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**INTERPRETATION OF NEW REGULATIONS:
KEY AMENDMENTS AND PRACTICAL ADVICE
FOR THE IMPLEMENTING
RULES OF THE PATENT LAW**



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◀ Special Issue ▶

Interpretation of New Regulations: Key Amendments and Practical Advice for the Implementing Rules of the Patent Law

To ensure the smooth implementation of the *2020 Revised P.R.C. Patent Law*, the revised *Implementing Rules of the P.R.C. Patent Law* were promulgated by the end of 2023 and will take effect on January 20, 2024. Watson & Band's Patent Team has provided an in-depth interpretation of the significant amendments within these rules and offered pragmatic guidance for patent management professionals and practitioners. This guidance aims to assist enterprises in effectively navigating and leveraging the new regulations.

Note: *This special report does not discuss changes related to open licensing, administrative mediation, or international design applications under the Hague Agreement.*

by Watson & Band's Patent Team

December 2023

	Keywords	Amendments/Additions	Interpretation and Significance in Practice
Rule 4	Deadline	<p>Where various documents are submitted electronically to the patent administrative department under the State Council, the date of entry into the specified electronic system of the patent administrative department under the State Council is recognized as the submission date.</p> <p>Similarly, documents electronically served by the patent administrative department under the State Council are considered delivered on the date of entry into the electronic system recognized by the relevant party.</p>	<p>For applications filed electronically, the traditional 15-day postal period is no longer applicable to the issuance of notices. Instead, such notices are considered delivered on the date of entry into the electronic system. <u>Accordingly, for notices that require a response within a specific deadline, the calculation of this deadline will commence from the date of receipt in the electronic system. This change necessitates applicants to diligently monitor their deadlines to ensure timely responses.</u></p>
Rule 11	Good Faith Principle	<p>Patent applications should adhere to the principle of good faith. All patent applications must be based on true inventive activities and must not involve any fraudulent or deceptive practices.</p>	<p>For the first time, the good faith principle is integrated into the patent grant and confirmation procedures, specifically during preliminary examination (Rule 50 of the Implementing Rules), and substantive examination (Rule 59 of the Implementing Rules). It also serves as a basis for patent invalidation (Rule 69 of the Implementing Rules).</p>

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			<p>Violations of this principle may result in administrative penalties, including warnings and fines, in accordance with Rule 100 of the Implementing Rules.</p> <p>Article 3 of the Provisions on Regulating Patent Application Conducts (2023) (Bureau Order No. 77) details eight specific instances of such violations, including simple combination, forgery, plagiarism, and assembly. Given the subjective element involved in adjudicating these instances, the impact on examinations after January 20 remains to be seen. <u>Applicants are therefore advised to maintain pertinent records of their invention and development processes to furnish as defensive evidence against potential allegations of violating the good faith principle.</u></p>
Rule 30	Partial Design	<p>Applicants are obligated to furnish relevant images or photographs of each design product for which protection is sought. In the case of applying for a partial design patent, applicants must provide a view of the entire product and distinguish the protected portion using a combination of dashed and solid lines or other methods.</p>	<p>The 2020 amendment to the Patent Law has expanded the scope of protection for design patents to partial designs. The amended Implementing Rules and Examination Guidelines have detailed specific principles and methods for examining partial design applications. Prior to this amendment, design patent applications, including those for Graphical User Interfaces (GUIs), were required to be filed in conjunction with the appearance of the product they were part of, which constrained the scope of patent protection available. The inclusion of partial designs broadens the scope of protection, effectively addressing the issues of partial “copying” and ensuring more robust protection for elements such as GUI as partial designs of the product.</p>
Rule 35	Domestic Priority for Design Patents	<p>If a design patent applicant claims domestic priority and the prior application pertains to an invention or utility model patent, the applicant may file a design patent application featuring the same subject matter as illustrated in the drawings; if the prior application is for a design patent, the applicant may file a design patent application regarding the same subject matter.</p>	<p>This amendment introduces domestic priority for design patents, permitting the filing of design patent applications based on designs included in prior applications for invention or utility model. In practice, the establishment of the domestic design priority system enhances design patent protection in China. It also facilitates the filing of joint applications for similar designs.</p>

