

Failure to Submit Deposit Receipt in China: Consequence and Remedy

A deposit of a biological material in support of a Chinese patent application is mandatory if the invention for the application involves or uses a new biological material, and the depository information shall be referenced in the application. Moreover, a deposit receipt and viability statement shall be submitted within a prescribed time limit under Rule 24 of the Implementing Regulations of the Chinese Patent Law.

As many biotechnology practitioners are aware, under current Chinese patent practice, it might be potentially fatal defects in a Chinese patent application if an applicant fails to submit a deposit receipt and viability statement within the Rule-prescribed time limit, even though the biological material has been deposited and the depository information has been referenced. This short article aims to interpret the provisions of Rule 24 and provide some suggestions on the examination procedure, which might have been implementing in the Chinese Patent Office.

Current Chinese Patent Practice

Under the Chinese Patent Law, a patent must describe the subject invention in detail sufficient for a person skilled in the art to which it pertains to carry it out, which is so-called the sufficiency requirement. For certain biological materials, such as fungi, viruses, cells, cell lines, and bacteria, written description may not be sufficient to enable one skilled in the art to carry out the invention. Thus, a deposit of a sample—referred to as a biological deposit—in a recognized institution, under Rule 24 of the Implementing Regulations of the Chinese Patent

Law,¹ before the filing date (or priority date) is one way to satisfy the sufficiency requirement. Furthermore, it stipulates under Rule 24 that the deposit receipt and the viability statement shall be submitted within the prescribed time limit.

During substantive examination and

¹ Rule 24 reads: Where an invention concerns a new biological material which is not available to the public and which cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant shall, in addition to the other requirements provided for in the Patent Law and these implementing Regulations, go through the following formalities:

- (1) depositing a sample of the biological material with a depository institution designated by the Patent Administration department under the State council before, or at the latest, on the date of filing (or the priority date where priority is claimed), and submit at the time of filing or at the latest, within four months from the filing date, a receipt of deposit and the viability statement from the depository institution; where they are not submitted within the specified time limit, the sample of the biological material shall be deemed not to have been deposited;
- (2) giving in the application document relevant information of the characteristics of the biological material;
- (3) indicating, where the application relates to the deposit of the biological material, in the request and the description the scientific name (with its Latin name) and the name and address of the depository institution, the date on which the sample of the biological material was deposited and the accession number of the deposit; where, at the time of filing, they are not indicated, they shall be supplied within four months from the date of filing; where after the expiration of the time limit they are not supplied, the sample of the biological material shall be deemed not to have been deposited.

reexamination procedures, a deposit is regarded not having been made if deposit receipt and viability statement are unable to be submitted within the prescribed time limit, which leads to a rejection on the ground of insufficient disclosure of the invention concerning or using the biological material to be deposited. It is not uncommon for applications rejected for this ground according to our searches in the database of the Patent Reexamination Board. Taking the Chinese application No. 200910146695.3 (with an effective filing date of June 1, 2007) for example. Claim 1 of the application is directed to an *enterobacter aerogenes* strain, in short rod shape, with accession No. CGMCC1969 deposited in China General Microbiological Collection Centre (CGMCC) on March 12, 2007. In this application, although the strain has been deposited before the filing date, and the deposit information including depositary institution and accession number has been disclosed in the specification, claim 1 has been finally rejected for failure to submit the deposit receipt and viability statements within the prescribed time limit in both substantive examination procedure and reexamination procedure.

Interpretation and Application of Rule 24

The law is clear on this point. An application for an invention involving or using biological materials must meet the same sufficiency requirement as other applications as set out in Article 26.3 of the Chinese Patent Law. Where the application refers to a biological material which cannot otherwise be described in the application to meet the sufficiency requirement, the deposit of such material is taken into consideration, whether the deposited material is available to public. It further stipulates in Rule 24 that the deposit receipt and the viability statement shall be

submitted within the prescribed time limit, and the sample of the biological material shall be deemed not to have been deposited if failure for submission. The aforesaid case is rejected in such a situation.

According to the provisions of Rule 24, a submission of the deposit receipt and viability statement of a biological material deposit becomes mandatory if the material meets two criteria: (1) unavailable to public and (2) insufficient description to enable one skilled in the art to carry out the invention. Specifically, the Guideline for Examination (“the Chinese Guideline”) defines the “biological material unavailable to public” as a material inaccessible to public or one skilled in the art cannot obtain the biological material according to the preparation method described in the description.

To the above case, while the claimed new *enterobacter aerogenes* strain in the application (application No. 200710028391.8) satisfies the first criterion of unavailability, a question would have been raised regarding whether the strain deposited in CGMCC before the filing date with depositary institution and accession number disclosed in the description meets the second criterion of enablement. In accordance with Rule 25,² after publication of an application, any entity or individual may file a request to the State Intellectual Property Office (SIPO) to use the deposited biological material for experimental purpose. CGMCC regulates³ that depositors shall deposit biological material for thirty (30) years and cannot withdraw the deposit within the period. Under

² Rule 25: Where the applicant of an application has deposited a sample of the biological material under Rule 24, after publication of the application, any entities or individuals that intends to make use of the biological material the application involves, for the purpose of conduct experiments, shall make a request to the State Intellectual Property Office (SIPO) for acquiring the biological material.

³ “Guideline for depositing biological material under Budapest”, China General Microbiological Collection Centre, <http://www.cgmcc.net/serve/guide.html>

depositor or SIPO's approval, CGMCC will provide the deposit material to the requester. Obviously, the claimed strain is available to public after publication of the application wherein the depositary institution and the accession number are described. Thus, the claimed strain does not meet the second criterion of enablement. Accordingly, we believe the application does not belong to the situation where the submission of the deposit receipt and viability statement under Rule 24 is mandatory. Therefore, the rejection based on insufficient disclosure for the application is misplaced.

