

## INTRODUCTION TO THE BUDAPEST TREATY

### (a) Deposit of Microorganisms for the Purposes of Patent Procedure

#### (i) Disclosure and the Requirement for Deposit

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 *recognition* 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 States<sup>1</sup> members of the Paris Union for the Protection of Industrial Property and observers from two non-member States<sup>2</sup> of the Paris Union, the Interim Committee of the European Patent Organisation, and 11 non-governmental international organizations,<sup>3</sup> 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.

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<sup>1</sup> 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.

<sup>2</sup> Democratic People’s Republic of Korea, Pakistan.

<sup>3</sup> Committee of National Institutes of Patent Agents (CNIPA), European Federation of Agents of Industry in Industrial Property (FEMIP), 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) International Depository Authorities and Recognition of Single Deposit

6. Under the Treaty, certain culture collections are recognized as “international depository 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.