According to the Implementing Regulations and Examination Guidelines before this law revision, the inventive step of utility models and designs are not examined at the preliminary examination stage. Rule 50 of the revised Implementing Regulations expands the scope of examination for utility models and designs to cover the examination on whether utility model and design applications obviously do not comply with the requirements on inventive step respectively, that is to say, the scope of preliminary examination of utility models includes the examination as to whether a utility models obviously does not comply with the provision on inventive step as stipulated by Article 22.3 of the revised Patent Law, and the scope of preliminary examination of designs includes the examination as to whether a design obviously does not comply with the provision that the design "shall significantly differ from a prior design or the combination of prior design features" as stipulated by Article 23.2 of the revised Patent Law. Such a change is in line with the CNIPA's regulation of the "abnormal patent application activities" in recent years. A close eye shall be kept on the specific standards adopted in the examination as to whether utility model and design applications obviously do not comply with the requirements on inventive step, such as the scope of searches conducted by the examiners and the criteria for inventive step assessment.

(III) Deferred examination

Before this law revision, the Examination Guidelines (2019) have stipulated the deferred examination for inventions and designs. The revised Implementing Regulations further specify the deferment of examination in the newly added Rule 56.2 which reads "the applicant may request the deferment of examination of a patent application". The revised Examination Guidelines further specify in Part V, Chapter Seven that the deferment of examination can be requested for all three types of patents (inventions, utility models and designs), with detailed provisions on, e.g., the time of filing such a request, the effective time, deferment period and withdrawal. To be specific, the request for deferment of examination of patent applications for invention shall be made at the time of filing a request for substantive examination, the request for deferment of examination takes effect from the date when the request for substantive examination takes effect, and the examination therefor can be deferred for one, two or three years from the effective date of the request for deferment of examination; the request for deferment of examination of patent applications for utility model shall be made at the time of submitting a patent application for utility model, and the examination therefor can be deferred for one year from the effective date of the request for deferment of examination; and the request for deferment of examination of patent applications for design shall be made at the time of filing an application for design, and the examination therefor can be deferred by months (at most 36 months) from the effective date of the request for deferment of examination. Such a request for deferment of examination can be withdrawn upon the applicant's request before the deferred period expires.

The deferred examination system after law revision is applicable in a wider scope. Different deferred periods are set in accordance with the characteristics of different patent types, and applicants are provided with the opportunity to withdraw their requests for deferment of examination, which is beneficial for the protection of applicant's interests. However, some applicants may have new demands on the claimed scope of protection after the expiration of the deferred period and may need to amend the application documents initiatively. In that case, the original opportunity for initiative amendment has missed. It is hoped that the CNIPA would notice this demand, relax the examination as to the timing for initiative amendment in practice, and make adjustment in this regard in the future law revision, thereby bringing the deferred examination system into full play.

(IV) Reexamination proceedings

There is controversy in practice over the nature of the reexamination proceedings and the scope of *ex officio* examination in the reexamination proceedings. Rule 67.1 of the revised Implementing Regulations is added with that the reexamination department can *ex officio* examine "whether a patent application obviously violates the Patent Law and the Implementing Regulations", which provides a legal basis for examination conducted by examiners *ex officio* in the reexamination proceedings. The revised Examination Guidelines further clarify that in the reexamination proceedings, the examiner can *ex officio* examine, based on Rule 11 of the revised Implementing Regulations, violation of the principle of good faith, in addition to the grounds and evidence on which the Decision on Rejection is based, and specify by means of enumeration that the *ex officio* assessment of inventive step of dependent claims, the change of applied law from Article 26.4 to Article 26.3 of the Patent Law, the *ex officio* examination on clarity, adjustment to combination of references or reduction of references, etc. all fall within the scope of *ex officio* examination. These examples have a certain universality and have been mostly upheld by judgements or judicial rulings. These rules are incorporated in the Examination Guidelines through law revision enhancing the public notice function, which deserves the applicants' attention.

(V) Invalidation proceedings

1. Reissuance of the amended claims in the invalidation proceedings

Rule 73.1 of the revised Implementing Regulations is added with the provision that "the patent administration department under the State Council shall issue the amended claims where it makes a decision to uphold the validity of the patent or partially invalidate the patent on the basis of the amended claims", which plugs the previous procedural loophole in practice and is conducive to the publication of the scope of protection of the patent.

2. Confirmation of renunciation of rights in invalidation proceedings

The CNIPA has explored the renunciation of all or part of the patent right in the invalidation proceedings in practice over recent years. In some invalidation cases, where the patentee renounces the patent right, the CNIPA issues an invalidation decision to declare the patent invalid.[4] The revised Examination Guidelines confirm such practice in Part IV, Chapter Three, Section 2.2, stating that "in the invalidation proceedings, if the patentee declares to renounce a claim or design, it shall be deemed that the patentee admits that the claim or design does not conform to the relevant provisions of the Patent Law and its Implementing Regulations and acknowledges the request for invalidation concerning the claim or design, and thus the burden of proof on the petitioner for invalidation of said claim or design is exempted. Where the renunciation of the patent right does not hinder others' legitimate rights and interests or the public interest, the invalidation decision shall confirm the disposal of the right." According to this provision, where the patentee renounces all or part of the patent right, the CNIPA shall issue an invalidation decision to confirm the renunciation of the patent right as long as others' legitimate rights and interests and the public interest are not hindered.

The above provision is also significant where the patentee settles with the invalidation requestor after amending the claims in the invalidation proceedings. Under such circumstances, the invalidation requestor usually withdraws its invalidation request. In the past practice, the CNIPA would usually issue a notification of termination of examination, and the status of the claims is automatically resumed to that before the invalidation proceedings. According to the above provision of the revised Examination Guidelines, where the patentee makes amendments to the claims in the invalidation proceedings, even if the request for invalidation was withdrawn (based on the amended claims), the collegial panel shall also issue a decision to partially invalidate the patent as a confirmation to the patentee's renunciation of the patent in part.

