



Announcements and Circulars

Order of the State Intellectual Property Office

(No. 69)

The *Measures on the Deposit of Biological Materials for Patent Application Process*, as deliberated and adopted at the executive meeting of the State Intellectual Property Office, is hereby issued and shall come in force on March 1, 2015.

Shen Changyu, the Commissioner

January 16, 2015

Measures on the Deposit of Biological Materials for Patent Application Process

Chapter 1 General Provisions

Article 1 These measures are formulated in accordance with the *Patent Law of the People's Republic of China* and the *Implementing Regulations of the Patent Law of the People's Republic of China* (hereinafter referred to as "*Implementing Regulations*") in order to regulate the deposit of biological materials for patent application process and the procedure for providing corresponding samples.

Article 2 Depository institutions are responsible for the deposit of biological materials for patent appli-

cation process and providing samples of biological materials to institutions or individuals which are entitled to obtaining these samples.

Article 3 Where any foreign person, foreign enterprise or foreign organization without regular residence or place of business in China intends to handle the related matters according to the measures, he or it shall entrust a legally established patent agency.

Chapter 2 The Deposit of Biological Materials

Article 4 When a patent applicant submits the deposit of the biological material in accordance with

the provisions of Article 24 of *Implementing Regulations*, he shall submit this material and specify the following items attached with a request for the deposit;

(I) the biological material requested for the deposit is only used for patent applications which shall not to be revoked during the deposit period provided for in Article 9 of the measures;

(II) name and address of the patent applicant;

(III) to state clearly on the conditions for the cultivation, deposit and survivability test on this biological material; when depositing the mixture of above two biological materials, it's required to state clearly on the components and at least one method of checking the existence of each component;

(IV) the identification mark on the biological material made by the patent applicant, and classification and nomination or scientific description on this material;

(V) to state clearly that the biological material has or may have the characteristic of endangering health or environments, or that the patent applicant has no idea about the characteristic.

Article 5 A depositary institution has no obligation to re-check biological characteristics of the biological material that is requested for the deposit; where the patent applicant requests the review on the biological characteristics and on the classification and nomination of the biological material, he shall sign a contract separately with the depositary institution while submitting the deposit of the biological material.

Article 6 After the depositary institution receives the biological material and the quest for the deposit, it shall issue a written certificate of the deposit which is signed by the principal and sealed by the in-

stitution to the patent applicant. The certificate of the deposit shall include the following items:

(I) name and address of the depositary institution;

(II) name or title and address of the patent applicant;

(III) date of the receipt of the biological material;

(IV) identification mark on the biological material made by the patent applicant, and classification and nomination or scientific description on this material;

(V) depositary number issued by the depositary institution.

Article 7 Under any of the following circumstances, the depositary institution has no obligation to deposit the biological material and shall notify the patent applicant:

(I) the biological material does not belong to the types of biological materials that shall be accepted by the depositary institution;

(II) the depositary institution fails to deposit the biological material under its technical conditions due to the special characteristics of the material;

(III) the depositary institution cannot accept the biological materials due to other reasons upon receiving the request of the deposit.

Article 8 When the depositary institution receives the biological material and the request for the deposit, it shall conduct a test on its survivability in a timely manner and issue a written certificate of the survivability which is signed by the principal and sealed by the institution as well. The certificate shall specify whether the biological material is alive and shall set out:

(I) name and address of the depositary institution;



(II) name or title and address of the patent applicant;

(III) date of the receipt of the biological material;

(IV) depositary number issued by the depositary institution;

(V) date of survivability test.

During the deposit period, upon the request put forward by the patent applicant and the patent holder, the depositary institution shall conduct a survivability test on the biological material and issue a written certificate of the survivability which is signed by the principal and sealed by the institution as well.

Article 9 The period of the deposit for biological materials for patent application process shall be at least 30 years, commencing from the date when the depositary institution receives the biological material.

