

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

Geneva, November 13 and 14, 2023

SUMMARY REPORT

prepared by the International Bureau

1. The present document, prepared by the International Bureau, contains a summary of discussions of the Meeting of Member States and International Depositary Authorities (IDAs) under the Budapest Treaty (BT), held at the World Intellectual Property Organization WIPO (WIPO) headquarters in an in-person format on November 13 to 14, 2023¹. The Meeting was attended by 92 participants from 36 Member States, two intergovernmental industrial property organizations and 29 IDAs.

2. Ms. Lisa Jorgenson, Deputy Director General (DDG), Patents and Technology Sector welcomed the participants and recalled the distinctive yet complementary roles of the Member States and IDAs, and the importance of their cooperation for the good functioning of the Budapest system. Ms. Jorgenson noted that the Meeting was an opportunity for the participants to share information and experiences on an international level for the implementation of the BT, to take stock of the technological advancements in the field of biotechnology, and to initiate discussions on the potential further development of the Budapest system.

Topic 1: Presentation of recent developments in the Budapest System

3. The International Bureau reported that since 2021, Saudi Arabia, the United Arab Emirates, Viet Nam, Malaysia, Indonesia, Paraguay and Rwanda (in the order of accession to the Treaty) have joined the BT, which has made the total number of the Contracting States to a total of 89. The African Intellectual Property Organization (OAPI) made a declaration of acceptance under Article 9(1) of the BT that entered into force on March 15, 2023. Since 2018, the Moroccan Coordinated Collections of Microorganisms (CCMM), Morocco, the National Agriculturally Important Microbial Culture Collection (NAIMCC), India, and the Collection of Plasmids and Microorganisms (KPD), Poland, had acquired the status of IDA. Consequently, the number of IDAs has reached a total of 49 in 2023.

¹ The program of the Meeting, list of participants, background documents prepared by the International Bureau as well as presentations are available at: https://www.wipo.int/meetings/en/details.jsp?meeting_id=76968

4. In addition, the International Bureau reported on the statistics relating to deposits received by, and samples of deposited microorganisms furnished from, IDAs in 2022.² While the total number of deposits of microorganisms increased around 12% from 2021 to 2022, the number of furnished samples had been decreasing since 2017. Furthermore, the International Bureau presented information on two WIPO webpages related to the BT³, the contents of the Budapest Guide⁴, and the changes introduced to the Budapest system by the Budapest Union Assembly in 2022.

Topic 2: Deposit of biological material

5. Under Topic 2, the participants considered how the requirements for the deposit of biological material under the applicable laws and the practices of IDAs supported the disclosure of inventions through the patent procedures.

6. A speaker from the Intellectual Property Office of the United Kingdom (UKIPO) presented the legal requirements regarding the sufficiency of disclosure and the deposit of biological materials as well as their rationale. While noting the limited number of relevant court cases in the United Kingdom (UK), he shared examples of the situations under which a deposit of a biological material was required to meet the enabling disclosure requirement under UK law. He, however, added that depending on the advancement of the technology to describe biological materials in writing, those examples might change in the future. In addition, he explained, *inter alia*, the formality requirements for a patent application referring to a deposit of a biological material, including those applied in cases where the applicant relied on the biological material deposited by a third party or where a sample of the deposited material was no longer available at the IDA.

7. Speakers from the *Colección de Microorganismos del Centro Nacional de Recursos* (CM-CNRG), the China General Microbiological Culture Collection Center (CGMCC) and CCMM shared their practices relating to the receipt and acceptance of biological material deposited to the IDAs under the BT. They detailed the various steps involved in that procedure, including the reception of material, viability and purity testing, preservation and storage of the material, recording the relevant information in the register, and issuance of a certificate of acceptance. Some speakers also presented biosafety or quantity requirements that must be complied by depositors.

