

Meeting of Member States and International Depositary Authorities under the Budapest Treaty

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BACKGROUND DOCUMENT: FURNISHING OF SAMPLES OF DEPOSITED BIOLOGICAL MATERIAL

Document prepared by the International Bureau

INTRODUCTION

1. One of the main aspects of the system allowing the deposit of biological material in a culture collection for the purposes of patent procedure is to make the deposited biological material¹ available to entitled parties. Biological materials are living materials that can be propagated. Therefore, there is a potential risk that the released samples of the deposited biological material would not be properly handled by the recipients or would be used in an inappropriate manner. To mitigate such risk, a number of countries have set up conditions in their patent laws for the furnishing of samples of deposited biological materials.
2. The Budapest Treaty (BT) also takes into account the specificity of the deposited material. It provides a framework in which samples of deposited biological materials are furnished by the IDAs only to the parties entitled to such samples, in accordance with the relevant provisions of the BT.

¹ In this document, the terms “microorganism” and “biological material” are used interchangeably. Having said that, the term “biological material”, which is found in many national patent laws and the Patent Cooperation Treaty (PCT) is used generally in this document, while the term “microorganism” is used when it refers to the provisions of the Budapest Treaty.

3. This document first provides an overview of the legal framework under the BT with respect to furnishing of samples by the IDAs. In certain situations, the BT refers to the provisions contained in national/regional patent laws that determine when, to whom and under what conditions samples of the deposited biological materials may be furnished. Therefore, the document also describes the typical requirements provided in some national/regional patent laws for the release of samples. That part was prepared on the basis of the information contained in Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty (Budapest Guide)². In addition, as the IDAs have developed their own operational practice in administering the furnishing of samples, such practices are also illustrated in the document. Finally, the latest statistical information regarding the furnishing of samples of deposited biological materials under the Budapest system is presented.

LEGAL FRAMEWORK UNDER THE BUDAPEST TREATY REGARDING FURNISHING OF SAMPLES

4. The BT prescribes the rules with respect to furnishing of deposited biological material referred to in a patent application to interested industrial property offices (IP offices) (Rule 11.1) and to, or with the authorization of, the depositor (Rule 11.2).

5. However, with respect to the furnishing of samples to other legally entitled third parties, the BT provides a framework that leaves it to the national/regional patent laws to provide conditions under which a sample may be furnished by the IDAs (Rule 11.3). Considering the differences among the national/regional laws in this regard, it is widely acknowledged that the IDAs cannot be expected to be familiar with the patent laws of all Budapest members. Thus, it would be unreasonable to require an IDA to judge for itself whether a particular third party is legally entitled to receive a sample of a particular deposit in accordance with one of the applicable laws of all the Contracting Parties and intergovernmental industrial property organizations. Thus, Rule 11.3 establishes a mechanism where the IDAs are permitted to furnish a sample only if the request is accompanied by a certificate from a competent industrial property office indicating the legitimacy of the request (Rule 13.3(a)), or, alternatively, if a competent industrial property office has already notified the IDA of a list of the microorganisms that may be distributed by the IDA, without the need for such certification upon each request.

Furnishing of samples to interested IP offices

6. According to Rule 11.1 of the Regulations under the BT, an IDA shall furnish a sample of a deposited microorganism at the request of an interested IP office. The IP office shall declare that, either it is processing a patent application or has granted a patent in respect of the deposited microorganism. It shall also declare that a sample of the deposited microorganism is necessary for the purposes of its own patent procedure, and that the sample (and any information accompanying or resulting from the sample) will be used only for that purpose.

Furnishing of samples to, or with the authorization of, the depositor

7. An IDA shall furnish a sample of a deposited microorganism at the request of the depositor or any party having the depositor's written authorization, in accordance with Rule 11.2.

² Section E of the Budapest Guide compiles information on the national/regional statutory requirements and practices of the industrial property offices of the States party to the Budapest Treaty and Intergovernmental Industrial Property Organizations relating to the Budapest Treaty, including the conditions for furnishing of samples. Section E is regularly updated, based on the information received from the Contracting States and intergovernmental IP organizations. Any correction or update should be sent to: budapest@wipo.int. The Budapest Guide is available at: https://www.wipo.int/budapest/en/guide/section_e/section_e.html.

