INTRODUCTION TO THE BUDAPEST TREATY

(a) <u>Deposit of Microorganisms for the Purposes of Patent</u> Procedure

(i) <u>Disclosure and the Requirement for Deposit</u>

1. A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself. Disclosure is normally achieved by means of a written description supplemented where necessary by drawings. However, inventions involving the use of new microorganisms (i.e., those not available to the public) present problems of disclosure in that repeatability often cannot be ensured by means of a written description alone. In the case of an organism isolated from soil, for instance, and perhaps "improved" by mutation and further selection, it would be virtually impossible to describe the strain and its selection sufficiently to guarantee another person obtaining the same strain from soil himself. In such a case, the microorganism itself might be considered to be an essential part of the disclosure. Moreover, if the microorganism was not generally available to the public, the written disclosure of the invention might be held to be insufficient. This line of reasoning led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a new microorganism be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure.

(ii) Need for a Uniform International Deposit System

2. Although by the early 1970s the depositing of microorganisms in culture collections for patent purposes had become fairly common, there was no uniform system of deposit, or, perhaps more importantly, of <u>recognition</u> of deposit. Most countries requiring or recommending deposit required it to be made in a "recognized" collection, but the minimum criteria to be met by such "recognized" collections were vague and ill defined. In most cases, "recognized" probably equated with "internationally known." The culture collections for their part, when confronted with the variety of national patent laws, were often unsure of how to proceed in respect of the furnishing of

samples to requesting parties. Lack of firm guidelines led some collections to allow the depositor almost complete control over the furnishing of samples of his microorganism, believing this to be the surest way of protecting themselves from the danger of releasing a sample illegitimately.

3. Faced with the above-mentioned uncertainties, many patent applicants saw no alternative but to deposit the same microorganism in several collections in different countries to guard against the possibility of any of their applications failing on the grounds of insufficient disclosure. Clearly this practice was wasteful, time-consuming and sometimes expensive, and, taken to its logical conclusion, would have resulted in applicants depositing the microorganism in every country in which they wished to file a patent application referring to that microorganism. In order to obviate the need for such multiple deposits, therefore, the Government of the United Kingdom proposed, in 1973, that the World Intellectual Property Organization (WIPO) should study the possibilities of one deposit serving the purposes of all the deposits that would otherwise be needed. This proposal was adopted by the Governing Bodies of WIPO.

(iii) The Budapest Treaty

4. In 1974, the Director General of WIPO convened a Committee of Experts to discuss the possibilities of international cooperation over the deposit of microorganisms for patent purposes. The essence of the solution prepared in discussions of this Committee was that certain culture collections should be recognized as depositary authorities and that a deposit made with any one of them should be recognized as valid for patent purposes by all the countries in which protection for the relevant invention was sought. The Committee of Experts also found that the conclusion of a treaty would be necessary to put this proposed solution into effect. At two further sessions in 1975 and 1976 the Committee of Experts examined drafts prepared by the International Bureau of WIPO of a Treaty and Regulations on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. A third draft of this Treaty and Regulations served as a basis for the deliberations of a Diplomatic Conference, convened by the Director General of WIPO, organized by him in cooperation with the Government of Hungary, and held in Budapest from April 14 to 28, 1977. The Diplomatic Conference, which was attended by representatives of 29 Statse ¹ members of the Paris Union for the Protection of Industrial Property and observers from two non-member States² of the Paris Union, the Interim Committee of the European Patent Organisation, and 11 non-governmental international organizations, adopted a treaty with the title "Budapest Treaty on the International Recognition of the Deposit of

Microorganisms for the Purposes of Patent Procedure," together with Regulations under the Treaty.

5. The Budapest Treaty came into effect in 1980 when it had been ratified or acceded to by the requisite minimum number (five) of States. The Regulations under the Budapest Treaty were modified in 1981 and in 2002.