8. During the discussion, a question was raised by a Member State in respect to the necessity of a deposit of a biological material where a patent application related to antibodies has been filed. In addition, some of the IDAs shared their experiences regarding the acceptance procedure, such as the timing of certain notifications to be sent from the IDA to a depositor, and practices regarding the number of batches of samples that must be submitted by a depositor.

9. Some IDAs also reported that not all biological materials that have been deposited under the BT (patent deposits) have been referred to in any subsequent patent application. However, the IDAs had to maintain those deposited materials during the mandatory storage period in accordance with BT Rule 9. They asserted that some depositors had been using patent deposits as a cheaper option to their private (safe) deposit services and emphasized the importance of informing depositors about the purposes of the BT, under which the deposited materials could be accessed by third parties under certain conditions. In addition, one IDA

² <https://www.wipo.int/budapest/en/>.

³ <https://www.wipo.int/budapest/en/> and <https://www.wipo.int/treaties/en/registration/budapest/>.

⁴ Guide to the Deposit of Microorganisms under the Budapest Treaty (<https://www.wipo.int/budapest/en/guide/>).

noted that offering a safe deposit service in parallel to the patent deposit could accommodate the different needs of depositors.

Topic 3: Furnishing of samples of the deposited biological materials

10. Under Topic 3, the participants considered the conditions prescribed in the national/regional patent laws and IDA practices regarding the furnishing of samples of the deposited material, which took into consideration certain features of biological materials, such as self-replication and biosafety. To support the discussion, a background document on the furnishing of samples of deposited biological materials (WIPO/IDAS/GE/23/3) was prepared by the International Bureau.

11. A speaker from the United States Patent and Trademark Office (USPTO) described the requirements applicable to deposit of a biological material referred to in a US patent application, including the timing of making a deposit of a biological material, and to furnishing of samples of such deposited material. Specifically, he explained the provisions contained in 37 CFR 1.801 to 1.809 and Chapters 2401 to 2412 of the USPTO Manual of Patent Examination Procedure (MPEP). He emphasized that those conditions applied to deposits of biological material made under the BT and non-Budapest deposits. Regarding the furnishing of samples, he indicated that, under US law, all restrictions of the depositor on the availability to the public of the deposited biological material is irrevocably removed upon the granting of the patent in the United States of America.

12. A speaker from the *Leibniz-Institut DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ)* provided information on the different situations and relevant procedures for releasing samples of deposited biological materials to the requesting parties. She explained the process of releasing a sample from receiving a request certified by the IP Office, the various checks carried out by DSMZ, to the shipment of the sample to the requesting party. She noted that there was a limited use by the IP Offices of the mechanism provided in Rule 11.3(b) to communicate to the IDAs a list of accession numbers of deposited microorganisms that were used/involved in granted and published patents, although that could facilitate IDAs to furnish samples to legally entitled parties. She suggested the creation of a database where information on the accession numbers of the deposited microorganisms referred to in patent applications or granted patents could be found. She was of the view that such database might also be used when the IDA handled the deposited microorganisms after the mandatory period of storage (see paragraph 21). In addition, noting that the IDAs shall furnish a sample of the deposited microorganism to the depositor upon request in accordance with BT Rule 11.2, she also pointed out the difficulties the IDAs had been facing in contacting the original depositors where the rights to the deposited material had been allegedly transferred from the original depositor to another party (i.e., the requesting party).

13. On the last point raised by DSMZ during the discussion, some IDAs shared their experiences on handling the transfer of the rights to the material deposited under the BT. A number of IDAs explained that they exercised due diligence by trying to have a clear statement from the requesting party that it had the right to the deposited material or to check the legal status of the requesting party in, for example, commercial registers. They, however, were of the view that searching or verifying the chain of title for the transfer of the rights to the deposited material was not the responsibility of the IDAs.

14. Some Member States explained their requirements and conditions applicable in their national patent laws, under which the requesting party could obtain and use samples of the deposited biological material. For example, some indicated that the applicant was given the possibility to decide, under certain conditions, that a sample of the deposited biological material could be released to an expert only.