Furnishing of samples to parties legally entitled

8. Rule 11.3 provides two types of mechanisms for furnishing of a sample of a deposited microorganism based on a request from a party other than an interested IP Office, the depositor or any party having the depositor's authorization. Such other parties (legally entitled parties) may be any authority, natural person or legal entity that meets the conditions stipulated in Rule 11.3.

9. According to the first mechanism provided in Rule 11.3(a), the IDAs shall furnish a sample of a deposited microorganism to a so-called "certified party" where a request is accompanied by a certificate from a competent IP office, indicating the legitimacy of the request.

10. The competent IP office shall certify that:

(i) an application referring to the microorganism deposited with the IDA has been filed with that office for the grant of a patent;

(ii) the application has been published by the IP office (or if it has not been published, the requesting party has the right to a sample prior to the publication according to the national law);

(iii) the party has a right to a sample under the national patent law, and if applicable, the IP office is satisfied that any conditions for such right are fulfilled. Alternatively, the IP office shall certify that the conditions for furnishing a sample to the requesting party are deemed to be fulfilled in accordance with the law governing patent procedure before that IP office, as a consequence of the requesting party having affixed his/her signature on a form before that IP office.

11. A request to the IDA for furnishing of a sample shall be made on a form whose contents has been fixed by the Budapest Union Assembly.³ The IDAs check that the form is filled in and accompanied by a certification issued by the IP office. However, they do not undertake a substantive review of the request.

12. Rule 11.3(b) provides an alternative mechanism for Contracting Parties to furnish samples of deposited microorganisms to parties legally entitled. If the request concerns a deposited microorganism that is used/involved in granted and published patents and whose accession number has been included in a list of the accession numbers that was communicated from the IP office to the IDA, the IDA shall furnish the sample to requesting parties without any certification of that IP office. Such mechanism may be chosen to simplify the tasks of the IP offices and IDAs, particularly where the applicable law requires that once a patent is granted and published, samples of relevant microorganisms must be available to any third party. The International Bureau has not been able to identify any IP office that communicates such a list to the IDAs.

Deposited biological materials disclosed in international applications under the Patent Cooperation Treaty (PCT)

13. An international application filed under the Patent Cooperation Treaty (PCT) may also be the basis of a request for furnishing of samples. In such cases, Rule 11.5 of the Regulations under the BT indicates that the reference to the filing of the application with the IP office in the declaration under Rule 11.1 or certification under Rule 11.3(a) shall be considered as a reference to the designation of the Contracting State in the international application under the

³ See Form BP/12. BP/12 as well as other forms relating to furnishing of samples under the Budapest Treaty, namely, BP/10, BP/11 and BP/13, are available at:
https://www.wipo.int/budapest/en/guide/appendix_3/index.html.

PCT, for which the IP office is the “designated Office” within the meaning of the PCT. Accordingly, an eligible party may request any “designated Office” to provide a certificate under Rule 11.3(a) with respect to the microorganism deposited with an IDA and disclosed in an international application under the PCT. Rule 11.5 also states that a certification of the publication of the relevant patent application by the IP office referred to in Rule 11.3(a)(ii) (see paragraph 10(ii), above), shall, at the option of the competent IP office, be either a certification of international publication under the PCT or a certification of publication by the IP office.

14. It should be noted that the Regulations under the PCT also provide a provision that relates to the timing of furnishing of samples of the deposited biological materials referred to in international applications under the PCT. Specifically, Rule 13*bis*.6 of the Regulations under the PCT provides for the delaying of any furnishing of samples under the national law applicable in each of the designated Offices until the start of the national phase. However, such “delaying effect” can become shorter if either of the following two events has occurred:

- (i) the applicant has, after international publication of the international application, taken the steps necessary to enter the national phase before the designated Office; or
- (ii) international publication of the international application has been effected, and that publication has the same effects, under the national law applicable in the designated Office, as the compulsory national publication of an unexamined national application (in other words, the international application has qualified for the grant of “provisional protection” given to patent applications under the national law).