1 Australia, Austria, Bulgaria, Czechoslovakia, Denmark, Egypt, Finland, France, German

Democratic Republic, Germany (Federal Republic of), Hungary, Indonesia, Italy, Japan, Mexico, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Senegal, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia.

- 2 Democratic People's Republic of Korea, Pakistan.
- 3 Committee of National Institutes of Patent Agents (CNIPA), European Federation of Agents of Industry in Industrial Property (FEMIPI), Council of European Industrial Federations (CEIF),

International Association for the Protection of Industrial Property (AIPPI), International Chamber of

Commerce (ICC), International Federation of Patent Agents (FICPI), International Federation of

Pharmaceutical Manufacturers Associations (IFPMA), Pacific Industrial Property Association (PIPA),

Union of European Patent Attorneys and Other Representatives Before the European Patent Office (UNEPA), Union of Industries of the European Community (UNICE), World Federation for Culture Collections (WFCC).

- (b) Main Features of the Budapest Treaty
- (i) <u>International Depositary Authorities and Recognition of Single Deposit</u>
- 6. Under the Treaty, certain culture collections are recognized as "international depositary authorities" (IDAs). Any Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for those purposes, a deposit made in any IDA, wherever that IDA may be. Similarly, if any intergovernmental industrial property organization (e.g., the European Patent Office) files a formal declaration with the Director General of WIPO to the effect that, for its own patent purposes, it accepts the provisions of the Treaty and the Regulations, then it too must recognize a deposit made in any IDA.

7. Any culture collection can become an IDA provided that it has been formally nominated by the Contracting State on whose territory it is located and that that Contracting State has furnished solemn assurances that the collection complies and will continue to comply with the requirements of the Treaty and the Regulations. The most important of these are that the IDA will be available on the same terms to any depositor, that it will accept and store microorganisms deposited with it for the full period specified by the Treaty, and that it will furnish samples of deposited microorganisms only to those entitled to receive them. An intergovernmental industrial property organization which has filed the declaration referred to in paragraph 6 similarly may furnish assurances in respect of a culture collection located on the territory of one of its member States.

(ii) Deposit and Furnishing of Samples

8. The Regulations under the Treaty lay down in detail the procedures which depositors and IDAs must follow, the duration of storage of deposited microorganisms (at least 30 years or five years after the most recent request for a sample, whichever is later), and the mechanisms for the furnishing of samples. The Regulations do not address the timing of deposit, however; this is left entirely to the relevant national law. So, to a large extent, are the timing and conditions of furnishing of samples. Provision is made for samples to be furnished at any time to the depositor, to anyone having the depositor's written authorization, and to any "interested" industrial property office (i.e., one dealing with a patent application concerning the deposited microorganism and which provides the IDA with a declaration to that effect), but in all other cases national law determines when, to whom and under what conditions samples are to be furnished. However, because IDAs may not be familiar with the national laws of different countries, the Regulations require that a third party requesting a sample from an IDA must make his request on a form on which the relevant industrial property office certifies that he is entitled to receive a sample of that particular microorganism. Alternatively, the industrial property office may, from time to time, notify IDAs of the accession numbers of those microorganisms referred to in patents granted and published by it, in which case such microorganisms become available to anyone without the need for certification.

(iii) Safeguard of Deposits

9. The Treaty and Regulations make various provisions to guard against the loss and consequent non-availability of deposited microorganisms. Thus the IDA must have the expertise and facilities necessary to keep the microorganism viable and uncontaminated throughout the storage period required by the Treaty. If for any reason an IDA is no longer

able to furnish samples of a microorganism, a new deposit of the same organism can be made and can benefit from the date of deposit of the original. If for any reason an IDA ceases to function as such, the Treaty provides for the microorganisms deposited with it to be transferred to another IDA.

