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It is widely acknowledged that the pharmaceutical sector is the most reliant on patent protection. The development of new drugs is characterized by high R&D costs, long R&D cycles, and significant risks. Moreover, due to the particularity of pharmaceuticals, most countries subject them to stringent administrative regulation, meaning that drug inventions cannot be implemented for a considerable period before obtaining marketing authorization, which shortens the actual protection period of drug patents. Therefore, some countries have established patent term compensation systems specifically for drugs, such as the Patent Term Extension ("PTE", 35 U.S.C §156) in the United States and the Supplementary Protection Certificate for medicinal products ("SPC", Regulation (EC) No. 469/2009) within the European Economic Area.

Following the fourth amendment of *the Patent Law of the People's Republic of China* in 2020, Paragraph 3, Article 42 of *the Patent Law* introduced the Patent Term Extension (PTE) system in China for the first time. This legal amendment has been in effect since June 1, 2021. The revised *Implementing Regulations of the Patent Law* and *the Patent Examination Guidelines 2023*, which both came into force on January 20, 2024, have provided detailed provisions for this system, marking the beginning of the practice of China's PTE system.

Paragraph 3, Article 42 of *the Patent Law* explicitly stipulates the drug patent term extension system: “For the purpose of making up the time required for the assessment and approval of the marketing of a new drug, the patent administrative department of the State Council may, at the request of the patentee, provide patent term extension for an invention patent relating to the new drug approved for marketing in China. The extension may not exceed 5 years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years.” Further provisions are laid out in Articles 80 to 84 of *the Implementing Regulations*. *The Patent Examination Guidelines* have added Section 3 in Chapter 9 of Part V, which provides detailed interpretations of the relevant provisions of *the Patent Law* and its *Implementing Regulations*, including 8 subsections from 3.1 to 3.8. Read our comprehensive introduction to China's PTE system.

In recent years, China has issued a series of policy documents emphasizing the need to further strengthen the protection of innovation in the pharmaceutical field. The establishment of the PTE system in China, which provides term compensation for patents related to innovative drugs and improved new drugs, will, on the one hand, strengthen the protection of the legitimate rights and interests of patentees and encourage pharmaceutical companies to develop new drugs. On the other hand, it will also encourage the development of generic drugs, ensuring the accessibility of medicines and safeguarding public interests and public health.

Introduction to Patent Term Extension in China

I. Related Articles of law

Paragraph 3, Article 42 of *the Patent Law*, which went into effect on June 1, 2021, explicitly stipulates the drug patent term extension system: "In order to compensate for the time taken for the review and approval process before the marketing of a new pharmaceutical product, the patent administration department under the State Council shall, at the request of the patentee, grant an extension of the term of an invention patent claiming the new pharmaceutical product which has been approved for marketing in China. The extension period shall not be more than five years, and the total effective term of the patent right shall not be more than fourteen years from the date of marketing approval."

Therefore, the Chinese Patent Term Extension (PTE) system is applicable to invention patents relevant to new pharmaceutical product ("new drug") which have received marketing approval in China.

II. How to interpret "new pharmaceutical product" and "new pharmaceutical-related invention patent"

2.1 New Pharmaceutical Product ("new drug")

According to the Part V, Chapter 9, Section 3.4 of the *Patent Examination Guidelines 2023*, the "new pharmaceutical product" refers to **innovative pharmaceutical product** and **improved new pharmaceutical product** in compliance with the provisions of this chapter, which are approved for marketing by National Medical Products Administration (NMPA). Among them, the "improved new pharmaceutical product" for which PTE may be granted are limited to the following categories of improved new pharmaceutical product listed in the certificate of drug registration issued by NMPA:

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

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

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

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

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

In addition, according to the "*Requirements for Registration Classification and Application Dossiers of Chemical Drugs*" and the "*Requirements for Registration Classification and Application Dossiers of Biological Products*" issued by the NMPA on June 29, 2020 and the "*Requirements for Registration Classification and Application Dossiers of Traditional Chinese Medicine*" issued on September 28, 2020, chemical drugs, vaccines, biological products for treatment or traditional Chinese medicine having been marketed abroad but not marketed in China do NOT fall into the category of Class 1 of "innovative drugs".