Topic 4: Cooperation between IDAs and IPOs

15. A speaker from the Japan Patent Office (JPO) explained the active cooperation that had been put in place between the JPO and the two IDAs located in Japan to ensure high quality and financially sustainable services. Such cooperation included: (i) the JPO's support to the IDAs for developing new preservation protocols and methods; (ii) coordination between the JPO and IDAs in responding to questions from depositors or requesting parties; and (iii) holding an annual meeting between the JPO and IDAs.

16. A speaker from the National Institute of Industrial Property (INAPI), Ministry of Economy of Chile stated that the creation of a positive environment for biotechnological innovation and to simplify and reduce the costs of patent deposits for local innovators were the motivation for joining the Budapest Treaty and hosting an IDA in its territory. She shared the experience of Chile in the journey of a depositary institution to apply for the status of the IDA and the support provided by INAPI throughout that process.

17. A speaker from the Westerdijk Fungal Biodiversity Institute (CBS) highlighted three areas in which the cooperation between IDAs and IP Offices might be further improved: (i) availability of information on granted patents that referred to a deposited biological material; (ii) establishment of points of contact in the IP Offices for IDAs (should they wish to contact an IP Office for example during the procedure for furnishing samples of deposited biological material); and (iii) availability of information relating to the change of the depositor or patent applicant.

18. Several IDAs supported the importance of improving the communication between the IPOs and IDAs on the three points mentioned in the previous paragraph. With respect to item (i) above, several Member States and IDAs were of the view that the search function of the current patent databases could be improved so that patent applications/patents that referred to deposit of biological materials would be retrieved more efficiently.

19. Several Member States also noted the importance of strengthening the cooperation between the IP Offices and IDAs, and welcomed the organization of meetings that involved both Member States and IDAs.

Topic 5: Practices of the IDAs under the Budapest Treaty

20. Discussions under Topic 5 were structured under three subitems: (i) handling of deposited biological material after the mandatory storage period prescribed in the BT; (ii) practices of the IDAs and the Nagoya Protocol (NP); and (iii) other issues. To support the discussion, speakers from the *Colección Española de Cultivos Tipo* (CECT), the *Collection Nationale de Cultures de Microorganismes* (CNCM), the DSMZ and the Microbial Culture Collection (MCC) introduced each topic. In addition, background documents relating to the subitems (i) and (ii) above (WIPO/IDAS/GE/23/2 and WIPO/IDAS/GE/23/4, respectively) were prepared by the International Bureau.

A. Handling of deposited biological material after the mandatory storage period prescribed in the BT

21. Speakers from the IDAs explained that, since the BT is silent on the question of how the IDAs should handle the deposited biological material after the mandatory period of storage prescribed in BT Rule 9, as a precautionary measure, they continued to store the material beyond that period. They noted, however, that while such a practice might be in line with the aim of maintaining the public availability of the information in published patent applications/patents, it could not be a reason for the continued preservation of deposited material that had not led to any invention for which a patent application had been filed. Thus, as observed under Topics 2 and 3, they reiterated the need to have information on the deposited

biological materials that had been referred to in patent applications. They also reported that some depositors had expressed their wish to get their materials back or to have them destroyed by the IDAs upon expiration of the mandatory storage period. Another issue raised was under which conditions samples of biological materials that were deposited more than 30+5 years ago should be furnished. One of the speakers noted that while some depositors might, in that situation, want to have their samples released under the conditions provided in Rule 11 of the BT, the public might want to have a public access to those samples. In addition, the speakers pointed out that continued preservation of the deposited biological materials after the mandatory period of storage had substantive impacts on their operation, such as the storage capacity of the IDAs and the associated expenses. In conclusion, the speakers were of the view that the issue needed to be clarified in the Regulations under the BT.