(iv) Meaning of the Term "Microorganism"

10. The term "microorganism" is not defined in the Treaty so that it may be interpreted in a broad sense as to the applicability of the Treaty to microorganisms to be deposited under it. Whether an entity technically is or is not a microorganism matters less in practice than whether deposit of that entity is necessary for the purposes of disclosure and whether an IDA will accept it. Thus, for example, tissue cultures and plasmids can be deposited under the terms of the Treaty, even though they are not microorganisms in the strict sense of the word.

17. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

Budapest Treaty (1977), modified in 1980 (Budapest Union)

Status on October 14, 2016

State	Date on which State bec party to the Treaty	same State	Date on which State became party to the Treaty
Albania	March 6, 2005 July 7, 1987 April 26, 1984 October 14, 2003 November 20, 2012	Latvia Liechtenstein Lithuania Luxembourg Mexico	December 29, 1994 August 19, 1981 May 9, 1998 July 29, 2010 March 21, 2001 January 23, 1999
Belarus Belgium Bosnia and Herzegovina Brunei Darussalam Bulgaria	December 15, 1983 January 27, 2009 July 24, 2012 August 19, 1980	Montenegro Morocco Netherlands ¹ Nicaragua Norway	June 3, 2006 July 20, 2011 July 2, 1987 August 10, 2006 January 1, 1986
Canada Chile China Colombia Costa Rica	August 5, 2011 July 1, 1995 July 26, 2016 September 30, 2008	Oman Panama Peru Philippines Poland	October 16, 2007 September 7, 2012 January 20, 2009 October 21, 1981 September 22, 1993
Croatia	February 19, 1994 January 1, 1993	Portugal Qatar Republic of Korea Republic of Moldova Romania	October 16, 1997 March 6, 2014 March 28, 1988 December 25, 1991 September 25, 1999
Denmark	July 3, 2007 August 17, 2006 September 14, 1996	Russian Federation	April 22, 1981 ² February 25, 1994 February 23, 1995 January 1, 1993 March 12, 1998
France	September 30, 2005 January 20, 1981 October 30, 1993 October 14, 2006	South Africa Spain Sweden Switzerland Tajikistan	July 14, 1997 March 19, 1981 October 1, 1983 August 19, 1981 December 25, 1991
Honduras	August 19, 1980 March 23, 1995 December 17, 2001 December 15, 1999	The former Yugoslav Republic of Macedonia Trinidad and Tobago Tunisia Turkey	August 30, 2002 March 10, 1994 May 23, 2004 November 30, 1998
Italy	March 23, 1986 August 19, 1980 November 14, 2008 April 24, 2002	Ukraine United Kingdom United States of America Uzbekistan	July 2, 1997 December 29, 1980 August 19, 1980 January 12, 2002

(Total: 80 States)

DECLARATIONS OF ACCEPTANCE FILED UNDER ARTICLE 9(1)(a) OF THE BUDAPEST TREATY BY INTERGOVERNMENTAL INDUSTRIAL PROPERTY ORGANIZATIONS

Organization	Effective Date		
African Regional Intellectual Property Organization (ARIPO)	•		
Eurasian Patent Organization (EAPO)	1 .		
European Patent Organisation (EPO)	November 26, 1980		
Ratification for the Kingdom in Europe, the Netherlands Antilles and Aruba. The Netherlands Antilles ceased to exist on October 10, 2010. As from that date, the Treaty continues to apply to Curaçao and Sint Maarten. The Treaty also continues to apply to the islands of Bonaire, Sint Eustatius and Saba which, with effect from October 10, 2010, have become part of the territory of the Kingdom of the Netherlands in Europe.			
Date of ratification of the Soviet Union, continued by the Russian Federation as from December 25, 19	991.		