Where the depositary institution receives the request for providing a sample of the biological material before the period of deposit expires, it shall deposit the biological material for another 5 years from the date of the request. During the period of the deposit, the depositary institution shall take all necessary measures to maintain the survivability of the biological material and protect it from contamination.

Article 10 Before the publication of patent application concerning the depositary biological material, the depositary institution bears the responsibility of keeping the biological material and related information confidential, and shall not provide the relevant sample and information to any third party.

Article 11 Where the biological material is dead or contaminated, the depositary institution shall notify the patent applicant or the patent holder in a timely manner. Where the patent applicant or the patent

holder re-submits the same biological material with the previous one from the date of receipt of the above-mentioned notification, the depositary institution shall deposit the material.

Chapter 3 Providing a Sample of the Biological Material

Article 12 During the period of the deposit, upon the request of the patent applicant or the patent holder, or any unit or individual it permits, the depositary institution shall provide a sample of the biological material.

Where the right to apply for a patent or patent rights is transferred, the right of request for providing a sample of the biological material and the right of permitting others to obtain the sample is also transferred.

Where the right to apply for a patent or patent rights is transferred, the assignee shall timely notify the depositary institution of the transfer of the right to apply for a patent or patent rights.

Article 13 With respect to the patent application examined by a patent office which is a contracting party to the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, or with respect to the patent rights granted by the patent office concerning the biological material deposited by the depositary institution, where the patent office requests the depositary institution to provide a sample of the biological material, the depositary institution shall provide it with the sample.

Article 14 Upon the receipt of the request for providing a sample in accordance with Article 25 of the *Implementing Regulations*, the State Intellectual

Property Office (hereinafter referred to as SIPO) shall verify the following:

(I) the patent application concerning the deposit of the biological material has been submitted to the SIPO and the subject matter of the patent application includes the biological material or its utilization;

(II) the patent application has been published or granted;

(III) the person submitting the request has made a promise in accordance with Article 25 of *Implementing Regulations*.

The SIPO shall transmit the copy of the request and related documents to the patent applicant or the patent holder, and ask the patent applicant or the patent holder to make comments on whether it agrees to provide a sample to the person submitting the request within a specified time limit. Where the patent applicant or the patent holder disagrees to provide a sample to the person, he shall state opinions and submit necessary evidence; where he fails to state opinions within the specified time limit, he shall be deemed to agree to provide the sample to the person.

The SIPO shall take into full consideration on the review and the opinion put forward by the patent applicant or the patent holder, and confirm whether to issue the certificate which he is entitled to obtaining the biological material to the person.

Article 15 Except for circumstances prescribed in Article 12 and Article 13 of these measures, where any unit or individual filing a request for providing a sample of the biological material submits a request to the depositary institution and the SIPO issues a certificate in accordance with Article 14 of the measures, the depositary institution shall provide him or it with

the sample of the biological material.

Article 16 Where a depositary institution which provides the biological material according to the measures, and a person who obtains the sample and uses it, he shall abide by the national laws and regulations on biological safety, entry and exit control.

Article 17 Where a depositary institution provides a sample of the biological material to other organizations or individuals other than the patent applicant or the patent holder; it shall notify the patent applicant or the patent holder in a timely manner.

Article 18 Within one year from the expiration date of the period of the deposit stipulated in Article 9 of the measures, the patent applicant or the patent holder may take back the depositary biological material or consult with the depositary institution on the handling of the material. Where the patent applicant or the patent holder fails to take back or handle it within the specified time limit, the depositary institution has the right to deal with the material.

Chapter 4 Supplementary Provisions

Article 19 The types of biological materials for the deposit and fee standards confirmed by the depositary institution shall be published and submitted to the SIPO for the record.

Article 20 The measures shall come into force on March 1, 2015. *The Measures of China General Microbiological culture collection center on the Deposit of Microorganisms for Patent Application Process* and the *Measures of China Center for Typical Culture Collection on the Deposit of Microorganisms for Patent Application Process*, promulgated on March 12, 1985 as No. 8 Announcement of the Patent Office of the People's Republic of China shall be abolished at the same time.