

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Note by the Secretariat

I. INTRODUCTION

1. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as the “Treaty”) was adopted by the Budapest Diplomatic Conference on April 28, 1977, and it entered into force on August 19, 1980. The Conference also adopted Regulations under the Treaty.

2. On July 29, 2020, the following States are party to the Treaty: Albania, Antigua and Barbuda, Armenia, Australia, Austria, Azerbaijan, Bahrain, Belarus, Belgium, Bosnia and Herzegovina, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Czech Republic, Democratic People’s Republic of Korea, Denmark, Dominican Republic, El Salvador, Estonia, Finland, France, Georgia, Germany, Greece, Guatemala, Honduras, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Mexico, Monaco, Montenegro, Morocco, Netherlands, New Zealand, Nicaragua, North Macedonia, Norway, Oman, Panama, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tajikistan, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Uzbekistan (82).

II. SUMMARY AND MAIN ADVANTAGES OF THE TREATY

BACKGROUND

3. Disclosure of the invention to the public is a generally recognized *quid pro quo* requirement for the grant of patents. Normally, an invention is disclosed by means of a written description. Where an invention involves a microorganism or other biological material (hereinafter referred to as “microorganisms”), or the use of it (in particular in agriculture, food and pharmaceutical industries), which is not available to the public, such a description may not be sufficient to comply with the requirements of disclosure. That is why in the patent procedure of an increasing number of countries, it is necessary not only to file a written description but also to deposit, with a specialized institution, a sample of the microorganism. Patent offices are not equipped to handle microorganisms, whose preservation requires special expertise and equipment to keep them viable, to protect them from contamination and to protect health or the environment from contamination. Such preservation is costly. The furnishing of samples also requires specialized expertise and equipment.

4. When protection is sought in several countries for an invention involving a microorganism or the use of a microorganism, the complex and costly procedures of the deposit of the microorganism would have to be repeated in each of those countries. In order to eliminate or reduce such multiplication, the Treaty was concluded so that one deposit serves the purpose of all the deposits which would otherwise be necessary.

SUMMARY OF THE TREATY AND THE REGULATIONS

5. Substantive Provisions. The main feature of the Treaty is that a Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any “international depositary authority” (Article 3(1)(a)), irrespective of whether such authority is on or outside the territory of the said State. In other words, one deposit, with one international depositary authority, will suffice for the purposes of patent procedure before the national patent offices (called “industrial property offices” in the Treaty) of all of the Contracting States and before any regional patent organization if such a regional organization declares that it recognizes the effects of the Treaty (Article 9(1)). The European Patent Organisation (EPO), the African Regional Intellectual Property Organization (ARIPO) and the Eurasian Patent Organization (EAPO) have made such a declaration.

6. What the Treaty calls an “international depositary authority” is a scientific institution – typically a “culture collection” – which is capable of storing microorganisms. In order to acquire the status of the “international depositary authority”, the Contracting State in which a depositary institution locates must furnish a declaration of assurances to the Director General of WIPO to the effect that the said institution complies, and will continue to comply, with certain requirements (Article 6(2)), including, in particular, that it will be available, for the purposes of the deposit of microorganisms, to any “depositor” (person, firm, etc.), that it will accept and store the deposited microorganisms and that it will furnish samples thereof to only those entitled to such samples. The said assurances may be furnished also by certain intergovernmental industrial property organizations (Article 9(1)(a)). To date, 48 depositary institutions have acquired the status of international depositary authority.¹

¹ Australia: Lady Mary Fairfax CellBank Australia (CBA); The National Measurement Institute (NMI)
Belgium: Belgian Coordinated Collections of Microorganisms (BCCM™)
Bulgaria: National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)

7. The Regulations contain detailed provisions (Rule 11) on who is entitled - and when - to receive samples of the deposited microorganism. The depositor himself has a right to a sample at any time (Rule 11.2(i)). He may authorize any third party (authority, natural person, legal entity) to ask for a sample, and such a third party will receive a sample upon producing such an authorization (Rule 11.2(ii)). Any "interested" industrial property office to which the Treaty applies may ask for a sample and will receive one; an industrial property office will be regarded as "interested" where the microorganism is needed for the purposes of patent procedure before the said office (Rule 11.1). Any other party may obtain a sample if an industrial property office to which the Treaty applies certifies that, under the applicable law, such a party has the right to a sample of the given microorganism; the elements of the certification are provided for in detail to ensure that the maximum extent of caution will be exercised by the industrial property office before it issues a certification (Rule 11.3(a)).