22. The discussion among the Member States and IDAs showed that the consideration of the issue might involve different aspects. With respect to the overall objective of the patent system, some underlined the role played by the patent system for the dissemination of technological information and the importance of maintaining that information being available beyond the term of the patent. In that regard, the view was expressed that access to the information contained in patent applications referring to a deposited biological material should be treated in the same manner as the information contained in other patent applications.

23. However, recalling that the deposit of biological material under the BT was provided for the purposes of the patent procedure, some others questioned the need of maintaining a deposit once it was no longer necessary for that purpose. Some also noted that the issue should be carefully considered in view of the practical feasibility for the IDAs to continue maintaining the deposited materials beyond the mandatory storage period and the current practice of each IDA. At least for certain materials deposited with certain IDAs, some participants mentioned the alternative means to physical preservation of biological materials, such as sequencing of microorganisms.

24. One Member State noted that it would also be an opportunity to review the duration of the mandatory period of storage prescribed in BT Rule 9, in light of the amendments to national patent laws regarding the term of patent protection since the adoption of the BT (e.g., patent term extensions or Supplementary Protection Certificates (SPCs)).

25. The general view of the participants was that the issue required careful reflection and further consideration among the Member States, taking into account the practical operation of the IDAs.

B. Practices of the IDAs and the Nagoya Protocol

26. Speakers from the IDAs under Topic 5 raised their questions regarding their obligations under the BT in relation to the NP. They noted that the implementation of the NP was carried out by each of its Member States and that the NP contained provisions regarding the relationship with other Treaties. They also noted that the obligations of the IDAs regarding the deposit and storage procedures under the BT were, in their view, not relevant to the NP. They, however, had questions regarding how the NP might be implemented when IDAs furnished samples of deposited biological materials to third parties under the BT. They also noted that, in some culture collections, deposits in the public collection were subject to compliance with the NP. They observed that for those culture collections, the transfer of the deposited biological material made under the BT to the public collection after the prescribed period of storage would not be possible if the depositor did not provide information regarding access to the genetic resources in accordance with the principles of prior informed consent and mutually agreed terms.

27. Several Member States underlined that the BT and the NP had different purposes, different memberships and were two separate international instruments. Recalling that the NP had been implemented differently by the Member States at the national level and considering the fact that the service of an IDA was relevant to potentially all BT Member States that had their own patent procedures, they stated that it was not appropriate to require information related to the NP in the BT, i.e., there was no element in the BT for further discussion on that matter.

C. Other issues

28. Speakers from the IDAs under Topic 5 detailed the other issues currently discussed among IDAs, as follows: (i) electronic documents or electronic signature accepted by IDAs, (ii) fee structures of IDAs that took into account the extra cost for the storage of certain kinds of microorganisms, and (iii) reproduction of batches of strains by IDAs when they no longer had a sufficient amount of samples to furnish to third parties.

29. In regard to the query on the electronic documents and signature, the International Bureau clarified that the BT and its Regulations did not limit the format of the documents or signature.

Topic 6: Deposit of biological materials: technology trends and emerging practices in IDAs

30. Under Topic 6, the latest technologies used by IDAs for receiving and storing biological materials were examined and the evolving practices of IDAs in handling different types of biological materials were discussed.

31. Speakers from the Guangdong Microbial Culture Collection Center (GDMCC) and the Microbial Type Culture Collection and Gene Bank (MTCC) shared their experience on how they use the latest technologies for their activities under the Budapest system. They provided examples of the application of new technologies for the isolation and preservation of certain kinds of microorganisms. In addition, they noted that while the development of cultivation and isolation techniques might facilitate uncultured microorganisms becoming cultured microorganisms and the discovery of their new applications, the IDAs might face challenges in keeping them viable and uncontaminated in the culture collection. They also referred to the challenges in preserving more complex composite microorganisms, such as microbiomes and synthetic microbial communities.