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Rule 36	Restoration of Priority	Applicants who fail to meet the deadline stipulated in Article 29 of the Patent Law and subsequently submit an invention or utility model patent application concerning the same subject matter are permitted to petition for restoration of priority. This petition must be filed within two months following the missed deadline and must be accompanied by a justified cause.	<p>This provision introduces a remedy for the loss of priority after missing the 12-month time limit, permitting the applicant to request for restoration of priority for invention or utility model patent filed after the 12-month priority period but within 14 months. From January 20, 2024 and within 14 months from the priority date, those whose initial applications date back to November 20, 2022, or later and who failed to claim priority within the 12-month time limit are eligible to seek restoration of priority.</p> <p>The petition for restoration must include an explanation of valid reasons. While the Patent Examination Guidelines do not specify what constitutes 'valid' reasons, it is generally understood that unintentional oversights are considered acceptable. Applicants are not obliged to provide extraordinary evidence to support their case. For r</p> <p>Despite the opportunity for restoration, <u>applicants are strongly advised to vigilantly monitor the priority and subsequent 2-month restoration deadlines.</u></p> <p>Failing to observe these time limits will result in the loss of chance for restoration, as no further remedies will be available beyond the 2-month restoration time limit.</p>
Rule 37	Correction of Priority	An applicant of an invention or utility model patent who has claimed priority is entitled to request amendments to or additions to the priority claims in the request within 16 months from the priority date, or within 4 months from the filing date.	<p>The newly introduced remedial measures allow applicants who erroneously stated or omitted priority to correct or add priority claims within 16 months from the priority date or within 4 months from the filing date. Effective from January 20, 2024, applicants are permitted to submit requests to correct priority for applications that initially contained incorrect or omitted priority.</p> <p>Prior to these measures, if an applicant provided incorrect priority information or omitted priority in initial filing, it will be deemed that no priority has been claimed and there will be no chance of correction.</p>
Rule 45	Supplementation by Reference	For invention or utility model patent applications that lack or erroneously include claims, specifications, or parts thereof, if priority is claimed on the filing date, the applicant is permitted to make supplementation by referencing documents from the prior application	<p>The incorporation by reference mechanism has been introduced in the patent application process. This mechanism allows applicant to incorporate part or all of the contents of claims and specifications from a prior application (namely the priority) into a subsequent application without altering the original application date. Under the existing Patent Law, where incorporation by reference is retained,if any contents</p>

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		<p>within two months from the filing date or within another period as stipulated by the patent administrative department under the State Council. If these supplementary documents meet the stipulated requirements, the initial submission date shall be the filing date.</p>	<p>of the prior application are to be incorporated into the subsequent application, the date of incorporation will be deemed as the application date of the subsequent application. The postponed application date could potentially lead to the loss of priority of the subsequent application due to exceeding the 12-month priority window, and may result in the serious consequence of denial of the patent due to lack of novelty or inventiveness.</p> <p>The amended Implementing Rules include the provisions on incorporation by reference, enabling applicants to supplement part of contents of claims and specifications by referencing to prior application within two months of the date of submission of the application or within a designated period. <u>It should be noted that only for applications submitted after January 20, 2024, will applicants be entitled to supplement documents by referencing to a prior application.</u></p>
Rule 56	Delay of Examination	<p>Applicants are entitled to request a delay in the examination of their patent applications.</p>	<p>The introduction of the provision for delayed examination offers applicants of invention patents with additional time to better ascertain the value of their application, refine the scope of protection of claims, and postpone the acquisition of the ultimate scope of protection by their competitors. Before this provision, applicants desiring to defer the examination process often resorted to indirect methods such as delayed responses or partial amendments. These methods were cumbersome and potentially disruptive to the standard examination procedure. The option for delayed examination presents a significant improvement in procedural flexibility for applicants.</p> <p><u>For design patent applications, opting for a delayed examination can narrow the gap between the patent announcement and the commercial release of the product, thereby mitigating the risk of imitation by competitors.</u></p>
Rule 62	Patent Evaluation Report	<p>After the public announcement of granted utility model or design patent rights, patentees, interested parties, and accused infringers, as per Article 66 of the Patent Law, are entitled to request a patent</p>	<p>1. Prior to this amendment, only patentees and interested parties were permitted to request a patent evaluation report. Accused infringers could only resort to patent invalidation proceeding to challenge the validity of the patent. The recent amendment permits accused infringers to request a patent evaluation report and present it as evidence in court, thereby facilitating dispute resolution and streamlining both administrative and judicial</p>