8. The Treaty and the Regulations also contain provisions allowing for what is called a "new" deposit where samples of the originally deposited microorganisms can no longer be furnished (Article 4); permitting the termination or limitation of the status of international depositary authority where the said authority does not or does no longer fully comply with its assumed duties (Article 8); requiring that all microorganisms deposited with an international depositary authority be transferred

[Footnote continued from previous page]

Canada: International Depositary Authority of Canada (IDAC)

Chile: *Colección Chilena de Recursos Genéticos Microbianos* (CChRGM)

China: China Center for Type Culture Collection (CCTCC); China General Microbiological Culture Collection Center (CGMCC); Guangdong Microbial Culture Collection Center (GDMCC)

Czech Republic: Czech Collection of Microorganisms (CCM)

Finland: VTT Culture Collection (VTTCC)

France: *Collection nationale de cultures de micro-organismes* (CNCM)

Germany: *Leibniz-Institut DSMZ - Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH* (DSMZ)

Hungary: National Collection of Agricultural and Industrial Microorganisms (NCAIM)

India: Microbial Culture Collection (MCC); Microbial Type Culture Collection and Gene Bank (MTCC); National Agriculturally Important Microbial Culture Collection (NAIMCC)

Italy: Collection of Industrial Yeasts DBVPG; *Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini"* (IZSLER); *Ospedale Policlinico San Martino IRCCS*

Japan: International Patent Organism Depositary (IPOD), National Institute of Technology and Evaluation (NITE); National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD)

Latvia: Microbial Strain Collection of Latvia (MSCL)

Mexico: *Colección de Microorganismos del Centro Nacional de Recursos Genéticos* (CM-CNRG)

Morocco: Moroccan Coordinated Collections of Microorganisms (CCMM)

Netherlands: *Westerdijk Fungal Biodiversity Institute* (CBS)

Poland: IAFB Collection of Industrial Microorganisms; Polish Collection of Microorganisms (PCM)

Republic of Korea: Korean Agricultural Culture Collection (KACC); Korean Cell Line Research Foundation (KCLRF); Korean Collection for Type Cultures (KCTC); Korean Culture Center of Microorganisms (KCCM)

Russian Federation: Russian Collection of Microorganisms (VKM); All-Russian Collection of Industrial Microorganisms (VKPM)

Slovakia: Culture Collection of Yeasts (CCY)

Spain: *Banco Español de Algas* (BEA); *Colección Española de Cultivos Tipo* (CECT)

Switzerland: Culture Collection of Switzerland AG (CCOS)

United Kingdom: CABI Bioscience, UK Centre (IMI); Culture Collection of Algae and Protozoa (CCAP);

European Collection of Cell Cultures (ECACC); National Collection of Type Cultures (NCTC); National Collection of Yeast Cultures (NCYC); National Collections of Industrial, Food and Marine Bacteria (NCIMB); National Institute for Biological Standards and Control (NIBSC)

United States of America: Agricultural Research Service Culture Collection (NRRL); American Type Culture Collection (ATCC); Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA)

to another such authority if the former is about to cease functioning as such (Rule 5.1); regulating the issue of receipt by the international depositary authority (Rule 7); providing for the testing of the viability of the deposited microorganisms and the issuance of viability statements (Rule 10); allowing the international depositary authority to charge a fee for each deposit, that fee covering the minimum 30 years during which the deposited microorganism must be stored (Rules 9 and 12); providing for a special status and a special role for certain intergovernmental organizations (Article 9).