3. Further limitations to amendments in invalidation proceedings

The revised Examination Guidelines set further limitations to the amendments to the invention or utility model patent documents in the invalidation proceedings in Part IV, Chapter Three, Section 4.6.1, i.e., in addition to the amendments to claims and several specific ways to make amendments, "amendments shall be made in response to the grounds for invalidation or the defects pointed out by the collegial panel", such that the ways to amend claims by the patentees in the invalidation proceedings are further restricted, which deserves the patentees' attention.

4. Parties in an ownership dispute can participate in invalidation proceedings

Where the CNIPA is requested to suspend relevant procedures due to a dispute over the right to apply for a patent or patent ownership, Rule 103.2 of the revised Implementing Regulations is newly added with the provision that "the patent administration department under the State Council may not suspend the relevant procedures if it deems that the grounds for suspension proposed by the party concerned are obviously untenable". The revised Examination Guidelines further enumerate, in Part V, Chapter Seven, Section 7.3.1.2, the circumstances where the invalidation proceedings may not be suspended, including:

(1) Where an examination decision on the request for invalidation can be made on the basis of the examination that has been done;

(2) Where the grounds for suspension proposed by the party concerned in the ownership dispute are obviously unsound, and the party concerned fails to provide sufficient evidence to prove the existence of the ownership dispute;

(3) Where there is evidence proving that the suspension of the invalidation proceedings obviously harms the interests of the parties concerned or the public interest; and

(4) Where there is evidence proving that the request for suspension is obviously a bad-faith and improper conduct.

According to the above provision, regarding a patent right in the invalidation proceedings, the request for suspension submitted by the party concerned in an ownership dispute will be subject to more stringent examination, and the party concerned in the ownership dispute shall submit the request for suspension as early as possible to avoid the failure to suspend the relevant procedures due to the first circumstance as mentioned above.

Accordingly, in Part IV, Chapter Three, Sections 3.7 and 3.8 of the revised Examination Guidelines, some remedies are provided for the parties concerned in an ownership dispute where the invalidation proceedings are not suspended. The parties concerned in the ownership dispute are allowed to participate in the invalidation proceedings, in which they can file opinions for the collegial panel's reference in the examination of the invalidation case, and the Re-examination and Invalidation Department shall issue a Notification of Examination Status of Request for Invalidation to the parties concerned in the ownership dispute that are allowed to participate in the invalidation proceedings.

5. Handling of multiple invalidation requests

In practice, multiple requests for invalidation may be submitted against one patent right. Where an examination decision on the request for invalidation has been issued and later appealed, shall the subsequent invalidation requests wait for the examination decision to take effect or shall they proceed? This will inevitably have a substantial impact on the parties concerned. Especially in invalidation cases concerning the early resolution mechanism for drug patent disputes (namely, the patent linkage system), the fairness and rationality of the handling of the multiple invalidation requests are more crucial due to the first generic drug exclusivity period [5].

The revised Examination Guidelines clarify, in Part IV, Chapter Three, the following rules based on the previous practice:

(1) "After an examination decision on partial or whole invalidation of the patent right has been made, a request for invalidation of the patent right which has been invalidated by the examination decision shall not be accepted, unless the examination decision is reversed by an effective judgment made by the people's court."

In practice, after the CNIPA has made a decision declaring one or more claims of a patent invalid, the infringement lawsuit filed against the invalidated patent claims will be rejected, [6] which implies the rule that the invalidation decision is presumed as taking effect at the time of its issuance. The above provision is in line with that of the said rule.

(2) "Where the accepted request for invalidation can-

not be examined for the time being due to the previously made examination decision on the request for invalidation, the Reexamination and Invalidation Department shall issue a notification to notify the requestor and the patentee; and the examination shall be resumed timely after influential factors are eliminated."

In practice, if the previously made invalidation decision upholds the patent right, the examination of the subsequently accepted requests for invalidation will usually not be affected regardless of whether the party concerned files a lawsuit against the examination decision. The above provision relates to the situation where an examination decision that declares the patent right invalid in whole or in part has been appealed and is still in administrative litigation proceedings, which means it has not taken effect yet, and the subsequent request for invalidation has been accepted (for example, the acceptance date of the subsequent request for invalidation is earlier than the date of issue of the previous examination decision). In this situation, the subsequent request for invalidation usually cannot be examined until the previous examination decision takes effect. The above provision clarifies the relevant procedures in this regard.

(3) As for the invalidation cases concerning the early resolution mechanism for drug patent disputes, the examination order is extremely vital due to the first generic drug exclusivity period. The revised Examination Guidelines clarify that "multiple invalidation requests filed against the same patent and concerning the early resolution mechanism for drug patent disputes shall be sequenced according to the order of the dates of filing the invalidation request".

Since timeliness plays a very important role in the early resolution mechanism for drug patent disputes, the revised Examination Guidelines set forth special provisions on the handling of multiple requests for invalidation as follows: "where the previously made examination decision upholds the patent right on the basis of the amendments to the application document made by the patentee, the examination on the later accepted request for invalidation can proceed on the basis of the abovementioned amendments". This is the situation where the patent is declared partially invalid. According to the item (2) as mentioned above, where the previous invalidation decision has been appealed and is still under administrative litigation proceedings, the subsequent request for invalidation "cannot be examined for the time being" under most of the circumstances. However, the revised Examination Guidelines provide an exception, which allows the further examination of the subsequent request for invalidation on the basis of the amended patent documents, the validity of which has been upheld by the previous invalidation decision. Thus, the indefinite delay of subsequent invalidation cases can be avoided under certain circumstances.

It should be noted that the prerequisite for applying the rules for examining the invalidation cases concerning the early resolution mechanism for drug patent disputes as mentioned above is that the invalidation requestor shall indicate in the Request for Invalidation that the present case is related to the early resolution mechanism for drug patent disputes, and shall submit evidence proving the same no later than the closure of the oral hearing (the issuance of the examination decision on the request for invalidation in cases without oral hearings); or otherwise, such a case shall not be subject to this rule, but to general rules.