Procedures for the furnishing of samples of deposited microorganisms

15. The BT also determines how IDAs shall furnish the material. These procedures ensure, *inter alia*, provision of necessary information to the recipient of the sample for the proper handling of the sample. For example, Rule 11.4(f) states that the IDAs shall mark the container in which the furnished samples are placed with not only administrative information regarding the deposited microorganism (i.e., the accession number of the deposit and a copy of the acceptance receipt), but also information relating to security and safety.

16. Furthermore, in accordance with Rule 11.4(g), the IDAs having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the sample was furnished and of the name and address of the party to which the sample was furnished. Such notification shall be accompanied by a copy of the relevant request, of any declaration of the IP office under Rule 11.1 or authorization by the depositor under Rule 11.2, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3.

REQUIREMENTS UNDER THE NATIONAL/REGIONAL LEGISLATIONS

17. In order for the IDAs to determine whether the requesting party has the right to a sample of the deposited material under the applicable patent law, Rule 11.3(a) of the Regulations under the BT refers to the submission of a certification issued by the competent IP office to the IDA. A number of national/regional laws, if not all, set specific requirements regarding third parties’ entitlement to samples of deposited biological material and the conditions that are attached to it. While there are some commonalities among the provisions in the national/regional laws in this regard, these requirements vary from one country to another.⁴

⁴ More information is available in Section W of the Budapest Guide.

Timing of the availability of samples

18. In general, biological materials are deposited to supplement the written description of the invention in the patent application. Thus, many laws of the BT members or intergovernmental industrial property organizations state that, from the date of the publication of the patent application or the date on which the application is laid open to public inspection, the deposited biological material referred to in the application shall be made available to any person making a request for furnishing of a sample of the deposited material.

19. In some national/regional laws, a sample of a deposited biological material before the publication of the relevant patent application is made available to certain limited parties and/or under certain circumstances. For example, some legislations indicate that the applicant or any person with the consent of the applicant is entitled to such sample before the publication of the patent application. In some jurisdictions, if the applicant invoked the rights derived from its patent application against a third party (e.g., a third party has been notified by the applicant that the procedure against him/her will be brought after patent grant), the third party may be entitled to receive a sample of the relevant deposited material even before the publication of the patent application. In addition, some national laws allow a third party to receive, before the publication of a patent application, a sample of the deposited biological material, if the sample is necessary for the preparation of a response to the negative examination report in relation to the patent application filed by that third party.

20. According to the legislation of the United States of America, in principle, the deposited biological material must be made available to the public at the date of the grant of the patent. Any restriction of public access to the samples of the deposited biological material referred to in a granted patent must be removed. However, access to a sample of a deposited biological material may be made available during pendency of the patent application that refers to the deposited material, if the person requesting a sample is determined by the United States Patent and Trademark Office (USPTO) to be entitled thereto under 37 CFR § 1.14 and 35 U.S.C. 122.

Availability of a sample by an independent expert ("expert solution")

21. In some countries, the patent applicant has the possibility to request that a sample of the deposited biological material shall only be provided to an independent expert, who is appointed in accordance with the applicable law. Such a request shall be typically made before the completion of the technical preparations for publication of the patent application or before the patent application is open to public inspection, depending on the applicable law.

22. In general, the applicant can restrict furnishing of a sample to an independent expert only during a certain period. The duration of such period varies among the national/regional laws. Some laws provide the possibility of such restriction until the grant of a patent or for 20 years from the filing date if the application is refused or withdrawn. In some other countries, the restriction is possible until the grant of a patent or until the application has lapsed, been withdrawn or been refused.

23. Depending on the national/regional legislations, the expert may be nominated by a person requesting a sample or by the patent applicant. In the former case, some laws require that it is subject to approval by the applicant, recognition by the Director General of the IP office concerned, or an objection by the applicant within a specific timeframe. In some other countries, the expert is nominated by the IP office, with the agreement of the applicant.

Undertakings by the party requesting a sample

24. According to a number of national/regional patent laws, access to a sample of a biological material is subject to certain undertakings that must be provided by the party requesting the sample.