9. Administrative Provisions. The States party to the Treaty constitute a Union (“the Budapest Union”) (Article 1). The Budapest Union has an Assembly consisting of the States members of the said Union, the main tasks of the Assembly being to deal with all matters concerning the maintenance and development of the Union and the implementation of the Treaty (Article 10(2)), including the powers to amend certain provisions of the Treaty (Article 14), to amend the Regulations (Article 12(3)) and to take away or limit the status of any given international depositary authority (Article 8(1)). Certain administrative tasks are entrusted to the International Bureau of WIPO (Article 11). The possibility of amending the Treaty in revision conferences is also provided for (Article 13).

10. Guide to the Deposit of Microorganisms under the Budapest Treaty. The Guide presents in a systematic manner information on the procedures and requirements concerning the deposit of microorganisms. It gives practical advice to persons depositing microorganisms for patent purposes, on the one hand, and to anyone wishing to obtain samples of such microorganisms, on the other hand. It is regularly updated and can be consulted on the WIPO website at: www.wipo.int/budapest.

MAIN ADVANTAGES OF THE TREATY

11. By acknowledging the multiple legal effect of a single deposit, the Treaty makes the patent procedure simpler and patenting more attractive in the States party to the Treaty, and reduces the biosafety risk of transferring microorganisms into several countries. The Treaty is primarily advantageous to the depositor who is an applicant for patents in several countries; the deposit of a microorganism under the procedures provided for in the Treaty will reduce his/her costs and strengthen his/her security. It will reduce his/her costs because, instead of depositing the microorganism in each and every country in which he/she files a patent application referring to that microorganism, deposit of the microorganism can be made only once, with one depositary institution. Consequently, in all but one of the countries in which he/she seeks protection, he/she will save the fees and costs that deposits would otherwise have entailed. In many cases, there may be at least one international depositary authority in the country, or in the region, of the depositor, which may allow him/her to deal with an authority located in the same geographical region, in his/her own language, and if the payment of the fee is required, to use the local currency for such payment; in other words, the depositor will be able to avoid dealing with distant authorities, in foreign currencies and in foreign languages. The depositor will probably have a natural trust in the authority carefully preserving the viability of the deposited microorganism and furnishing samples only to those who are entitled to receive them under the applicable rules concerning public access to deposited microorganisms.

12. The security of the depositor is increased by the fact that, for an institution to become an international depositary authority, solemn assurances as to the seriousness and continued existence of that institution must be given; such assurances must be given by a State or by an intergovernmental organization, and they are addressed to all the Contracting States of the Budapest Union. Consequently, it may be expected that the assurances will be strictly respected,

all the more so since, if they are not so respected, the Contracting States may take away from the defaulting institution the status of international depositary authority.

13. It is to be noted that the Treaty does not require the establishment of an international depositary authority in a Contracting State. Presently, 26 out of 82 Contracting States have established at least one international depositary authority. In case an international depositary authority is established, that facilitates the availability of the deposited material in the country and reduces the necessity of the transnational movement of that material.

14. The Regulations under the Budapest Treaty provide for a regulated access to the deposited material by third parties and further the use of the microorganisms for R&D. It should also be noted that the Regulations under the Budapest Treaty guarantee the traceability of any samples furnished to third parties both domestically and internationally. Therefore, those features of the Budapest Treaty facilitate the transparency regarding the access to genetic material in the framework of patent procedures.

15. The Treaty contains no financial provisions. No State can be requested to pay contributions to the International Bureau of WIPO on account of its membership in the Budapest Union.

III. RATIFICATION OF AND ACCESSION TO THE TREATY

16. Any State member of the International (Paris) Union for the Protection of Industrial Property may become party to the Budapest Treaty (Article 15(1)).

17. The States that have signed the Treaty may become party to it by depositing an instrument of ratification. Those that have not signed it may become party to it by depositing an instrument of accession.

18. Instruments of ratification or accession are to be deposited with the Director General of WIPO (Article 15).

19. A model instrument of accession is attached to this Note (see Annex).

[Annex follows]

MODEL

INSTRUMENT OF ACCESSION TO THE BUDAPEST TREATY
ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT
OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

(to be deposited with the Director General of WIPO in Geneva)

The Government of [name of State] hereby declares that [name of State] accedes to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on April 28, 1977, and amended on September 26, 1980.

Done at, on, 202..

Signature *

(Seal)

* The instrument should be signed by the Head of State, the Head of Government or the Minister for Foreign Affairs.