EP – EUROPEAN PATENT ORGANISATION (EPO)

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1. Requirements for Deposit

If an invention which is the subject of a European patent application involves the use of or concerns biological material which is not available to the public and which cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicant must make the deposit of the biological material with a recognized depositary institution on the same terms as those laid down in the Budapest Treaty *(Rule 31(1)(a) EPC)*.

Furthermore the depositary institution and the accession number of the deposited biological material shall be stated in the application and where the biological material has been deposited by a person other than the applicant, the name and address of the depositor shall be stated in the application and a document shall be submitted to the EPO 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 *(Rule 31(1)(c), (d) EPC)*.

This information may be submitted:

- within a period of 16 months after the date of filing of the European patent application or, if priority is claimed, after the priority date; this time limit is deemed to have been met if the information is communicated before the technical preparations for publication of the application are completed *(Rule 31(2)(a) EPC)*;

- up to the date of submission of a request for early publication of the application under Article 93(1)(b) EPC *(Rule 31(2)(b) EPC)*;

- within one month after the EPO has communicated to the applicant that a right to inspection of the files, pursuant to Article 128(2) EPC, exists *(Rule 31(2)(c) EPC)*.

The ruling period is the one which is the first to expire. The communication of this information is considered as constituting the unreserved and irrevocable consent of the

applicant to the deposited biological material being made available to the public in accordance with Rule 33 EPC *(Rule 31(2)EPC)*.

The EPO publishes in its Official Journal the list of depositary institutions recognized for the purpose of Rules 31, 33 and 34 EPC *(Rule 33(6) EPC).*

Requirements for New Deposit of Biological Material

If biological material deposited in accordance with Rule 31 EPC ceases to be available from the recognized depositary institution, an interruption in availability shall be deemed not to have occurred:

- if a new deposit of that material is made with a recognized depositary institution on the same terms as those laid down in the Budapest Treaty, and

- if a copy of the receipt of the new deposit issued by the depositary institution is forwarded to the EPO within four months of the date of the new deposit, stating the number of the European patent application or the European patent.

(Rule 34 EPC)

2. Time of Deposit

A sample of the biological material shall be deposited not later than the date of filing of the European patent application *(Rule 31(1)(a) EPC)*.

Where the European patent application claims a priority, the deposit of the biological material must have been made no later than the date of filing of the previous application whose priority is claimed.

3. Duration of Storage

As provided for in Rule 9 of the Budapest Treaty and in point 11 of the bilateral agreements between the EPO and the depositary institutions (at least five years after the most recent request for furnishing a sample of the deposited biological material and in any case at least thirty years after the date of deposit.

4. Conditions for the Furnishing of Samples

(i) Time of Availability of Samples

The deposited biological material becomes available upon request to any person from the date of publication of the European patent application and to any person having the right to inspect the files pursuant to Article 128(2) EPC, prior to such date *(Rule 33(1) EPC)*.

(ii) Restrictions Concerning the Furnishing of Samples

(a) Undertaking of the Requester vis-à-vis the Applicant or the Proprietor of the Patent

A sample of the deposited biological material can only be issued to the requesting party if such a party undertakes *vis-à-vis* the applicant or the proprietor of the patent:

- not to make the deposited biological material or any biological material derived therefrom available to any third party and

- to use the deposited biological material or any biological material derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or before the European patent has expired in the designated State in which it last expires,

unless the applicant or the proprietor of the patent expressly waives such an undertaking.

The undertaking to use the biological material for experimental purposes only does not apply in so far as the requesting party is using the culture under a compulsory license. The term "compulsory license" includes *ex officio* licenses and the right to use patented inventions in the public interest.

(Rule 33(2) EPC)

(b) Expert Solution

Until completion of the technical preparations for publication of the application, the applicant may inform the EPO that:

- until the publication of the mention of the grant of the European patent or, where applicable,

- for twenty years from the date of filing if the application has been refused or withdrawn or deemed to be withdrawn,

the availability of the deposited biological material referred to in Rule 33 EPC is effected only by the issue of a sample to an independent expert nominated by the requester.

(Rule 32(1) EPC)

Under Rule 32(2) EPC, any natural person may be nominated as an expert provided that they fulfil the requirements and obligations laid down by the President of the EPO. These have been laid down in detail in a decision of the President dated 10 July 2017 (Decision of the President of the European Patent Office dated 10 July 2017 concerning the requirements and obligations for experts nominated under Rule 32 EPC, OJ EPO 2017, A60. The publication in OJ EPO 1981, 359 is superseded by this decision). See also the notice from the European Patent Office dated 10 July 2017 concerning amended Rules 32 and 33 EPC,(OJ EPO 2017, A61).

Rule 32(2) EPC also provides that the nomination must be accompanied by a declaration from the expert that they undertake to comply with the aforementioned requirements and obligations, and know of no circumstances which might give rise to justified doubts as to their independence or which might conflict in any other way with their function as expert.

Pursuant to Rule 33(2) EPC, the nomination must also be accompanied by a declaration from the expert *vis-à-vis* the applicant in which they enter into the undertaking given pursuant to Rule 33 EPC until either the date on which the patent expires in all the designated States or, where the application has been refused, withdrawn or deemed to be withdrawn, until the date referred to in Rule 32(1)(b) EPC, the requester being regarded as a third party.

(Rule 32(2) EPC)

c) Request for the Issue of a Sample of Deposited Biological Material

The request of a sample of the deposited biological material must be submitted to the EPO on a form recognized by that Office:

- EPO Form 1140: Request for the issue of a sample of deposited biological material

- EPO Form 1141: Declaration for the purposes of obtaining a sample of deposited biological material (see also the Notes concerning the forms for the issue of a sample of deposited biological material)

- EPO Form 1142: Request for deposited biological material to be made available by issuing a sample to an expert and declaration by the nominated expert under Rule 32 EPC (Form 1142A). See also the Notes concerning the request for deposited biological material to be made available by issuing a sample to an expert.

The EPO certifies on the form that a European patent application referring to the deposit of the biological material has been filed, and that the requester or the expert nominated by the requester is entitled to the issue of a sample of that material. After grant of the European patent, the request must also be submitted to the EPO *(Rule 33(4) EPC)*.

The EPO transmits a copy of the request, with the certification, to the depositary institution as well as to the patent applicant or the proprietor of the patent *(Rule 33(5) EPC)*.

The aforementioned forms are available at https://www.epo.org/en/applying/forms.