6. Limitations to "citizen representatives"

The revised Examination Guidelines restrict and standardize the qualifications of citizens who serve as representatives, specifying that citizen representatives are confined to a close relative or staff of the party concerned, or a citizen recommended by a relevant social organization, and relevant certifying materials need to be provided for the entrustment. Referring to the relevant expressions in the Civil Procedure Law and the provisions of the people's court, citizen representatives in the invalidation proceedings are specified in the revised Examination Guidelines. To be specific, the party concerned may entrust a patent agency, or a close relative or staff of the party concerned, or a lawyer recommended by the All China Lawyers Association to act as his agent during oral hearing of an invalidation case.

7. Simplification of requirements for extraterritorial evidence

The revised Examination Guidelines revise, in Part IV, Chapter Eight, the requirements for evidence formed abroad or in Hong Kong, Macao and Taiwan, i. e., the phrase "verified by the Chinese Embassy or Consulate in the country" has been deleted. This revision, which is consistent with the Several Provisions of the Supreme People's Court on Evidence in Civil Litigation, generally simplifies the verification formalities for extraterritorial evidence, thereby reducing the burden of proof for the party concerned, and shortening the examination time to some extent. Meanwhile, this revision also accords with the Convention Abolishing the Requirements of Legalization for Foreign Public Documents, which China has entered and came into effect on 7 November 2023.

III. Computer program related inventions

The revised Examination Guidelines extend the subject matters of computer implemented inventions to computer program products, and provide more examples of qualified subjects in emerging technical fields so as to adapt to the innovative development of artificial intelligence, Internet Plus, big data, blockchain, business methods and the like. The major revisions are as follows:

1. More types of claims are allowed

The patent applications for invention relating to computer programs may have claims drafted as a method, device or a computer-readable storage media, or as a computer program product for realizing the claimed method.

2. The scope of patentable subjects is expanded

For a claim including algorithmic features or commercial rules and method features, the following factors can be highlighted and emphasized to meet the requirements for the subjects of technical solutions:

(1) Data processed in the algorithm claims are data having specific technical meanings, and the algorithm is executed in accordance with the laws of nature. For example, data processed in a convolutional neural network are image data that can reflect the close association between the algorithm and image information processing. Furthermore, in the field of knowledge graph reasoning, textual data or semantic information in a natural language is also clarified as technical data.

(2) The improvement of artificial intelligence and big data algorithms has a specific technical association with the internal structure of computer systems to enhance hardware computational efficiency or execution efficiency (such as, reducing stored data, reducing transmitted data and increasing hardware processing speed). For instance, a neural network model training method adopts a processor training scheme with different processing efficiencies for different volumes of training data, and improves the hardware execution performance of the computer system by automatically selecting a single processor or multi-processor training scheme.

(3) In the field of big data, the purpose of using such methods as classification, clustering, regression analysis and neural network is to explore the inherent correlations of data that conform to the laws of nature, thereby resolving the technical problems related to the reliability or accuracy of big data analysis in a specific application area and achieving a corresponding technical effect. For instance, the inherent correlations between users' behaviour characteristics and the tendency to use electronic vouchers are excavated, thereby resolving the technical problem of how to improve the accuracy of analyzing users' tendency to use electronic vouchers and achieving the corresponding technical effect.

3. It is expressively required that consideration shall be given to technical correlation or improvement in user experience in inventive step examination

Where there is a specific technical correlation between algorithms and the internal structure of the computer system to improve the internal performance of the computer system, such as increased computing efficiency or enhanced execution effect of the hardware, the contribution made by the algorithm features to the inventive step of the claims will be recognized. If the technical features or technical features and their closely associated algorithm features lead to the improvement in user experience, then the improvement in user experience shall be taken into account in the inventive step examination.

It can be seen that China has relaxed the requirements for examination of patent applications for invention relating to computer programs, such as in the examination of subjects or examination of inventive step. These requirements may differ from the practices in other countries or regions and are worthy of high attention and in-depth studies by applicants and patentees.

IV. Designs

Before 5 May 2022 when the Hague Agreement for the International Registration of Industrial Design (1999) (hereinafter referred to as the Hague Agreement) took effect in China, the revised Patent Law had set forth some provisions for the purpose of being in line with the Hague Agreement, such as Article 2 that expands the scope of protection of designs to partial designs and Article 42 that extends the term of a design patent to 15 years. The revised Implementing Rules and the revised Examination Guidelines further refine important rules for the design system including international applications for design. The major revisions are listed as follows:

(I) Protection of partial designs

As a patent application for design, a partial design as newly introduced shall first meet the general requirements for a design. In addition, the revised Implementing Regulations and the revised Examination Guidelines also stipulate other additional requirements that a patent application for partial design shall satisfy.

1. Views required for application

As far as a partial design is concerned, the relevant views submitted by the applicant shall clearly indicate the partial design of the product for which patent protection is sought and the position and proportion thereof in the overall product. Accordingly, the applicant who applies for a partial design patent shall submit the views showing the overall product.

The claimed partial design shall be clearly shown in the views, differentiated from the unclaimed part, and form a relatively independent area or constitutes a relatively complete design unit of the product. For instance, the boundaries of the claimed part shall be able to be clearly identified. When the claimed part is indicated by solid lines and other parts are indicated by dashed lines, said boundaries are usually delimited by solid lines or dot-and-dash lines.

If the claimed part involves a three-dimensional shape, then the views submitted shall include a perspective view that clearly shows the part, and usually also orthographic views.

2. Product name

The product name should clearly indicate the claimed part and the overall product it belongs to. For instance, if the overall product is a mobile phone and the claimed part is its camera, the "camera of a mobile phone" can be used as the product name. When determining whether a partial design is of the same or approximate category of a product, both the category of the part and that of the overall product are valuable as a reference.