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		evaluation report from the patent administrative department under the State Council. <u>Furthermore, during the patent right registration process, applicants also have the option to request the issuance of such a report from the same authority.</u>	processes. 2.Previously, the request for a patent evaluation report were confined to the post-announcement phase of granting utility model or design patent rights. The amendment expands this period to include the patent right registration phase, thus aiding applicants in assessing the stability of their patent rights and determining whether to retain the same. It is helpful to enhance the overall quality of utility model and design patents.
Rule 67	Examination Ex Officio	Upon conducting a reexamination, should the patent administrative department under the State Council determine that the reexamination request fails to comply with the Patent Law and its Implementing Rules <u>or the patent application has other clear violations of the same</u> , the patent administrative department under the State Council shall notify the reexamination requester to submit opinions within a specified time limit.	Before the amendment, reexamination was confined solely to addressing defects identified in the rejection decision. However, the amended Implementing Rules have expanded this scope to include the examination of additional obvious defects. Additionally, it provides requesters with the opportunity to present their opinions. This amendment is designed to streamline procedures.
Rule 73	Patent Invalidation	Where the patent administrative department under the State Council makes a decision to uphold or partially invalidate a patent on the basis of the amended claims, it shall announce the amended claims.	Amendments to a patent's claims during invalidation proceedings result in alterations to the patent's original scope of protection as initially announced. Previously, without publishing the amended claims, the actual protection scope could only be ascertained through a search of patent examination archives and the patent invalidation decisions. The CNIPA is obligated to inform the public of any changes to a patent's scope. The recent amendment addresses this issue.
Rule 77	Patent Term Compensation	Any request for patent term compensation pursuant to Article 42.2 of the Patent Law must be submitted by the patentee to the patent administrative department under the State Council within three months from the date of the announcement of the patent grant.	The 2020 amendment of the Patent Law introduced the patent term compensation system, and the newly amended Implementing Rules and Examination Guidelines provide detailed provisions for the application and examination of the patent term compensation. This Rule clarifies that the compensation request must be made by the patentee and that the request for compensation of the invention patent term must be made within three months following the announcement of the patent grant.

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			<p><u>In practice, patentees are advised to assess the need for term compensation promptly upon receipt of the patent grant notice, or to monitor the deadline for making compensation request, so that the compensation requested could be made in a timely manner to protect their lawful rights and interests.</u></p>
<p>Rule 78</p>	<p>Patent Term Compensation</p>	<p>Where patent term compensation is granted under Article 42.2 of the Patent Law, the duration of the compensation shall be calculated based on the actual number of days of unreasonable delay in the patent grant process. The "actual days of unreasonable delay", as referred to in the preceding paragraph, are calculated from the date marking the expiration of four years from the filing date of the invention patent application or three years from the date of the request for substantive examination, whichever is later, up to the date of the patent grant announcement. This calculation shall deduct any days of reasonable delays and days of unreasonable delays attributable to the applicant.</p> <p>Reasonable delays include: (1) Delays due to amendments of the patent application pursuant to Rule 66 of the Implementing Rules, which ultimately result in a granted patent right;</p>	<p>This Rule outlines the method for calculating days eligible for patent term compensation. It specifies that any days attributed to unreasonable delays caused by the applicant, as stipulated in Article 42.2 of the Patent Law, and all reasonable delay periods, will be excluded from the calculation. the remaining period constitutes the compensable time.</p> <p>Additionally, this Rule lists specific scenarios that are not eligible for compensation. These include periods consumed in reexamination procedures and suspensions due to ownership disputes or preservation measures adopted by the court. For dual applications in one case where the utility model patent has been granted, the invention patent is ineligible for term compensation.</p> <p>It is important to note that compensation for unreasonable delays and for time consumed in new drug review and approval are two distinct clauses in Article 42 of the Patent Law, addressing different type of delays and patents. For a new drug patent, there may be an opportunity to seek compensation for both unreasonable delays and time consumed in drug review and approval concurrently.</p>