25. Specifically, a number of the legislations of the BT members and intergovernmental industrial property organizations state that the requesting party must agree not to make the biological material (or any culture derived from the biological material) available to any other person, and/or to use the deposited material (or any culture derived from it) only for experimental purposes or research. In some countries, the requesting party may use the sample in relation to the opposition proceedings or relevant proceedings in relation to the patent.

26. In general, in a number of countries, such limitations apply only during a certain period. In some jurisdictions, limitations such as not to make the sample available to any other person and/or not to use the sample for the purposes other than experiment or research apply as long as the patent application is pending or the patent is in force. In some other countries, the requesting party shall give such undertaking until the time that the patent application is refused, withdrawn or deemed to be withdrawn or the patent is granted. Yet, in some other legislations, while the undertaking not to make the biological material available to any other person is applicable as long as the patent application is pending or the patent has ceased to produce its effects, the undertaking to use the biological material for research or experimental purposes is only applicable as long as the patent application is pending or until the patent is granted.

27. The laws of some BT members stipulate that these restrictions do not apply to certain situations. For example, in certain legislations, the undertaking shall not impede the deposit of a derived biological material which is necessary for the purpose of the patent procedure (i.e., to deposit a derived biological material, which will be referred to in a patent application that will be filed by the legally entitled party who had received a sample of the biological material). A number of legislations also provide that, where the samples are used under, for example, a compulsory license, Crown use or a license of right, the limitation to the use of the sample for experimental or research purposes only is not applicable.

28. Furthermore, the laws of some BT members also provide the possibility for the patent applicant or patent holder to waive the undertaking or to limit its effects.

OPERATIONAL PRACTICE OF THE IDAS

29. The IDAs have developed their operational practices in furnishing samples of the deposited biological materials. Practices that are widely accepted among the IDAs are summarized in the Code of Practice for IDAs.⁵ With respect to furnishing of samples, it notes that the IDAs should verify the capability of the end user to handle the furnished sample. In this regard, it also notes that some IDAs ask the requester to complete a form stating that they are capable of handling the requested material. In addition, it indicates that samples are only shipped to laboratories and not to offices or to private addresses. Finally, the Code of Practice states that the IDAs must follow the applicable export and import restrictions.

30. The provisions in the BT with respect to furnishing of samples of the deposited microorganisms focus on the eligibility of the recipients and the related requirements under patent law and patent procedures. They do not override any requirements to be met in respect of import and quarantine regulations, health and safety procedures, plant disease regulations and similar rules that control the movement of goods.

⁵ The Code of Practice for IDAs is available at: https://bccm.belspo.be/documents/files/deposit/code-of-practice-for-idas_2022_02_09.pdf.

STATISTICS REGARDING THE FURNISHING OF SAMPLES

31. The yearly statistics⁶ provided by the IDAs show that the total number of samples of deposited microorganisms furnished by the IDAs increased from 995 in 2015 to more than 1,700 in 2022. It is to be noted that the vast majority of the samples of deposited microorganisms are furnished by IDAs under Rule 11.2 of the Regulations under the BT, i.e., to the depositor or to a party authorized by the depositor.

32. The total number of samples furnished under Rule 11.1 (i.e., to IP offices) had been very low: either in a single digit number per year or zero in some years. However, the number has risen sharply in 2021 – in total, 100 samples were furnished to IP offices. This trend continued in 2022 – in total, 87 samples were furnished to IP offices in 2022.

33. With respect to the total number of samples furnished to legally entitled parties under Rule 11.3, it had been falling steadily from 467 samples in 2017 to 246 samples in 2021. This is almost 50% decrease during this five-year period. In 2022, the number increased slightly to 287 furnished samples.

Table 1: Total Number of Samples Furnished by the IDAs

	2017	2018	2019	2020	2021	2022
Total Samples to Industrial Property Offices (Rule 11.1)	5	1	3	8	100	87
Total Samples to Depositor or Authorized Parties (Rule 11.2)	1,243	1,275	1,174	1,619	1,354	1,377
Total Samples to Parties Legally Entitled (Rule 11.3)	467	413	307	259	246	287

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⁶ The Budapest Statistics on the deposit of microorganisms, available at <https://www.wipo.int/budapest/en/>, provides yearly statistical information relating to deposits received, and samples furnished, by each IDA, based on the information collected from the IDAs.