3. Brief description

First, where the claimed partial design is indicated by both dashed and solid lines, the claimed part shall be clearly stated in the brief description. Second, where the boundaries between the claimed part and other parts are indicated by dot-and-dash lines, it shall be clearly stated in the brief description if necessary. For instance, where there is ambiguity or unclarity that may easily lead to confusion about the claimed content, it shall be clearly stated in the brief description. Third, whether the use of the claimed part needs to be indicated in the brief description depends on the circumstances: if the use is well-known to average consumers, it does not need to be stated in the brief description; and if the use is unclear or not well-known to average consumers, it needs to be stated in the brief description. Finally, the drawing or photograph that best shows the essential features of the design designated in the brief description of the partial design application shall include the claimed design of the part.

4. Graphical User Interface (GUI)

If the patent application relating to a GUI design is submitted as a partial design application, the GUI design no longer has to be bound to a specific type of electronic device (such as a smartphone, tablet or computer). The revised Examination Guidelines allow to submit only the views showing the GUI itself, which means the electronic device used to show the GUI does not need to be illustrated in the views. However, the product name must contain such keywords as "electronic device", and clearly indicate the claimed part, such as "search bar of mobile payment graphical user interface for electronic device".

5. Divisional application

If one or more designs are deleted from the original application containing multiple designs, a divisional application may be filed for the deleted design(s). However, when submitting a divisional application, the applicant is not allowed to amend the design. For instance, it is not allowed to amend the overall design to a partial design, the partial design to the overall design, or the claimed part to another part.

(II) Application for international registration of a design under the Hague Agreement

Since 5 May 2022 when the Hague Agreement (1999) took effect in China, applicants can seek protection for designs in China by filing international design applications, and Chinese applicants can also obtain international protection for designs in the 96 countries (by the date of publication of this article) covered by the Hague System in a quick and convenient manner. As of 20 January 2024, the revised Implementing Regulations and the revised Examination Guidelines provide legal basis and practical guidance for accepting international design applications and handling international design applications designating China, and the Interim Measures for Handling Relevant Operations after China's Accession to the Hague Agreement (the CNIPA Announcement No. 511) was abolished simultaneously.

1. International design applications

Applications for international registration of design can be filed directly with the International Bureau. The applicant having a habitual residence or business office in China can also file an application for international registration of design with the International Bureau through the CNIPA. Where an application for international registration of design is submitted through the CNIPA, other subsequent documents should be submitted to the International Bureau directly in the international procedure.

An application for international registration of design must meet the following basic requirements: using an official language, i. e. English / French / Spanish, submitting a copy (views), designating a contracting party, providing information of the applicant. Otherwise, the date of application for international registration may be re - determined, thereby affecting the protection of right.

In addition, during the process for applying for international registration of design, some items, such as the priority declaration, declaration for non - prejudicial disclosure and designated contracting party, must be stated and confirmed when filing the application. If these items are not specified at the time of filing the application, they cannot be restored or supplemented in the subsequent process.

Where an application for international registration of design is filed through the CNIPA, the application documents for the international registration of design must be written in English with China as the applicant's contracting party and correspondence information in mainland China written in Chinese, and should not include any information that violates laws or social morality or is detrimental to the public interest.

It should be noted that filing an application for international registration of design with the International Bureau through the CNIPA is only an alternative, and filing such an application directly with the International Bureau is a preferred option in terms of both economy and efficiency.

2. Application for international registration of design designating China

(1) Conversion from application for international registration of design to Chinese design patent

According to the revised Implementing Regulations and revised Examination Guidelines, the international application designating China with its date of international registration determined in accordance with the Hague Agreement shall be deemed as an application filed with the CNIPA. The date of the international registration shall be deemed as the filing date referred to in Article 28 of the revised Patent Law. After being published by the International Bureau, the CNIPA shall assign a national application number to and examine each international application transmitted by the International Bureau. When going through relevant formalities at the CNIPA, the party concerned of the international design application shall submit relevant documents that are written in Chinese and comply with relative provisions, indicate the national application number clearly, and go through the entrustment procedures according to Article 18 of the revised Patent Law.

(2) Chinese national examination of international design application

The form or content of the international design application is subject to the Hague Agreement and the Common Regulations Under the 1999 Act and the 1960 Act of the Hauge Agreement, and the examiner shall not reject the international design application due to formality defects of the application documents.[7] The examination of obvious substantive defects, as well as other documents and relevant formalities, is subject to the China's Patent Law, the Implementing Regulations, and the Examination Guidelines. The examination criteria for international design applications are identical to those for Chinese design patent applications.

If the international design application has an obvious substantive defect, the CNIPA shall send a notification of rejection to the International Bureau within 12 months of international publication, and the applicant is required to make a response within a prescribed time limit (generally 4 months).

Where it is found after examination that there is no cause for rejection of the international application, the examiner shall make a statement of grant of protection and send the same to the International Bureau.

It should be noted for the applicants that:

(a) In the international phase, a copy of the earlier application documents can be submitted only together with the international design application. The International Bureau does not accept any document submitted after the filing of the new application. Thus, if the international design application designating China is not filed along with a copy of the earlier application documents in the international phase, said documents shall be filed with the CNIPA within 3 months from the date of international publication. If the applicant of the later application is inconsistent with the applicant recorded in the copy of the earlier application, the relevant certifying documents shall be filed with the CNIPA within 3 months from the date of international publication. If any of the above-mentioned documents is not filed within the prescribed time limit, it shall be deemed that no priority claim has been requested in China, and the priority cannot be restored.

(b) An application for international registration of design may contain up to 100 different designs. However, in comparison with other countries and regions, China sets forth relatively stringent requirements for designs filed in one application, i.e., only similar designs, designs of products sold or used in set, designs of combination products and the like can be filed in one application. For multiple designs that do not meet China's requirement on unity, the applicant may initiatively file a divisional application within 2 months from the date of international publication or upon the examiner's request during examination, and the divisional application is a Chinese national application. The applicant may determine the different routes for filing design patent applications in China according to such factors as price and timeliness on a case-by-case analysis: filing an application designating China under the Hague System, filing multiple applications in China claiming the priority of an international application, or directly filing Chinese applications.

