Bilingual Chinese-English Translation[1]
of
CNIPA Amendment of the Patent Examination Guidelines (PTA PTE Phase one)

Chapter 3 of Part IV

9. Special Provisions Concerning the Examination of Cases of Requests for Invalidation Involving Early Resolution Mechanisms for Drug Patent Disputes

The case of a request for invalidation involving the early resolution mechanism for drug patent disputes means the case in which, as the petitioner for invalidation, the applicant for drug marketing authorization (also known as the applicant for a generic drug), as set forth in Article 76 of the Patent Law of the People's Republic of China (the "Patent Law"), files a request for invalidation in respect of the patent right registered on the China's Patent Information Registration Platform for Drugs Marketed.

9.1 Written Requests and Certified Document

Where, in accordance with the provisions of the Measures for the Implementation of the Early Settlement Mechanism for Drug Patent Disputes (Trial), the generic drug applicant puts forward category IV statement and then files a request for invalidation, he shall clearly indicate in the request that the case involves the early resolution mechanism for drug patent disputes, namely, the patent involved is a patent right registered on the China's Patent Information Registration Platform for Drugs Marketed, the petitioner is the applicant for the generic drug of the corresponding drug, the applicant has put forward category IV statement, and relevant

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certified document such as the notification to accept the registration application for the generic drug, and the duplicate copy of category IV statement shall be attached.

Where, the generic drug applicant files the request for invalidation and then puts forward category IV statement in accordance with the provisions of the Measures for the Implementation of the Early Resolution Mechanism for Drug Patent Disputes (Trial), he shall promptly submit the evidence that shows that the case of the request for invalidation involves the early resolution mechanism for drug patent disputes. For any case to be heard through oral proceedings, he shall submit the said evidence no later than the closing of the argument in the oral proceedings; otherwise, he shall submit such evidence no later than the date when the decision on the invalidation is made.

Where, within a specified time limit, the petitioner fails to provide the evidence showing that the request for invalidation involves the early resolution mechanism for drug patent disputes, this section shall not apply.

9.2 Examination Sequence

Where a patent right is related to multiple requests for invalidation involving the early resolution mechanism for drug patent disputes, such requests for invalidation shall be examined in accordance with the sequence of their filing dates.

9.3 Examination Base

If any examination decision of validation previously made is to maintain the patent right valid on the basis of the revised document submitted by the patentee, any subsequently accepted request for invalidation might continue to be examined pursuant to the aforesaid revised document.

9.4 Notification of Examination State and Case Settlement

The panel may, at the request of the people's court or the medical products administration of the State Council, issue a notification of the examination state for the request for invalidation to the said court or department.

Where, prior to the hearing of the request for invalidation, the people's court or the medical products administration of the State Council has been notified of this matter, the panel shall, after making an examination decision, serve the aforesaid relevant departments with the examination decision and the notification of case settlement on the examination of the request for invalidation.

Chapter 9 of Part V

2. Patent Term Extension (PTE) under Article 42.2 of the Patent Law

In accordance with the provision of Article 42.2 of the Patent Law, where a patent for an invention is granted four years from the date of filing of application for the patent for invention and three years from the date of filing of a request for substantial examination, the Patent Office shall, at the request of the patentee, provide a PTE for unreasonable delay in the patenting process for the invention, except for unreasonable delay caused by the applicant.

If an applicant applies for both a patent for utility model and a patent for invention on the same day, and if he is granted first the patent for the utility model and then the patent for invention, the granting term for the patent for invention shall not apply to the provision of Article 42.2 of the Patent Law.

2.1 Filing of Requests

A request for a PTE shall be filed by the patentee. Where the patentee applies for being granted a PTE, the patentee shall, within three months after the announcement date of grant of a patent, file a request to the Patent Office and pay corresponding fees.

Where a patent is owned by multiple patentees, a request for a PTE shall be filed by their representative. Should the request for a PTE be entrusted to a patent agency, filing such request shall be the responsibility of the said patent agency.

2.2 Determination of PTE

Where any PTE is granted, the extension shall be calculated on the basis of actual days of unreasonable delay of the patent for invention in the patenting process. Such actual days of unreasonable delay mean the unreasonable delay of the patent for invention in the patenting process less the unreasonable delay caused by the applicant.

2.2.1 Unreasonable Delays in the Patenting Process

Any unreasonable delay in the patenting process means the announcement date of grant of an invention patent less the date both following four years from the date of filing an application for a patent for invention and following three years from the date of filing of a request for substantial examination.