32. Some IDAs recalled the importance for them to keep updated on the new technologies that would facilitate their operation. As the BT requires the long-term preservation of deposited biological materials, in general, acceptance of complex cultures was considered particularly challenging. Several IDAs indicated that, while there was a growing interest in the deposit of microbiomes, the current technologies do not allow the testing of their viability.

Topic 7: Technological advancement in biotechnology: impacts on the enabling disclosure requirement and the deposit of biological materials

33. Under Topic 7, the participants considered the advancements of biotechnology and how they might impact the deposits under the Budapest system. To facilitate the discussion, Dr. Stéphane Duboux, Senior R&D Specialist, Biotechnology Department, Nestlé Research, presented the existing technological capabilities and possible future development in microbial biotechnology. He provided different examples where technological advancements might be used to copy or enhance the natural capacities of the strains (for example, genetic mutagenesis or CRISPR-Cas9 tools) to produce new products. In his view, those advancements might facilitate the disclosure of the products, as they make it possible to track the genetic changes made on the strains. He also referred to the use of metagenomic sequencing and AI tools that provide the possibility of creating metagenomic assembled genomes (MAG). From those MAG, it was possible to predict new functions without having the physical strains.

34. It followed from the discussion on whether disclosure of the sequencing of the material (without a deposit of the physical material) might be enough to fulfill the sufficiency of disclosure requirement that it depended on different factors: the kind of the biological material concerned (e.g., general availability of the synthesized material), the application of the disclosure requirement by each national IP Office, and the way the material was claimed in the patent application. One IDA noted that a depositor may submit a sequence listing as associated data of the physical deposit of the material. With respect to disclosure of sequence listing information in patent applications, WIPO standard ST.26 provides a standardized format for such disclosure. Concerning the prediction of functions, some IP Offices explained how the patentability requirements, such as the sufficiency of disclosure requirement and the industrial applicability (utility) requirement, were applied in their jurisdictions, and articulated on the disclosure of experimental data versus *in silico* data and the doctrine of sound prediction.

Topic 8: Future development in the Budapest System

35. Based on the presentations and discussions held in Topics 1 to 7, the participants had an exploratory discussion and brainstorming on whether there would be any areas in the Budapest system that might be improved and how they might be addressed.

36. To facilitate the debate, four panelists, i.e., the panelists from the Polish Collection of Microorganisms (PCM), the National Collection of Yeast Cultures (NCYC), China National Intellectual Property Administration (CNIPA) and Dr. Duboux had a roundtable discussion moderated by the International Bureau on the three broad themes: (i) the areas that might be improved in the Budapest system and three issues of particular importance to be addressed; (ii) the impacts of the recent technological advancement on the development of the Budapest system; and (iii) how the future of the Budapest system may be shaped in view of (i) and (ii). For each theme, the roundtable discussion was followed by an open discussion among all participants.

37. The discussion was lively and benefited from the active participation of both Member States and IDAs. It covered a wide range of issues, including legal questions, technological and operational challenges, and cooperation between IP Offices, IDAs and the International Bureau. The general view from the participants was that the Budapest system would remain relevant in the future and that the system has the capacity to adapt in order to support innovation in the biotechnology field.

38. In summary, the following main messages emerged from the discussion:

- communication among IP Offices, IDAs and the International Bureau, at the national and international level, and with depositors and patent applicants, should be improved;
- IP Offices, IDAs and the International Bureau may consider creating more opportunities for exchange of best practices and experiences;
- IDAs and IP Offices may explore new means of sharing information and data in order to support the operation of the organizations;
- BT Member States may provide guidance on how samples of deposited biological material should be handled by the IDAs after the storage period prescribed in the BT;

- technological advancements that may assist IDAs to better preserve and transmit the deposited biological material, including new kinds of material, should be followed;
- potentials of genome sequencing information to complement the deposit of physical biological materials may be explored.

Closing of the Meeting

39. The International Bureau closed the Meeting on November 14, 2023.

[End of the report]