(3) Term of protection and renewal

If the CNIPA grants protection to an international design application, the term of protection of the design in China lasts up to 15 years. The patentee needs to go through the renewal formalities according to the Hague Agreement, i.e., the patentee shall renew the international registration with the International Bureau and pay the individual designation fees for designating China before the expiration of the 5-year and 10-year renewal periods from the date of international registration respectively. Otherwise, the patent right will terminate after the expiration of the renewal periods.

(III) Examination standards for design patents in invalidation proceedings

In view of examination practice, the revised Examination Guidelines further clarify and improve, in Part IV, Chapter Five, the examination standards for design patents in invalidation proceedings. The major changes are listed as follows.

(1) As for the determination of substantially identical designs, the term "cannot" in the circumstance where "the difference lies in only slight changes in some fine details which cannot be noticed with normal attention" is amended to "are not easy to", thereby rendering the determination standard more reasonable.

(2) As for the standard of "whole observation and comprehensive judgment" in the comparison and judgment of designs, the statement that "the approach of whole observation and comprehensive judgment means to determine on the observation of the patent in suit and the comparative design as a whole rather than on part or details of the designs" is amended to that "the approach of whole observation and comprehensive judgment means to observe the patent in suit and the comparative design as a whole by average consumers as judging subjects so as to determine the similarities and differences therebetween and judge their impact on the overall visual effect, in such a way to draw a conclusion comprehensively", and the provision that "the comparison shall be made based on the whole comparison of all design elements" is deleted. The judging subjects and steps of the approach of whole observation and comprehensive judgment are clarified to make the judging standards more practicable.

(3) It is clarified that one-to-one comparison and combination comparison are two ways to examine the obvious differences between designs, i.e., the patent in suit can be compared with one prior design, or with the combination of two or more prior design features.

(4) The standards for determining the prior design features used in combination in the examination of obvious differences between designs are clarified, that is, the prior design features "should be physically or visually naturally distinguishable designs with relatively independent visual effects, and points, lines or planes randomly made are not the prior design features that can be used in combination. However, where the patent in suit relates to a partial design, the corresponding part of a prior design can be regarded as the prior design features used in combination".

(IV) Service in relation to international design applications in invalidation proceedings

The revised Examination Guidelines stipulate in Part IV, Chapter Three, Section 7 (Service in relation to international design applications) that "during the examination of an international application upon request for invalidation, relevant documents can be served to the patentee with no domicile in the Chinese mainland via e-mail, or other means such as mail, fax, bulletin, and the like. If the documents are served via bulletin, at the expiration of one month from the issuance date of the bulletin, the documents shall be deemed to have been served.

This provision is set forth on the grounds that after China's accession to the Hague Agreement, there arose the issue as to how to serve documents to patentees with no domicile in the territory of China, and feasible extraterritorial service means need to be specified. A patentee cannot predict when others will file a request for invalidation or always keep an eye on relevant bulletins. In order to avoid the failure to obtain relevant documents mentioned in the request for invalidation and take the opportunity to safeguard the rights and interests in the invalidation proceedings, it is recommended that the applicant should entrust a Chinese agency as early as possible where an international registration for design application was filed under the Hague Agreement and granted, and go through relevant formalities with the CNIPA, to ensure the timely acquisition of documents in invalidation proceedings.

V. Protection and utilization of patents

(I) Patent term adjustment

Articles 42.2 and 42.3 of the revised Patent Law stipulate two situations for patent term adjustment respectively, namely, Patent Term Adjustment (PTA) due to unreasonable delay during the prosecution and Patent Term Extension (PTE) for pharmaceutical-related patents. Since the revised Patent Law took effect on 1 June 2021, relevant patentees have submitted a considerable number of requests for PTA and PTE according to Article 6 of the CNIPA Announcement No. 423, but none of them were examined because the revised Implementing Regulations and revised Examination Guidelines were not promulgated at that time.

The revised Implementing Regulations and revised Examination Guidelines clarify the specific rules for PTA and PTE. Article 13 of the Transitional Measures further specifies that starting from 20 January 2024, the requests for PTA and PTE submitted since 1 June 2021 are examined according to the revised Implementing Regulations and revised Examination Guidelines. Where a patent right which had expired before 20 January 2024 meets the compensation conditions, the patent term thereof can still be compensated and the compensation term shall be calculated from the original date of expiration of the patent right.

1. PTA

(1) Application conditions:

(a) PTA applies where a patent right for an invention is granted after the expiration of four years from the filing date and after the expiration of three years from the date of requesting for substantive examination of the application.

(b) Filing date in the case of PTA:

- For ordinary applications: the date of filing;
- For international applications: the date of entry of the international application into the Chinese national phase;
- For divisional applications: the date of filing the divisional application.

(c) Date of requesting for substantive examination in the case of PTA: the date of requesting for substantive examination with full payment of substantive examination fee; where the date of requesting for substantive examination is earlier than the date of publication, the date of publication shall be deemed as the date of requesting for substantive examination.

(2) Subjects of the requests and time limit:

(a) Patentees can request PTA within 3 months from the date of grant of patent;

(b) According to Article 2 of the Notification of Handling Patent Term Compensation issued by the CNIPA on 18 January 2024, if the time limit for filing the request for PTA is missed, there shall be no restoration period, that is, the right cannot be restored in the light of Rule 6.2 of the revised Implementing Regulations.