For an international application and a divisional application for patent, any unreasonable delay in the patenting process means the announcement date of grant of a patent for invention less the date following four years from the date of entering the Chinese national phase by such an international application or from the date of presenting such a divisional application and following three years from the filing of a request for substantial examination.

An unreasonable delay in the patenting process shall exclude a delay resulting from the following circumstances: suspension procedures, preservation measures, administrative proceedings, and review procedures of patenting through revision of the patent application document in light of Article 66 of the Rules for the Implementation of the Patent Law of the People's Republic of China (the "Rules for the Implementation").

The date of the filing of a request for substantial examination means the date on which the applicant files a request for substantial examination under Article 35.1 of the Patent Law and pays in full fees of substantial examination for the patent for invention under Article 113 of the Rules for the Implementation. Where the date of the filing of a request for substantial examination is earlier than the date of publication as mentioned in Article 34 of the Patent Law, three years from the date of the filing of a request for substantial examination, as mentioned in Article 42.2 of the Patent Law, shall be calculated from such date of publication.

2.2.2 Unreasonable Delays Caused by the Applicant

For any unreasonable delay caused by the applicant under the following circumstances:

(1) where any delay is resulted from failure to respond to the notification issued by the Patent Office within a specified time limit, the delay shall be equivalent to the period from the expiration of the time limit to the date for actual presentation of a reply;

(2) where a request for examination delay is filed, the delay shall be equivalent to an actual examination delay;

(3) where any delay is caused by addition of omitted content by quotation, the delay shall be equivalent to such delay as caused under Article 45 of the Rules for the Implementation;

(4) where any delay is caused by a request for right restoration, the delay shall be equivalent to the period from the expiry date of the original time limit to the date of issuance of the approval notification, giving consent to such restoration, on the request for right restoration, except for such delay caused by the Patent Office if proved; and

(5) for any such international application whose formalities of entering the national phase are handled within 30 months from the date of priority, if any delay is caused by the applicant's failure to request the prior handling of such formalities, the delay shall be equivalent to the period from the date of entering the national phase to the date following 30 months from the date of priority.

2.3 Review and Approval of Requests for PTE

Where any request for a PTE is deemed to fail to meet conditions for term extension upon examination, the Patent Office shall provide the petitioner with at least one opportunity to state

his opinions and/or correct relevant documents. Should any request for a PTE thereafter still fail to meet such conditions, the Patent Office shall make a decision on rejecting a term extension.

Where any request for a PTE is deemed to meet conditions for term extension upon examination, the Patent Office shall make a decision on granting a term extension, and notify the petitioner of the number of days of the extension.

2.4 Registration and Announcement

After deciding to grant a PTE, the Patent Office shall register relevant matters in the Patent Register and announce them in the Patent Gazette.

3. PTE under Article 42.3 of the Patent Law

In accordance with the provision of Article 42.3 of the Patent Law and the provisions of Articles 81-84 in the Rules for the Implementation, for any such innovative drug as marketed upon approval from the medical products administration of the State Council and any such improved new drug as meet corresponding provisions, the Patent Office may, at the request of the patentee, grant a term extension of the patent relating to the drug to the eligible patent for invention in order to make up the time required for the evaluation and approval of the marketing of the new drug within the effective term of patent.

3.1 Conditions for PTE

Any request for a PTE of a drug shall meet the following conditions:

(1) the announcement date of grant of a patent requesting a term extension shall be earlier than the approval date of the marketing license application for the related drug;

(2) when a request for a PTE is filed, the patent shall remain effective;

(3) the patent has yet to be granted any PTE of the drug;

(4) technical solutions relating to a new drug approved for marketing shall fall under the protection of the claims of the patent requesting a term extension;

(5) where a drug involves multiple patents at the same time, the patentee can but request the grant of a PTE of the drug to one patent among them; and

(6) where a patent involves multiple drugs at the same time, the patentee can but file a request for a PTE of one drug among them.

3.2 Filing of Requests

Any request for a PTE of a drug shall be filed by the patentee. Where the patentee is not the holder of the drug marketing authorization, filing a request for a PTE shall entail the written consent of such holder of the drug marketing authorization.

Where the patentee requests any PTE of a drug, he shall, within three months from the date of obtaining the marketing authorization for the drug in China, file such a request to the Patent Office and pay corresponding fees. For any drug having obtained the conditional marketing authorization, the patentee shall, within three months from the date of obtaining the official marketing authorization in China, file such a request to the Patent Office, provided that the calculation of a term extension shall be based on the date of obtaining the conditional marketing authorization.

Where a patent is owned by multiple patentees, its request for a PTE of the drug shall be filed by their representative. Should the request for a PTE be entrusted to a patent agency, filing such request shall be the responsibility of the said patent agency.

