

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

Geneva, November 13 to 14, 2023

**BACKGROUND DOCUMENT: HANDLING OF MICROORGANISMS DEPOSITED
UNDER THE BUDAPEST TREATY AFTER THE PERIOD OF STORAGE**

Document prepared by the International Bureau

INTRODUCTION

1. After having accepted a microorganism¹ for deposit, the International Depositary Authorities (IDAs) are obliged to maintain the microorganism in a manner that is viable and uncontaminated during the period prescribed in Rule 9 of the Regulations under the Budapest Treaty (BT). The BT, however, does not regulate how the IDAs should handle the deposited microorganisms after such storage period. Consequently, the IDAs and depositors may face operational uncertainties unless there is an agreement concluded between the two parties at the time of the deposit.
2. This document provides background information surrounding the issue of handling of the deposited biological materials after the mandatory storage period under Rule 9 to assist the discussion on this topic to be held under Topic 5 of the Meeting of Member States and International Depositary Authorities under the Budapest Treaty.

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.

FRAMEWORK PROVIDED IN THE BUDAPEST TREATY ON THE STORAGE OF DEPOSITED MICROORGANISMS

3. Rule 9.1 of the Regulations under the BT states that any microorganisms deposited with an IDA shall be stored for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the IDA and, in any case, a period of at least 30 years after the date of the deposit of the microorganism (the so-called “30+5 years”).

4. This rule is the result of the discussions that took place from the very beginning of the negotiations among WIPO Member States to establish an international cooperation framework for the deposit of microorganisms for the purposes of the patent procedure. The Committee of Experts on the Deposit of Microorganisms for the Purposes of Patent Procedure was a body that negotiated the draft Treaty and Regulations up to the Diplomatic Conference for the adoption of the BT in 1977. The working documents and reports of the Committee as well as the Records of the Diplomatic Conference are the main source of the legislative history of the BT.²

Availability of deposited materials and the sufficiency of disclosure requirement

5. The BT requires its Contracting Parties to accept the effect of the deposit of microorganisms with any IDA for the purposes of their national patent procedure, i.e., to complement the written description of the claimed invention with such deposit to meet the sufficiency of disclosure requirement under their respective patent law. There was thus a common understanding that the deposited materials under the BT system should be made available as part of the disclosure of the claimed inventions, and IDAs should have the obligation to store the deposited materials for a certain minimum period to ensure such availability. Rule 11 therefore provides a rule regarding furnishing of samples of deposited microorganisms by the IDAs.

6. The importance of maintaining the storage of the deposited biological materials and making them available to entitled parties is also reflected in other provisions of the BT. For example, in accordance with Rule 6.1(a), once a microorganism is deposited under the BT, the depositor has no right to withdraw it for the entire period of “30+5 years”. Moreover, as indicated in Rule 12.1(b), the storage fee charged by the IDAs shall cover the whole duration of the storage period, i.e., “30+5 years”. In other words, once the microorganism has been deposited under the BT system, its storage in the IDAs during such period no longer depends on the willingness of the depositor.

7. It also follows from Rule 9.1 that the storage period of a microorganism will be extended by an additional five years as long as a new request for furnishing of a sample of that microorganism is received by the IDA within five years from the previous request, even beyond the initial 30-year period. It ensures in a pragmatic manner that deposited microorganisms for which an interest from third parties has been shown will continue to be made available from the IDAs.

8. These various provisions in the BT allow the Contracting Parties to rely on international deposits with the IDAs to ensure the disclosure function of their national patent system.

² With respect to the issues discussed in this document, see the following Committee documents and reports: DMO/III/3 and 16, DMO/III/2, 3 and 16, and DMO/IV/2, 3, 3 Corr. and 10. The Records of the Budapest Diplomatic Conference for the Conclusion of a Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure is available at: https://www.wipo.int/treaties/en/preparatory-documents.html#accordion__collapse__05_a.

The length of the storage period

9. During the Committee of Experts meetings, various views were expressed by delegations on the appropriate length of the period during which the IDAs must store the deposited microorganisms. Some delegations noted that since the availability of the microorganisms was relevant to the sufficiency of disclosure requirement, there was an interest, for patent offices, patent applicants and the public, to have the deposited microorganisms maintained during the lifespan of the patent concerned. At the same time, a subsisting public interest in the availability of the deposited material after the expiration of a patent was also noted.

10. More specifically, the Committee discussed the point that once a patent application is withdrawn (sometimes before the publication of a patent application) or after the expiration of the patent, the patent applicant/owner would normally have no interest in maintaining the deposit of the relevant material under the BT for the purposes of the patent procedure. However, even after the patent has expired, third parties might still be interested in having the deposited material maintained. It could allow them to obtain a sample of the material, and based on the published patent information supplemented by the deposit, they may carry out the invention on which the patent was already expired. It was observed that the need for maintaining the deposited materials would particularly arise in cases where they were not readily available otherwise.