(3) Determination of the compensation term

The compensation term is calculated according to the actual number of days unreasonably delayed during the prosecution of an invention patent. The actual number of days is calculated as the date of grant minus 4 years from the filing date or 3 years from the date of requesting for substantive examination (whichever is later), and then minus the number of days reasonably delayed and the number of days unreasonably delayed by the applicant. It can be expressed by the following formula:

Compensation term A = L - D1 - D2

A: the actual number of days unreasonably delayed during the prosecution of the invention patent

L: the date of grant minus 4 years from the filing date or 3 years from the date of requesting for substantive examination, whichever is later

D1: the number of days reasonably delayed during prosecution

D2: the number of days unreasonably delayed by the applicant

Reasonable delays (D1 in the above formula), which are not counted in the compensation term, include:

- The time of reexamination procedure where the application documents are amended during reexamination;

- The time of suspension due to ownership dispute or assistance in preservation of patent application rights/patent rights;

- Other reasonable delays including, for example, delays caused by administrative litigation proceedings

Unreasonable delays caused by the applicant (D2 in the above formula) include:

- Delays caused by failure to respond to the office action issued by the patent office within the prescribed time limit;

- Deferred examination;

- Delays caused by incorporation by reference;

- Delays caused by restoration of right;

- Delays caused by entry of PCT international application into Chinese national phase within 30 months without requesting early processing.

(4) Approval and remedy

During examination, the requestor shall be provided with at least one opportunity to make observations and/or supplement documents. The conclusion shall be drawn in the form of a decision to compensate for the patent term or a decision not to compensate for the patent term. Where a decision to compensate for the patent term is made, the relevant matter shall be registered in the Patent Register and announced in the Patent Gazette.

If not satisfied with the decision on PTA, the patentee or an interested party who is involved in a dispute over infringement of the patent or has applied for registration of a relevant drug may file a request for administrative reconsideration with the CNIPA.

(5) Limitations:

(a) PTA is only applicable to invention patents, not utility model or design patents.

(b) Where an applicant files applications for both an invention patent and a utility model patent for the same invention-creation on the same date, if a patent for invention is granted according to Rule 47.4 of the revised Implementing Regulations, PTA is not applicable to such an invention patent.

(c) PTA is only applicable to invention patents granted on and after 1 June 2021, and has no retroactive effect on previously granted invention patents.

2. PTE

(1) Applicable scope

PTE is applicable to product invention patents, preparation method invention patents and medical use invention patents in relation to active pharmaceutical ingredient (API) contained in innovative drugs and improved new drugs approved for marketing.

"Improved new drugs" are limited to:

(a) Chemical drugs of Class 2.1 that perform esterification or salification on known active ingredients;

(b) Chemical drugs of Class 2.4 (i.e. drugs containing known active ingredients for new indications);

(c) Preventive biological products of Class 2.2 that are vaccines improved against bacterial or viral strains;

(d) Therapeutic biological products of Class 2.2 for new indications; and

(e) Traditional Chinese medicine of Class 2.3 (i.e., traditional Chinese medicine with increased indications).

In the light of relevant provisions on drug registration in China, both innovative drugs and improved new drugs must be "world-new", i.e., "not launched into the market domestically or internationally", which means that drugs which apply for marketing in China after their launch into the international market cannot enjoy the benefits of PTE.

According to the above provisions, it shall also be noted that PTE is only applicable to invention patents, not utility model or design patents. PTE is only available to three types of patents in relation to API, which means that PTE is not applicable to non-API patents, such as patents in relation to excipients.

According to the Transitional Measures and CNIPA Announcement No. 423, as well as relevant policy interpretations,[8] PTE is only applicable to new drugs approved for marketing as of 1 June 2021, not to new drugs approved for marketing prior to or on 31 May 2021.

(2) Application conditions

Patents which are eligible for PTE must meet the following requirements:

(a) The date of grant of patent shall be earlier than the date of approval for drug marketing;

(b) The patent right is still valid;

(c) The patent has never been granted PTE before;

(d) The patent claims cover the technical solution in relation to the new drug approved for marketing;

(e) Where a drug is covered by multiple patents, the patentee can only request PTE for one of the patents; and

(f) Where a patent covers multiple drugs, PTE can only be requested for the patent based on one drug.

Special attention shall be drawn to items (e) and (f). Appropriate strategies shall be formulated for right holders owning multiple drugs or patents in hope of better utilizing the PTE system to maximize their interests. For instance, if an active ingredient covered by a patent has multiple possibly marketed dosage forms or may be approved for multiple indications, account may be taken of filing multiple divisional applications to maximize the advantage of PTE.

(3) Scope of protection during the compensation term

During PTE, the scope of protection of the patent is confined to a new drug approved for marketing by the drug supervision and administration department under the State Council and to the technical solutions of the new drug for approved indications; and within the scope of protection, the rights and obligations of the patentee during PTE are the same as those before. The scope of protection of product claims is only limited to marketed new drugs for approved indications, the scope of protection of medical use claims is only limited to approved indications for which the marketed new drugs are used, and the scope of protection of preparation method claims is only limited to the process of producing the marketed new drugs used for the approved indications as recorded at the drug supervision and administration department under the State Council.

(4) Compensation term

The compensation term of PTE is calculated as the date of approval for drug marketing minus the date of filing the patent, and then minus 5 years. The compensation term shall not exceed 5 years, and the total effective patent term from the date of approval for the drug marketing shall not exceed 14 years. PTE and PTA can be applied simultaneously. Where PTE and PTA can both be applied for one patent, PTA should be taken into consideration in the calculation of the above 14-year term.

(5) Time limit, subjects of the requests and required documents

Patentees shall file a request for PTE with the CNIPA within 3 months from the date of approval for drug marketing and pay corresponding fee. The request for PTE for drugs approved for conditional marketing shall be filed within three months from the date of official approval for marketing in China; however, the compensation term shall be calculated based on the date of conditional approval for marketing. Similar to PTA, according to Article 2 of the Notification of Handling Patent Term Compensation issued by the CNIPA on 18 January 2024, if the time limit for filing the request for PTE is missed, there shall be no restoration period, that is, the right cannot be restored in the light of Rule 6.2 of the revised Implementing Regulations.

Regarding the subjects, the request for PTE shall be submitted by the patentee. Where the patentee is different from the marketing authorization holder (MAH), a document proving the written consent of the MAH shall be submitted.