3.3 Evidentiary Materials

When the petitioner files a request for a PTE of a drug, he shall submit the following materials:

(1) where the patentee is not the holder of the drug marketing authorization, the petitioner shall present the written consent of such holder of the drug marketing authorization and other materials;

(2) where relevant technical information is available to determine the scope of protection of a patent during the PTE of a drug, for example, the petitioner files a request for a term extension of a patent involving the preparation method, he shall submit the drug production process material to the medical products administration of the State Council for approval;

(3) other evidentiary materials required by the Patent Office.

In his request, the petitioner shall state the name of the drug, the approved indication and the number of the patent requesting a term extension, designate the claims relating to the drug approved for marketing, detail the reasons for classifying the drug-related technical solution into the protection scope of the designated claim in light of the evidentiary materials and the basis for calculating the requested term extension, and define the technical solution to be protected during the PTE of the drug.

3.4 Applicable Scope

In accordance with the provision of Article 42.3 of the Patent Law and the provision of Article 80 of the Rules for the Implementation, for any such innovative drug as marketed upon approval

from the medical products administration of the State Council and any such improved new drug meeting the provisions of this chapter, a PTE of a drug may be granted to the patent for invention relating to any active pharmaceutical ingredient, or preparation method or medical use in such drug. The meaning of an innovative drug or improved drug shall be determined pursuant to laws and regulations as well as the provisions of the medical products administration of the State Council.

Any such improved new drug as may be granted a term extension shall be limited to the following categories of improved new drugs, as recorded in the drug registration certificate issued by the medical products administration of the State Council:

(1) in category 2.1 chemical drugs, drugs that are obtained by esterification of or salification of known active ingredients;

(2) in category 2.4 chemical drugs, drugs for new indications that contain known active ingredients;

(3) in category 2.2 preventive biological products, vaccines whose bacterial/viral strains are improved;

(4) in category 2.2 therapeutic biological products, biological products that are fit for new indications; and

(5) in category 2.3 traditional Chinese medicines, medicines that contain new functions.

3.5 Examination of Whether It Falls into the Scope of Protection

Any technical solution relating to a new drug shall be subject to the structure, composition and content of the new drug as approved by the medical products administration of the State Council, and to the approved production process and indications of such drugs. Where any technical solution relating to a new drug does not fall into the scope of protection of the claims of the designated patent, no PTE shall be granted.

During the PTE of a drug, the scope of protection of the patent shall apply only to any new drug approved for marketing by the medical products administration of the State Council and to any technical solution relating to the approved indications of the new drug. Within the scope of protection, the patentee shall have the same rights and obligations as those before the PTE. The scope of protection of product claims shall apply only to any marketed new drug for approved indications; the scope of protection of medicine use claims shall apply only to the approved indications of marketed new drugs; the scope of protection of preparation method claims shall apply only to such production processes of marketed new drugs for approved indications as filed in the medical products administration of the State Council.

3.6 Determination of PTE

Where a PTE of a drug is granted, the PTE shall be the period that is obtained by deducting five years from the number of days between the date of application for the patent and the date of the marketing authorization of the new drug in China. The PTE shall not exceed five years, and the total effective term of the patent after the drug marketing authoriztion application is approved shall not exceed 14 years.

3.7 Review and Approval of Requests for PTE of Drugs

Where any request for a PTE of a drug is deemed to fail to meet conditions for term extension upon examination, the Patent Office shall provide the petitioner with at least one opportunity to state his or its opinions and/or correct relevant documents. Should any request for a PTE thereafter still fail to meet such conditions, the Patent Office shall make a decision on rejecting a term extension.

If a PTE of a drug shall be granted on the basis of the examination, and if the patentee has filed a request for a PTE but the Patent Office has yet to decide to approve the request, the examiner shall wait for the approval decision made on the request for a PTE, and then determine to grant time for the PTE of the drug. In the event that the patentee has not filed a request for a PTE yet, and the time limit of three months from the announcement date of grant of the patent remains unexpired, the examiner shall wait for the expiration of the time limit for requesting a PTE, and then determine to grant time for the PTE of the drug, unless the patentee clearly indicates that he has waived the filing of a request for a PTE.

Where any request for a PTE of a drug is deemed to meet conditions for the PTE upon examination, the Patent Office shall make a decision on granting the PTE, and notify the number of days of the PTE.

3.8 Registration and Announcement

After deciding to grant a PTE of a drug, the Patent Office shall register relevant matters in the Patent Register and announce them in the Patent Gazette.