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		<p>(2) Delays resulting from situations described in Rules 103 and 104 of the Implementing Rules;</p> <p>(3) Delays attributable to other reasonable circumstances.</p> <p>If the same applicant simultaneously applies for both a utility model patent and an invention patent for the same invention-creation on the same day, and is subsequently granted an invention patent right in accordance with Rule 47.4 of the Implementing Rules, then Article 42.2 of the Patent Law shall not apply to the term of this invention patent.</p>	
Rule 79	Patent Term Compensation	<p>Unreasonable delays attributable to the applicant as stipulated in Article 42.2 of the Patent Law include:</p> <p>(1) Failure to respond to notifications issued by the patent administrative department under the State Council within the specified time limit;</p> <p>(2) Request for delayed examination;</p> <p>(3) Delays resulting from situations described in Rule 45 of the Implementing Rules;</p> <p>(4) Other unreasonable delays attributable to the applicant.</p>	<p>This Rule identifies specific instances of unreasonable delays caused by the applicant, as defined in Article 42.2 of the Patent Law. These include failures to respond to Office Actions (such as requesting a delayed response) within the designated time limits, actively seeking a delayed examination, and supplementing application documents through incorporation by reference.</p>
Rule 80	Patent Term Compensation for New Drugs	<p>The term "new drug-related invention patents," as referred to in Article 42.3 of the Patent Law, means patent for new drug products, their preparation methods and medical uses, all of which must adhere to relevant regulations.</p>	<p>This Rule specifies types of patents eligible for drug patent term compensation, which are confined to patents of new drug products, their preparation methods and medical uses. It explicitly excludes other drug-related patents, such as impurities and intermediates.</p> <p>The Patent Examination Guidelines further elaborate this Rule, stating that for innovative drugs and improved new drugs conforming to the stipulations of this chapter approved for market by the drug regulatory department</p>

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			under the State Council , only the product invention patents, preparation method invention patents, or medical use invention patents for the active ingredients of these drugs qualify for drug patent term compensation. The definitions of "innovative drugs" and "improved new drugs" are determined based on relevant laws and regulations and the specific rules of the drug regulatory department under the State Council.
Rule 81	Patent Term Compensation for New Drugs	<p>In order to request patent term compensation for new drug-related invention patents under Article 42.3 of the Patent Law, applicants must satisfy the following criteria and submit their request to the patent administrative department under the State Council within three months from the date of the new drug's marketing approval:</p> <p>(1) In cases where a new drug is covered by multiple patents, the patentee is eligible to request term compensation for only one of these patents.</p> <p>(1) If a single patent covers multiple new drugs, term compensation may be sought for only one of these drugs.</p> <p>(3) The patent in question must be valid and not have been previously granted patent term compensation for a new drug-related invention.</p>	<p>This Rule outlines the entities eligible to request drug patent term compensation, the deadline for such requests, and the necessary conditions to be met. Furthermore, the Patent Examination Guidelines specify that for the patent seeking term compensation, the date of announcement of patent grant must precede the drug marketing approval date. Furthermore, the claims of the patent in question must include the technical solution of the new drug that has been granted marketing approval.</p> <p><u>Thus, in practice, applicants should carefully assess and collate the various patents associated with the new drug or the multiple new drugs related to a single patent. This assessment should take into consideration factors such as the protection scope, patent term, and others to determine the most advantageous patent or new drug for which to request term compensation.</u></p>
Rule 82	Patent Term Compensation for New Drugs	<p>Where any patent term compensation is granted under Article 42.3 of the Patent Law, the duration of compensation shall be the period from the patent application</p>	<p>This Rule outlines the formula for calculating patent term compensation for drugs. The period of compensation is calculated as the time from the marketing approval date in China to the patent application date, minus 5 years. For example, if a drug receives marketing approval on June 20, 2020, and the patent application was filed on June 15, 2012, the period eligible for compensation would be 3 years and 5 days, calculated as (2020.6.20-2012.6.15-</p>