Regarding the Request Form, the requestor shall indicate therein the name of the drug, drug registration classification, approved indications and patent number of the patent for which PTE is requested, specify the claims in relation to the drug approved for marketing, explain with certifying documents how the specified claims cover the technical solutions in relation to the new drug and the basis for calculating the compensation term, and clarify the technical solutions protected during PTE.

Regarding certifying documents, the patentee shall submit materials capable of proving the time of drug marketing approval, drug classification, technical solutions related to the drug, etc. Materials required for proving the technical solutions related to the drug may vary with the different scopes of protection of claims. For example, where a claim is directed to a compound, the drug instruction that recites the APIs is generally sufficient to prove that “the claim covers a technical solution in relation to a new drug”; but where a claim seeks to protect a preparation method, documents on drug production processing approved by the drug supervision and administration department under the State Council shall usually be submitted. Article 4 of the Notification of Handling Patent Term Compensation [9] issued by the CNIPA on 18 January 2024 provides certain guidelines for submitted materials. Meanwhile, it is also stipulated in said article that “where the submitted materials involve a trade secret, the relevant information may be blurred; however, the blur shall not affect the judgement as to whether the specified claim covers the technical solution in relation to the new drug”, which prevents the parties concerned from being hindered by a trade secret that is irrelevant to PTE to the maximum extent.

In practice, the preparation of the PTE Request Form is time-consuming and laborious. It is recommended that the right holder should collect relevant materials and prepare the PTE Request Form before the expected approval of the drug, so as not to miss the deadline or harm the rights and interests due to hasty preparation.

(6) Approval and remedy

Having found that the request for PTE does not meet the requirements after examination, the CNIPA shall provide the requestor with at least one opportunity to make observations and/or supplement documents. The conclusion shall be drawn in the form of a decision not to compensate for the patent term or a decision to compensate for the patent term. Where a decision to compensate for the patent term is made, the relevant matter shall be registered in the Patent Register and announced in the Patent Gazette.

According to the CNIPA Announcement No. 560, if not satisfied with the CNIPA's decision on PTE, the patentee or an interested party who is involved in a dispute over infringement of the patent or has applied for registration of a relevant drug may file a request for administrative reconsideration with the CNIPA. The interested party herein should include the accused infringer in a dispute over infringement and the applicant who has applied for registration of generic drug.

(II) License of Right

Patent License of Right (LOR) is a new rule added to Articles 50 to 52 of the revised Patent Law. Rules 85 to 88 of the revised Implementing Regulations, and Part V, Chapter 11 of the revised Examination Guidelines further stipulate LOR and examination thereof.

The basic procedures of LOR are as follows:

The patentee that is willing to endorse its granted patent with an LOR submits a written declaration for LOR to the CNIPA.

↓

The CNIPA shall examine the declaration for LOR and shall announce the same if the requirements are met. The declaration for LOR will take effect from the date of announcement.

↓

After any entity or individual notifies the patentee in writing and pays the royalty in accordance with the announced payment method and standard for the royalty, it or he obtains the license for patent exploitation.

LOR is a non-exclusive license and differs from other non-exclusive licenses only in its special platform. LOR can coexist with other non-exclusive licenses, but not with exclusive or sole licenses.

LOR is endorsed for granted patents, excluding pending patent applications. LOR can be granted for invention, utility model and design patents. However, if a declaration for LOR is made for a utility model or design patent, a patent evaluation report is required to be submitted. LOR is possible only when the patent evaluation report finds that the utility model or design patent meets all the conditions for patentability.

In addition, LOR shall not be granted for patents under the following circumstances: a. the patent is within the term of a sole or exclusive license; b. relevant procedures have been suspended due to a dispute over patent ownership or preservation order granted by the people's court; c. required patent annuities are not paid; d. the patent has been pledged and the consent of the pledgee has not been obtained; e. the patent has terminated; f. the patent has been declared invalid in whole; and g. other circumstances that hinder the effective exploitation of the patent.

The declaration for LOR shall be made in a prescribed format, the template of which is available on the CNIPA's official website.[10] The payment method and the standard of the royalty shall be clearly specified in the declaration for LOR. The revised Examination Guidelines set the upper limit for patent royalties, to be specific, the patent royalties paid at a fixed rate are generally not more than RMB 20 million. Where patent royalties are more than RMB 20 million, the patentee may license its patent by other means, instead of LOR, as stipulated in Article 50 of the revised Patent Law. Where patent royalties are paid on a percentage basis, for net sales it is generally not higher than 20%, and for profits it is generally not higher than 40%.

After the declaration for LOR is announced, the patentee may withdraw the declaration for LOR, the withdrawal shall not be conditional. The withdrawal of the declaration for LOR shall be made in writing and announced by the patent administration department under the State Council. Where the declaration for LOR is withdrawn by announcement, the validity of the previous LOR shall not be affected.

Where the license for patent exploitation is granted under LOR, the patentee or licensee may file documents capable of proving the grant of license in writing with the patent administration department under the State Council for recordal. Without recordal, the validity of the LOR will not be affected, but the patentee is not entitled to annuity reduction. Where a request for recordal of the LOR agreement is filed, it is deemed that the patentee also requests for annuity reduction. Where the recordal is approved, the patentee is entitled to reduction in annuities, the time limit for payment of which has not expired, since the date of recordal during the implementation of LOR. If the declaration for LOR is withdrawn, the patentee is no longer entitled to annuity reduction due to LOR from the subsequent patent year.

Where a dispute arises over the implementation of LOR, the licensor and the licensee may either request the patent administration department under the State Council to mediate, or file a lawsuit with the people's court. However, the CNIPA has no authority to adjudicate disputes over LOR.

Since the CNIPA only functions to provide a platform for the LOR system, the CNIPA's decision on whether to announce the declaration for LOR is not subject to administrative reconsideration. However, the patentee can re-submit the declaration for LOR. If the resubmitted declaration for LOR meets the relevant provisions, there is still a chance that the LOR can be announced. However, if the patentee is not satisfied with the decision on whether to reduce the annuities during the implementation of the LOR made by the CNIPA according to Article 51.2 of the revised Patent Law, the patentee may apply for administrative reconsideration with the CNIPA.