11. The discussions in the Committee also showed that, from the perspective of ensuring that the teaching of patents be shared with others, some delegations were of the view that deposits should be maintained without any time limit. However, others considered that, for practical reasons, requiring IDAs to maintain the deposited materials *ad infinitum* was neither necessary nor feasible. They suggested that maintenance of the deposited materials by the IDAs during a fixed term, or until the expiration of a time limit during which the IDA has not received any request for furnishing of a sample, whichever of the two periods expires later, be obligatory.

12. The international dimension of the deposits with the IDAs was also discussed in the Committee. In a system of recognition of international deposits, countries should be able to rely on the deposits made with, and furnishing of samples from, the IDAs, regardless of the different national patent laws and procedures. Similarly, the availability of samples should not be affected by the fates of patent family applications filed, and the legal status of the patents granted, in different countries.

13. Considering these aspects, the length of the “30+5 years” emerged in the draft Regulations under the BT, and was adopted by the Diplomatic Conference without much discussion.

Handling of the deposited materials after the storage period under the BT

14. Prior to drafting provisions of the draft Treaty and Regulations, the International Bureau prepared a study on the various aspects relating to the international recognition of deposit of microorganisms for the purposes of patent procedures. In that document, in conjunction with the analysis of the length of the storage period, the question of whether an IDA would be free to decide discontinuation of the deposit after the expiration of the minimum duration was considered.³ The document, however, merely notes that since a number of countries will rely on the international deposit, an interest in maintaining the deposit may subsist in some of these

³ Document DMO/II/3, paragraph 23.

countries. While the International Bureau presented a possible solution to it,⁴ that was not further pursued during the course of the negotiation of the Treaty.

15. Accordingly, neither Rule 9 (Storage of Microorganisms) nor any other provisions of the BT touch upon the question as to how IDAs shall handle the deposited microorganisms after the expiration of the “30+5 years”. In the absence of a provision in the BT, national laws governing each IDA are deemed to be applicable on this matter.

NATIONAL/REGIONAL FRAMEWORK ON THE STORAGE OF DEPOSITED MICROORGANISMS

16. Section E of the Guide to the Deposit of Microorganisms under the Budapest Treaty⁵ compiles the requirements of industrial property offices of States party to the Budapest Treaty and of intergovernmental industrial property organizations that accept the effects of the deposit made with the IDAs. The duration of the storage period is one of such information compiled in Section E, based on the information received from the Contracting Parties and intergovernmental organizations. Information concerning the handling of the deposited materials after the storage period under the BT, however, has not been systematically collected in the Guide.

17. When a BT member (or an intergovernmental organization) regulates the duration of the storage in its legislation, it is understood that such provision is only applicable to culture collections that are located in its territory and are recognized by that country (or that organization) for the purposes of its patent procedure. If a national law requires that deposits must be made with one of the IDAs, there may be no need to prescribe the storage period in the national legislation, particularly where no IDA is located in that country.

18. According to Section E of the Guide, more than half of the BT members' legislations contain no provision on the storage period.⁶ Some BT members, while not having a specific provision in their laws, apply Rule 9.1 of the Regulations under the BT.⁷ The laws of some other countries contain a provision that refers to Rule 9.1 or a provision that mirrors Rule 9.1.⁸

19. Some BT members' laws provide a provision that stipulates the duration of storage. According to the practice informed by Bulgaria, the duration of storage is unlimited. In some countries, the duration of storage is, according to their practice or applicable law, at least the term of the patent⁹ or the term of the patent plus three years¹⁰.

20. Some members of the BT have explicitly set up a duration of storage that is different for international deposits (i.e., deposits made with IDAs) and for national deposits (i.e., deposits made with other culture collections that are recognized under the national patent law). For example, under the patent practice of Japan, with regard to national deposits, a deposited microorganism is to be kept in storage until the expiration of the relevant patent, whereas, with

⁴ The International Bureau suggested that IDAs be obliged to notify their intention to discontinue the deposit, and upon request of any interested government, possibly against reimbursement of the cost of maintaining the deposit, IDAs shall continue the deposit, at least for a certain period of time.

⁵ <https://www.wipo.int/budapest/en/guide/index.html>.

⁶ Albania, Australia, Austria, Azerbaijan, Bahrain, Belgium, Bosnia and Herzegovina, Brunei Darussalam, Canada, Chile, Costa Rica, Cuba, Czech republic, Democratic People's Republic of Korea, Dominican Republic, El Salvador, Estonia, Guatemala, Honduras, Kazakhstan, Kyrgyzstan, Ireland, Israel, Jordan, Latvia, Lithuania, Luxembourg, Monaco, Morocco, Nicaragua, Oman, Panama, Peru, Qatar, Romania, Serbia, Singapore, Slovakia, South Africa, Spain, Tajikistan, Trinidad and Tobago, Tunisia, Türkiye, United Kingdom, and Uzbekistan.

⁷ Australia, Armenia, Croatia, Italy, Malaysia, Mexico, Portugal, Republic of Moldova, Russian Federation and Viet Nam.

⁸ Finland, Germany, Greece, Hungary, Republic of Korea, Switzerland and Ukraine.

⁹ Armenia, Belarus, Georgia, North Macedonia and Slovenia.