Serbia is the continuing State from Serbia and Montenegro as from June 3, 2006. -35 -

17. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

(continued)

Status on October 14, 2016

INTERNATIONAL DEPOSITARY AUTHORITIES UNDER ARTICLE 7 OF THE BUDAPEST TREATY

Institution	Country	Date status acquired
Advanced Biotechnology Center (ABC)	. Italy	February 29, 1996
Agricultural Research Service Culture Collection (NRRL)	United States of America	January 31, 1981
American Type Culture Collection (ATCC)		January 31, 1981
Banco Español de Algas (BEA)		October 28, 2005
Belgian Coordinated Collections of Microorganisms (BCCM TM)		March 1, 1992
CABI Bioscience, UK Centre (IMI)		March 31, 1983
Centraalbureau voor Schimmelcultures (CBS)	Netherlands	October 1, 1981
China Center for Type Culture Collection (CCTCC)		July 1, 1995
China General Microbiological Culture Collection Center (CGMCC)		July 1, 1995
Colección Chilena de Recursos Genéticos Microbianos (CChRGM)	. Chile	March 26, 2012
Colección de Microorganismos del Centro Nacional de Recursos Genéticos		
(CM-CNRG)	. Mexico	August 25, 2015
Colección Española de Cultivos Tipo (CECT)	Spain	May 31, 1992
Collection nationale de cultures de micro-organismes (CNCM)		August 31, 1984
Collection of Industrial Yeasts DBVPG		January 31, 1997
Culture Collection of Algae and Protozoa (CCAP)		September 30, 1982
Culture Collection of Yeasts (CCY)		August 31, 1992
Czech Collection of Microorganisms (CCM)	Czech Republic	August 31, 1992
European Collection of Cell Cultures (ECACC)		September 30, 1984
Guangdong Microbial Culture Collection Center (GDMCC)		January 1, 2016
IAFB Collection of Industrial Microorganisms		December 31, 2000
International Depositary Authority of Canada (IDAC)		November 30, 1998
Patent Organism Depositary (IPOD), National Institute of		•
Technology and Evaluation (NITE)	Japan	May 1, 1981
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia	-	-
Romagna "Bruno Ubertini" (IZSLER)	. Italy	February 9, 2015
Korean Agricultural Culture Collection (KACC)	Republic of Korea	May 1, 2015
Korean Cell Line Research Foundation (KCLRF)		August 31, 1993
Korean Collection for Type Cultures (KCTC)		June 30, 1990
Korean Culture Center of Microorganisms (KCCM)		June 30, 1990
Lady Mary Fairfax CellBank Australia (CBA)		February 22, 2010
DSMZ - Deutsche Sammlung von Mikroorganismen und	114544114 20101112 1115111111	10014411 22, 2010
Zellkulturen GmbH (DSMZ)	. Germany	October 1, 1981
Microbial Culture Collection (MCC)	3	April 9, 2011
Microbial Strain Collection of Latvia (MSCL)		May 31, 1997
Microbial Type Culture Collection and Gene Bank (MTCC)		October 4, 2002
National Bank for Industrial Microorganisms and Cell Cultures (NBIMCC)		October 31, 1987
National Collection of Agricultural and Industrial Microorganisms (NCAIM)		June 1, 1986
National Collection of Type Cultures (NCTC)		August 31, 1982
National Collection of Yeast Cultures (NCYC)		January 31, 1982
National Collections of Industrial, Food and Marine Bacteria (NCIMB)		March 31, 1982
National Institute for Biological Standards and Control (NIBSC)	. United Kingdom	December 16, 2004
National Institute of Technology and Evaluation, Patent Microorganisms	e e e e e e e e e e e e e e e e e e e	,
Depositary (NPMD)	Japan	A
	•	April 1, 2004
National Measurement Institute (NMI)		September 30, 1988
Polish Collection of Microorganisms (PCM)		December 31, 2000
Provasoli-Guillard National Center for Marine Algae and Microbiota (NCMA		April 26, 2013
Russian Collection of Microorganisms (VKM)		August 31, 1987
		August 31, 1987
VTT Culture Collection (VTTCC)	. Pillialiu	August 25, 2010

(Total: 45 Authorities)