The China's patent LOR system provides a new platform for patentees that are willing to license patents and individuals or entities that are willing to exploit others' patents, thereby reducing costs of all parties for information search and negotiations. As a result, the patentees enjoy the benefit of annuity reduction, which is conducive to transformation and utilization of some patents. While, in comparison with the similar systems in other countries, such as the UK, the China's LOR system has significant differences: the China's LOR must specify the payment method and standard for patent royalty with no room for negotiations between the parties, and the CNIPA has no authority to adjudicate disputes over LORs; but in the UK, the patentees do not need to specify the conditions such as patent royalties in the declarations for LOR, and the intellectual property office has the authority to adjudicate disputes where the parties fail to reach an agreement on the LOR conditions. [11] The China's LOR system is relatively simpler, but meanwhile leaves less room for the parties to make adjustment. A close eye shall be kept on the effect of the LOR system on patent transformation and utilization in practice.

(III) Administrative protection of patents

Article 70 of the revised Patent Law empowers, for the first time, the CNIPA to deal with patent infringement disputes that have a significant impact in China upon the request of the patentee or any interested party. In the past, only local intellectual property offices had the authority to deal with patent infringement disputes, but the CNIPA did not. Rule 96 of the revised Implementing Regulations further specifies the circumstances where the patent infringement disputes "have a significant impact in China". The Administrative Adjudication Measures for Major Patent Infringement Disputes previously issued by the CNIPA in 2021 have provided specific criteria for determining whether the patent infringement disputes "have a significant impact in China".

Rule 95 of the revised Implementing Regulations is amended to clarify that the patent administration department of the governments of prefecture-level cities and districts of municipalities can handle and mediate patent disputes. According to this amendment, the district-level intellectual property offices of municipalities, such as the Intellectual Property Office of Haidian District in Beijing, or the Intellectual Property Office of Pudong District in Shanghai, have the authority to make administrative rulings on patent disputes, which expand the scope of intellectual property offices having the authority to make administrative rulings on patent disputes.

Compared with judicial routes for patent disputes, administrative adjudication primarily outstands in its short duration, which usually lasts a few months. For instance, in the first major infringement case adjudicated by the CNIPA, the whole procedure from acceptance to the issuance of the ruling lasted only about 8 months, including the 5-month suspension due to invalidity proceedings. [12] Administrative protection of patents is an optional protection route for patentees hoping to obtain injunctions in the shortest possible time.

VI. Conclusion

The comprehensive revision of the Implementing Regulations and the Examination Guidelines is made to comply with the fourth revision of the Patent Law, and is also an important part of supporting legislation after China's accession to the Hague Agreement. It is almost fourteen years that the Implementing Regulations have not been revised. This law revision covers a wide range of amendments and involves large institutional adjustments, actively responds to the demands of innovative entities on patent application, examination, protection and the like, and comprehensively optimizes and improves the current patent system from various aspects, which marks a milestone in the development of China's patent system and is of great significance to further improve China's patent application and examination systems and to enhance the level of patent creation, utilization, protection, management and service in China. ■

The authors: Sun Zhigang, Ke Ke, Qiao Haoran,
Wen Dapeng, Wang Danqing, Cao Ruo, Liu Peng
and Li Liantao

---

[1] Literally speaking, the "justified reasons" may be different from the "unintentional" or "due care" standard as stipulated by Rule 26*bis*.3 of the Regulations under the Patent Cooperation Treaty.

[2] Standardized Request Form for invention or utility model patents currently provided by the CNIPA includes the declaration for incorporation by reference. Where a standardized Request Form is used, it is deemed that the declaration for incorporation by reference has been made.

[3] Li Mingde (2014). *American Intellectual Property Law* (2nd edition, pp. 121-124). Law Press·China.

[4] For instance, the Invalidation Decision No. 53902.

[5] Article 11 of the Implementing Measures of Early Resolution Mechanism for Drug Patent Disputes (Trial).

[6] Article 2 of the Interpretation (II) of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Disputes over Patent Infringement (No. Fa-shi [2016]).

[7] Also see Article 12(1) of the Hague Agreement.

[8] Retrieved from https://www.cnipa.gov.cn/art/2021/5/27/art_66_159677.html.

[9] Retrieved from https://www.cnipa.gov.cn/art/2024/1/18/art_75_189871.html.

[10] Retrieved from https://www.cnipa.gov.cn/col/col187/index.html.

[11] Article 46(3)(a) of the UK Patents Act (2017).

[12] See Nos. Guozhibaocaizi 1/2021 and 2/2021.

2024 World Intellectual Property Day | IP and the SDGs: Building our common future with innovation and creativity

The World Intellectual Property Organization invites all Member States and stakeholders to join in celebrating World Intellectual Property Day on 26 April 2024. The campaign theme is: IP and the SDGs: Building our common future with innovation and creativity.

World Intellectual Property Day has become a truly global event with celebrations taking place in every region of the world. In 2024, we celebrate change makers around the world who are driving the innovation and creativity needed to achieve the Sustainable Development Goals (SDGs) and build a better and more sustainable future for everyone. IP is central to addressing the global challenges we face. IP is a powerful catalyst for growth and development and, as such, has a key role to play in improving livelihoods, and safeguarding our planet. World Intellectual Property Day 2024 is an opportunity to showcase the central role that IP, innovation and creativity play in achieving the SDGs for the benefit of everyone.

The 2030 Agenda for Sustainable Development, adopted by the international community in 2015, provides a shared blueprint for peace and prosperity for people and the planet, both now and in the future. The 2030 Agenda is underpinned by 17 SDGs. The SDGs are an urgent call to action for all countries to come together in a global partnership to carve pathways to a better and more sustainable future.

To build our common future and achieve the SDGs, we need to re-think how we live, work and play. World Intellectual Property Day 2024 is an opportunity to explore how intellectual property encourages and can amplify the innovative and creative solutions that are so crucial to building our common future.

Source: WIPO China