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IP Insights

Chinese Patent Term Compensation System - PTA & PTE

In the latest revision of Chinese *Patent Law* (effective from June 1, 2021), a long-awaited patent term compensation system has been introduced under Article 42, providing for invention patent term adjustment (PTA) and pharmaceutical patent term extension (PTE) in China practice. More detailed provisions are set forth in Rules 77-84 of the *Implementing Regulations of the Patent Law* and in Part V of the *Patent Examination Guidelines* (both effective from January 20, 2024).

I. Patent Term Adjustment (PTA) under Article 42.2

Article 42.2 of the *Patent Law* stipulates, 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 the request for substantive examination** of the invention patent application, the CNIPA shall, at the request of the patentee, extend the term of the patent to compensate for the unreasonable delay in the granting process of the invention, except for the unreasonable delay caused by the applicant.

1.1 Time Limit for Filing PTA Request

A request for PTA must be filed by the patentee **within three months** from the date of the CNIPA's announcement of granting the invention patent.

1.2 Calculation of PTA

$PTA = (D_{grant} - D_{expiration\ of\ 4\text{-}/3\text{-}yr}) - T_{reasonable} - T_{unreasonable/Applicant}$

where: D_{grant} refers to the date of the CNIPA's announcement of grant;

$D_{expiration\ of\ 4\text{-}/3\text{-}yr}$ refers to the later of (i) expiration of four years from the date when the invention patent application is filed with CNIPA (for a PCT or divisional application, the China national stage entry date or the actual filing date is used for calculation, respectively) or (ii) expiration of three years from the date of requesting substantive examination (or three years from publication date, if the examination request is submitted before the CNIPA's publication of the application);

$T_{reasonable}$ refers to days of reasonable delay during prosecution, including those attributable to reexamination procedure during which amendment is made to the application, suspension of relevant procedures due to ownership dispute and the like;

$T_{unreasonable/Applicant}$ refers to days of unreasonable delay caused by the applicant, including those caused by the applicant's request to extend specified time limits or postpone examination and the like.

Please note that for dual-filing applications (i.e., the same applicant files applications for both a utility model patent and an invention patent with regard to the identical invention-creation on the same day), PTA does not apply if the invention patent is granted on the condition that the applicant has chosen to declare abandonment of the utility model patent in response to the CNIPA's notification regarding double-patenting matter.

II. Pharmaceutical Patent Term Extension (PTE)under Article 42.3

Article 42.3 of the *Patent Law* stipulates, in order to compensate for the time taken for the review and approval process before the marketing of a new drug, the CNIPA shall, at the request of the patentee, extend the term of the invention patent related to the new drug which has been approved for marketing in China. The compensation term should **not exceed five years**, and **the total effective term of the patent right should not exceed fourteen years from the date of marketing approval**.

2.1 Eligibility Requirements for PTE

For innovative drugs and certain modified new drugs that have been approved by National Medical Products Administration (NMPA) for marketing in China (collectively referred to as "new drugs"), PTE

applies to invention patents which claim products, preparation methods or medical uses of the active pharmaceutical substances of the new drugs. The terms "innovative drugs" and "modified new drugs" are those defined in drug regulatory laws and provisions of NMPA. The said certain modified new drugs are limited to those classified in any of the following categories in the Drug Approval Licenses issued from NMPA:

(1) a drug in an ester or salt form of a known active ingredient, in Class 2.1 of Chemical Drugs;

(2) a drug comprising a known active ingredient for new indications, in Class 2.4 of Chemical Drugs;

(3) a vaccine having an improved bacterial or viral vaccine strain, in Class 2.2 of Preventive Biological Products;

(4) a biological product for additional new indications, in Class 2.2 of Therapeutic Biological Products; and

(5) traditional Chinese medicine for additional new functions or indications, in Class 2.3 of Traditional Chinese Medicine.

2.2 Conditions for PTE Request

To request a PTE, the following conditions should be fulfilled:

- the patent should be granted before the approval date of the new drug and remain valid when the PTE request is filed;

- the claims of the patent should include the new drug-related technical solutions; and

- the patent has never acquired a PTE under Article 42.3, and if the drug is covered by multiple patents or the patent covers multiple drugs, the PTE request should be directed to only one of the patents or the drugs (i.e., "one PTE per drug per patent").

2.3 Time Limit for Filing PTE Request

A request for PTE must be filed by the patentee **within three months** from the approval date of the drug, accompanied with relevant materials supporting that the designated claims include the new drug-related technical solutions.

2.4 Calculation of PTE

PTE = $D_{\text{marketing approval}}$ - D_{filing} − 5 years (PTE ≦5 years)

Total effective patent term after marketing approval = ($D_{\text{expiration of 20-yr}}$ - $D_{\text{marketing approval}}$) + PTA (if any) + PTE (Total≦14 years)

where: $D_{\text{marketing approval}}$, D_{filing}, and $D_{\text{expiration of 20-yr}}$ refer to the date of NMPA approval of the drug marketing in China, filing date of the patent application, and expiration date of 20-year patent term, respectively.

Please note that during the PTE period, the protection scope of the patent is limited to the new drug and the drug-related technical solutions for the indications that have been approved by NMPA.

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