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		<p>date to the marketing approval date of the new drug in China minus five years. In addition, the compensation shall also comply with Article 42.3 of the Patent Law.</p>	<p>5 years). However, the actual compensatory time granted is subject to the following two conditions as stipulated in Article 42.3 of the Patent Law:</p> <ol style="list-style-type: none"> 1. The compensated time must not exceed 5 years. In other words, the compensated time \leq 5 years; and 2. The total effective patent term after the marketing approval of the new drug must not exceed 14 years. This is calculated as follows: (Patent expiration date - new drug marketing approval date + compensated time) \leq 14 years.
Rule 83	Patent Term Compensation for New Drugs	<p>Throughout the patent term compensation period, the protection scope of the new drug-related invention patents is confined to the technical solutions pertinent to the new drug and its approved indications. The rights and obligations of the patentee within this defined scope of protection shall remain consistent with those established prior to the commencement of the compensation period.</p>	<p>This Rule establishes the boundaries for protection during the compensation period, limiting it to the actual new drug and specifically approved indications. This limitation ensures that the extended protection does not broadly include all aspects typically covered by the patent claims.</p> <p>The Patent Examination Guidelines further elaborate that the related technical solutions must correspond to the structure, composition, and content of the new drug as approved by the state drug regulatory authority, including the approved manufacturing process and indications. No patent term compensation will be granted if the patent claims don't include the technical solution of the new drug with marketing approval. The protection scope of product claims is limited to the marketed new drug for approved indications. The protection scope of medical use claims is confined to the approved indications of the marketed new drug. The protection scope of preparation method claims is limited to the manufacturing process of the marketed new drug for approved indications as recorded with the state drug regulatory department.</p>
Rule 84	Patent Term Compensation for New Drugs	<p>The patent administration department under the State Council is responsible for reviewing requests for patent term compensation submitted pursuant to Articles 42.2 and 42.3 of the Patent Law. Should a request satisfy the compensation criteria, the department shall</p>	<p>This Rule outlines the review procedures for the request for patent grant and drug patent term compensation.</p> <p>The Patent Examination Guidelines further stipulate that upon reviewing requests for drug patent term compensation, if the criteria are not met, the Patent Office must provide the requester at least one opportunity to present</p>

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		<p>issue a decision to grant the term compensation, which will then be registered and published. If the request fails to meet the compensation criteria, the department will issue a decision of denial and notify the patentee who submits the request.</p>	<p>opinions and/or amend the documents. Should the request still fail to meet the compensation criteria, a denial decision will be issued. If upon reviewing, it's deemed that drug patent term compensation should be granted, and the patentee has already made a request for patent term compensation without a decision yet from the Patent Office, the examiner shall withhold determining the compensation duration until a decision is reached. If the patentee has not yet made a request for patent term compensation, and the three-month period from the date of patent grant announcement has not expired, the examiner should wait until this period expires to determine the compensation duration, except in cases where the patentee explicitly waives this right.</p>
Rule 128	Restoration of Priority	<p>If an international application is filed within 2 months after the expiration of the priority period, and the international phase's receiving office has approved the restoration of priority, it shall be deemed that a request for priority restoration has been made in accordance with Rule 36 of the Implementing Rules. If the applicant does not seek priority restoration during the international phase, or if such a request is made but not approved by the receiving office while the applicant has justified reasons, the applicant is entitled to submit a request for restoration of priority to the patent administration department under the State Council within two months of entering the national phase.</p>	<p>This Rule adapts the priority restoration rules for PCT international applications in response to Rule 36 of the Implementing Rules. It acknowledges the restoration of priority approved by the receiving Office during the international phase and permits applicants to request priority restoration upon entering the Chinese national phase. This allowance is granted irrespective of whether such a request was previously made or approved during the international phase. Applicants must submit the request within two months from the date of entry into national phase.</p>