¹⁰ Poland.

regard to international deposits, the duration of storage of microorganisms is at least 30 years. In Germany, while Rule 9.1 is applicable for deposits made under the BT, for deposits made outside the BT, the deposited biological material must be stored for a period of five years from the receipt of the most recent request for furnishing a sample of the deposited biological material and, in any case, for at least another five years after expiry of the maximum statutory term of protection of all IP rights referring to the deposited biological material.

21. In the Philippines, one of the requirements for an application relating to biological materials and microorganisms is that the depositary institution should be under contractual obligation to place the culture in its permanent collection.

22. Finally in the United States of America, a deposit must be made for the term of at least 30 years after the date of deposit and at least five years after the most recent request for furnishing a sample of the deposit. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made (i.e., the patent term plus six years to include the statute of limitations). The Manual of Patent Examining Procedure (MPEP) clarifies that the above obligation relating to the storage of samples is applicable, regardless of whether a deposit is made under the BT or not.¹¹

IDAS' PRACTICES REGARDING THE HANDLING OF DEPOSITED MICROORGANISMS AFTER THE PRESCRIBED PERIOD OF STORAGE

23. The BT entered into force in 1980. For many years, the issue of the handling of deposited biological materials after the prescribed period of storage was not in actuality. However, slowly but certainly, biological materials that were deposited in the 1980s have reached, and will continue to reach, the expiration of the "30+5 years" storage period. Therefore, how they should be treated is a real question for the IDAs.

24. Given that Rule 9.1 of the Regulations is silent on the obligations of the IDAs regarding the handling of deposited microorganisms after the expiration of the prescribed period of storage, IDAs have started to consider how to handle such deposits appropriately.

25. The result of these discussions is summarized in the Code of Practice for IDAs, which is a document that provides non-binding best practices on technical and operational aspects that are not regulated in the BT, but nevertheless are relevant to the IDAs in carrying out their daily work in the BT system, e.g., receipt and storage of biological materials and their viability tests. It is a living (continuously updated) document developed by the IDAs, and not a normative instrument. Consequently, IDAs have no legal obligation to follow the Code of Practice that does not have any legal basis under the Treaty or the Regulations.

26. On the issue of the handling of deposited biological materials after the period of storage, the Code of Practice advises the IDAs to make suitable arrangements with the depositor about what to do with the deposited material when the period is over. Such arrangements should be specified in a contract between the IDA and the depositors. Possible arrangements listed in the Code of Practice are to make the material publicly available, e.g., in the public catalogue of the collection, or to extend the deposit against a fee. For the biological materials that have been deposited without any arrangement with the depositor regarding the handling of the deposited material after the storage period, the Code of Practice recommends that in the 29th year of the storage, the IDA asks the depositor whether it wishes to extend the storage period against a fee. In the absence of an agreement to such extension, it is recommended that the IDA makes the deposit available to the public.

¹¹ See Section 2408, Chapter 2400 of the MPEP of the USPTO.

27. There are still pending questions regarding the practical operation of such practice. In particular, for old deposits with respect to which no arrangements have been concluded with the depositors, it may be difficult for IDAs to contact the respective depositor after almost 30 years or more from the time when the deposit was made, and obtain an agreement on the handling of the deposit. In addition, some IDAs reported that certain depositors wished to have the deposited microorganism to be returned to them, or to be destroyed, after the prescribed period of storage.

HANDLING DEPOSITED MICROORGANISMS UNDER THE BUDAPEST TREATY AFTER THE PRESCRIBED PERIOD OF STORAGE: ISSUES FOR CONSIDERATION

28. As the legislative history of the BT suggests, the issues relating to the storage period, availability of the deposited material, and the handling of deposited materials by the IDAs after the storage period under the BT are interrelated. They play an important role in facilitating the public disclosure mechanism underpinning the patent system. Therefore, how the deposited materials that reached the end of the prescribed term of storage should be handled by the IDAs is also a real question for the Member States of the BT.

29. The question, which has long been neglected, appears to be a complex one, as it may need to be considered from the different angles:

- the legitimate interest of depositors/patent applicants/patentees in their biological materials after the “30+5 years”;
- the legitimate interest of third parties in accessing the deposited biological materials after the “30+5 years”; and
- the expected role of the IP offices and the patent system in the continued availability of information contained in patents, of which deposits are considered to be an integral part.

30. In addition, the impact of different handling models on the operation and administration of the IDAs and on the sustainable functioning of the Budapest System is also one of the essential aspects that should be taken into account. As alluded in the earlier discussions within the Committee of Experts, to ensure the public availability of the deposited material after the “30+5 years”, someone has to bear the cost of maintaining the material in the IDA or in any other culture collection.

31. As no answer can be found in the current BT, the IDAs have been handling the question based on the applicable law in their respective countries. However, all Contracting Parties to the BT are potentially relying on the deposits made with any of the IDAs for the purposes of disclosure of the inventions concerned. Therefore, as a first step, the International Bureau invites the Member States and IDAs to express their views on best practices for handling deposited materials after the “30+5 years”, in order to explore the feasibility and desirability of further international discussion on this matter.

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