Therefore, "new drug" eligible for Chinese PTE specifically include:

Category	Innovative drug	Improved new drug
Chemical Drugs	Innovative chemical drugs of Class 1	Chemical drugs of Class 2.1 that perform esterification or salification of known active ingredients
		Chemical drugs of Class 2.4, i.e., drugs containing known active ingredients for new indications
Biological Products	Innovative vaccines of Class 1	Preventive biological products of Class 2.2 that are vaccines improved against bacterial or viral strains
	Innovative therapeutic biological products of Class 1	Therapeutic biological products of Class 2.2 for new indications
Traditional Chinese medicine	Traditional Chinese medicine of Class 1	Traditional Chinese medicine of Class 2.3, i.e., traditional Chinese medicine with increased indications

2.2 New pharmaceutical-related Invention Patent

According to the Part V, Chapter 9, Section 3.4 of the *Patent Examination Guidelines 2023*, "new pharmaceutical-related invention patent" refers to a **product patent, preparation method patent or pharmaceutical use patent of the active pharmaceutical ingredient (API) contained in a new drug**.

2.3. Restrictions for PTE

The Rule 87 of *The Implementing Regulations of the Patent Law (2023 Revision)* and the Part V, Chapter 9, Section 3.1 of the *Patent Examination Guidelines 2023*, provide for the following restrictions for the drug patent term extension:

(I) The grant date of patent for which patent term extension is requested should be earlier than the date of marketing approval;

(II) The patent right is still valid when the patent term extension request is made;

(III) The patent has not previously been granted the drug patent term extension;

(IV) The claims of the patent for which PTE is requested cover the technical solutions related to the new drug that has obtained marketing approval;

(V) Where one drug is covered by more than one patents concurrently, the request for drug patent term extension shall be directed to only one of these patents;

(IV) Where one patent covers more than one drug concurrently, the request for drug patent term extension for the patent shall be made based on only one of these drugs.

2.4 Non-retroactive

The Chinese PTE system is only applicable to the new drug that have been granted marketing authorization

after the effective date of the fourth amendment to the Patent Law (June 1, 2021). Therefore, the invention patents for the new drug approved for marketing before (or on) May 31, 2021 shall not be entitled to the non-retroactive PTE.

III. Request Procedure and related Materials

3.1 Form

If a request for PTE is filed from January 20, 2024, or if a request for PTE filed in paper from June 1, 2021 needs to go through subsequent procedures, the current processing mode of the patent concerned shall be followed, i.e., electronic form for electronic applications and paper form for paper applications.

3.2 Time Limit

PTE must be requested **within three months from the date of marketing approval of the drug in China**. For pharmaceutical products granted conditional marketing authorization, the request for PTE shall be submitted to the Patent Office of CNIPA within three months from the date of obtaining the formal marketing authorization in China, but the calculation of the compensation period shall be based on the date of obtaining the conditional marketing authorization. The right for PTE **cannot be restored** if the above stipulated period is missed.

3.3 Fees

If a request for PTE is filed before the release and implementation of the fee policy, the fee shall be paid within three months from the date of implementation of the fee policy in accordance with the patent fee schedule announced in the fee policy. After the release and implementation of the fee policy, the fee shall be paid in accordance with the patent fee schedule announced in the fee policy within three months from the date of obtaining the marketing authorization of the new drug in China. Where such fee is not paid or not paid in full within the time limit, the CNIPA will issue a decision to reject the PTE request.

3.4 Materials

According to the Part V, Chapter 9, Section 3.3 of the *Patent Examination Guidelines 2023*, when filing a request for PTE, the following materials shall also be submitted:

(1) The written consent of the Marketing Authorization Holder ("MAH") and other materials, if the patentee and the MAH are not the same;

(2) Relevant technical information for determining the scope of patent protection during the PTE; for example, if a PTE request is made for a preparation method patent, the information on the production process of the drug approved by the NMPA shall be submitted;

(3) Other supporting materials required by the Patent Office of CNIPA. The petitioner shall, in the request, indicate the name of the drug, the classification of the drug registration, the approved indications and the patent number for which the term compensation is requested, designate the claims related to the new drug for which the marketing authorization has been granted, elaborate in conjunction with the supporting materials the reasons that the designated claims include the relevant technical solutions of the new drug as well as the basis of calculation of the extension period requested, and specify the technical solutions that are to be protected during the PTE.