Comparison of Practice in China and in Europe

The regulation on depositing a biological material is built upon the principle of disclosure for monopoly for a patent.

In Europe, Rule 31 stipulates the invention shall only be regarded as being disclosed sufficiently, if (a) a sample of the biological material has been deposited with a recognized depositary institution no later than the date of filing of the application; (b) the application as filed gives such relevant information on the characteristics of the biological material; (c) the depositary institution and the accession number of the deposited biological material are stated in the application, and (d) where the biological material has been deposited by a person other than the applicant, the name and address of the depositor are stated in the application and a document is submitted to the European Patent Office providing evidence that the depositor has authorized the applicant to refer to the deposited biological material in the application and has given his unreserved and irrevocable consent to the deposited material being made available to the public. The information of (c) and (d) may be submitted (i) within sixteen months after the date of filing of the application or, if priority has been

claimed, after the priority date, (ii) before completion of the technical preparations for publication of the European patent application; (iii) up to the date of submission of a request for early publication and (iv) within one month of the communication issued by the European. The ruling period shall be the one which is the first to expire.

It is not stipulated in EPC or Implementing Regulations thereof that a deposit receipt shall be submitted, while the Notice strongly recommend the applicant submit it to ensure EPO to evaluate the application whether or not meet the requirement of Rule 31⁴. For missing depositary information or no deposit receipt is submitted, the applicant is informed to supplement the depositary information or submit the deposit receipt⁵ according to the Guideline for Examination ("the European Guideline").

Similarly, China has the requirements of (a), (b), (c) and (d) as Europe, according to Rule 24 and the Chinese Guideline (9.2.1, Chapter 10, Part II). Differently, China stipulates the time limit for submitting deposit receipt, *i.e.*, no later than the time within four months from the filing date, while EPO does not set a fixed time to submit the deposit receipt. Additionally, SIPO is not obliged to notify the applicant to supplement depositary information or submit a deposit receipt, while examination division of EPO is.

Suggestions

1. Stipulating Various Time Limits for Submitting Deposit Receipts

This author suggests setting various time limits for submitting deposit receipts depending on various applications based on whether depositary information

⁴ The Notice from the EPO dated 7 July 2010, OJ EPO 2010, 498, <http://xepc.eu/node/oj2010-498>

⁵ Guidelines for Examination, Part A, Chapter IV, 4.2

is described or not in the applications. For example, with regard to an application wherein depositary information, for example, depositary institution, accession date and accession number has stated in the description, failure for submitting the deposit receipt would not affect the invention to be carried out. In such a case, deposit receipt acts as evidence for ascertaining the depositary information. Accordingly, the deposit receipt may be submitted at latest within the time limit prescribed in examiner's invitation for checking the information to judge the availability of the biological material. With regard to an application lack of depositary information, if deposit receipt is as a basis on which the depositary information is incorporated into the application, submitting the deposit receipt or not would be relevant to acceptable amendments and sufficient disclosure. In such a case, the deposit receipt shall be submitted, for example, within the time limit as prescribed in Rule 24, or at latest, by the completion of technique preparation for publication.

2. Adjusting Procedures of Examination to Oblige SIPO to Notify Applicant for Submitting Deposit Receipt

In China, examiners are not obliged to notify applicants to submit a deposit receipt or supplementing depositary information⁶. In practice, there are a number of applications rejected for failure of submitting deposit receipt. It is the situation that the applicant of the aforesaid application came to realize the deposit receipt and viability statement had not been submitted after receiving the office action in the procedure of substantive examination. While the time limit for submitting the documents has been past.

⁶ Under Chinese practice, sometimes, applicants may receive a notification for submitting deposit receipts.

In Europe, it stipulates in the Notice or Guideline for Examination⁷, when the Receiving Section notices that the information required under Rule 31(1)(c) is not contained in or has not yet been submitted with the application, it should notify the applicant of this fact. In respect of a deposit receipt, the EPO examination division will still notify the applicant to submit it. It is believed that such regulations are established for the purpose of protecting applicant's right and encouraging inventions.

This author suggests, like Europe, Chinese examiners are obliged to notify applicants to submit deposit receipt and viability statement. Furthermore, some relief procedure shall be built up to avoid loss of applicant's interests. This does comply with the principle of administrative hearing procedure.

3. Building up Remedy Procedures

Under current Chinese patent practice, there are no remedy procedures for the result from failure for submitting deposit receipt, which leads to loss of opportunity for a patent right for the application the biological material concerned or used. As the applicant of the application (200910146695.3) complained to the Board that, the present application has indeed deposited the claimed strain, and the subsequently submitting the deposit receipt would not damage the interest of public, while the rejection causes a great loss of the applicant's interests. On the one hand, the applicant loses possibility for a patent grant. On the other hand, one skilled in the art can obtain the biological material and accomplish the invention. This not only contradicts the principle of disclosure of technique for monopoly, but also inhibits the protection of inventor's right and encouraging

⁷ The Notice from the EPO dated 7 July 2010, OJ EPO 2010, 498, <http://xepc.eu/node/oj2010-498>

inventions.

4. Unifying Provisions of Rule 24 with Chinese Patent Practice

The applications discussed herein do not belong to those required to submit the deposit receipt in accordance with Rule 24. In contrast, both of SIPO

and the Board are of opinion that such applications shall submit the deposit receipts. The regulation of Rule 24 is inconsistent with the Chinese patent practice, both of which need to be unified.

The newsletter is not intended to constitute legal advice. Special legal advice should be taken before acting on any of the topics addressed here.

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