3.5 Examination and Notification

If the conditions for term compensation are met after examination, the CNIPA shall issue a Notification of

Decision on Drug Patent Term Extension, making a decision to grant term compensation and informing the number of days of term compensation. If the conditions for term compensation are not met after examination, the CNIPA shall, depending on the circumstances, issue a Notification to Rectify Formalities or a Notification of Examination Opinions on Drug Patent Term Extension, and if the conditions for term compensation are still not met after the completion of the rectification or the statement of opinions, the CNIPA shall issue a Notification of Decision on Drug Patent Term Extension and make a decision to reject term compensation. In the examination procedure of PTE, the designated period to respond to a notification is one month.

3.6 Registration and Publication

After the CNIPA makes a decision on granting term compensation, the relevant matters will be registered in the Patent Register and published in the Patent Gazette, which include: IPC main classification number, filing date, patent number, announcement date of patent grant, name of the pharmaceutical product and approved indications, the expiration date of the original patent term, and the expiration date of the extended patent term.

3.7 Information Query

The official decision on PTE can be searched in the "Patent Examination Information Query" of the Patent Business Processing System (https://cponline.cnipa.gov.cn/index).

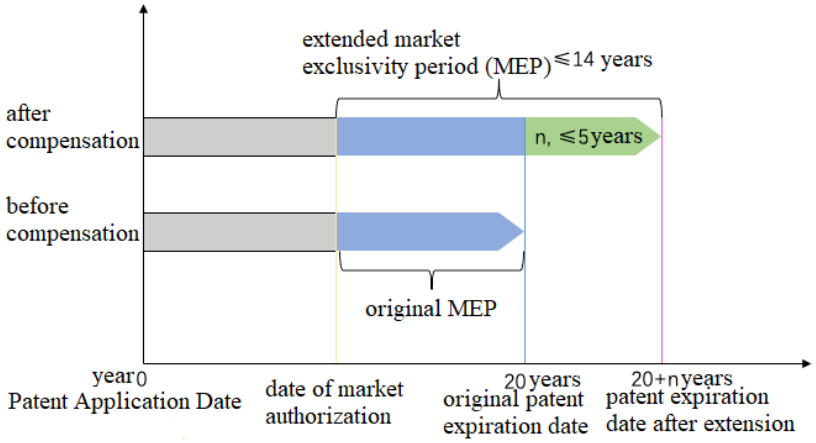
3.8 Remedies

If not satisfied with the decision on PTE made by the CNIPA, an administrative reconsideration may be applied to the CNIPA.

IV. How long can be extended

According to the provisions of Paragraph 3, Article 42, of the *Patent Law*, **the compensation term may not be more than five years, and the total effective term of the patent right may not be more than fourteen years from the date of marketing approval**.

The extended term shall be calculated to be [the date of market authorization in China] minus [the patent filing date] minus five years. If the calculated result is zero or negative, the patent term extension will not be granted. The patent term calculated according to the above method shall be determined as the drug patent extended term for compensation when complying with Paragraph 3, Article 42 of the *Patent Law*. See the bar graph below for more details:



VI. Protection Scope of the Patent

According to Rule 83 of *The Implementing Regulations of the Patent Law (2023 Revision)*, during the period of term extension, the scope of protection of a patent for an invention related to a new drug is limited to the technical solution(s) related to the new drug and its approved indication(s).

References:

1. The Implementing Regulations of the Patent Law (2023)

https://www.gov.cn/zhengce/content/202312/content_6921633.htm

2. Patent Examination Guidelines (2023)

https://www.cnipa.gov.cn/art/2023/12/21/art_526_189193.html?xxgkhide=1

Transition Measures for the Handling of Examination Services Related to the Implementation of the Revised Patent Law and its Implementing Regulations

https://www.cnipa.gov.cn/art/2023/12/21/art_74_189199.html

4. Classification and Application Requirements for Chemical Drug Registration

https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20200630180301525.html

5. Classification and Application Requirements for Biological Products Registration

https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20200630175301552.html

Classification and Application Requirements for Traditional Chinese Medicine Registration

https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20200928164311143.html

Notice on Handling Patent Term Extension

https://www.cnipa.gov.cn/art/2024/1/18/art_75_189871.html

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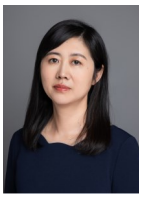

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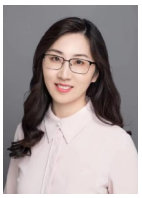

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