

February 2021

## Requirements for Deposits of Biological Materials for Patents Worldwide

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Thomas D. Denberg & Ellen P. Winner, Requirements for Deposits of Biological Materials for Patents Worldwide, 68 Denv. U. L. Rev. 229 (1991).

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# REQUIREMENTS FOR DEPOSITS OF BIOLOGICAL MATERIALS FOR PATENTS WORLDWIDE\*

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\* This article is based on information received in correspondence between the authors and their attorney contacts in various countries throughout the world. Due to the difficult nature of verifying certain sources of information through usual legal research methods, a list of contributors is included at the end of the article.

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## I. INTRODUCTION

This article addresses various procedural issues involved in patenting biological materials, including the requirements for depositing microorganisms. Since patentable subject matter and deposit requirements vary among countries, there is no easy way of knowing when or how to proceed. The following is a discussion of the requirements and policies regarding deposits, and access to deposits, in many countries around the world.

The statutory law of the United States is representative of the law adopted by many other countries on this subject. It states:

Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible or repeatable manner, access to the biological material is necessary . . . .<sup>1</sup>

A deposit is an actual, viable sample of biological material that is stored in a culture collection and made accessible to authorized parties for the purpose of obtaining or maintaining a patent.<sup>2</sup> Deposits complement written specifications in patent applications by providing tangible information which cannot be expressed in words alone. Deposits, in conjunction with written descriptions, provide the information necessary to enable a skilled person to carry out inventions involving microorganisms. For example, a written description is often insufficient by itself to enable others to make and use a microorganism when the microorganism has been isolated from the soil and may be difficult to isolate again. A written description may also be insufficient when there is a lack of genetic sequence data for the functional component of the organism, such as in DNA coding for certain antibiotics. In general, deposits do

1. 54 Fed. Reg. 34,864 (1989) (supplemental information describing the statutory requirements under 35 U.S.C. § 112 (1988)). See 37 C.F.R. Part 1.

2. This article deals with the requirements for patenting of microorganisms. In some cases, the law may be applicable to plants as well, but industrial patent offices often have different requirements for plants. In the United States, for regulations pertaining to the deposit of biological material for purposes of patents,

[t]he term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material. 37 C.F.R. § 1.801 (1989).

To be considered a novel invention, the microorganism will most commonly be newly discovered, man-mutated, adapted, or genetically engineered.

not take the place of written descriptions; they simply supplement them to make them complete.<sup>3</sup>

When attempting to obtain a patent for an invention that involves biological material, a deposit is often required. The question of whether to make a deposit can often be complex; it is not always clear under what conditions a deposit is necessary.<sup>4,5</sup> It is frequently preferable to avoid making deposits at all.<sup>6</sup> The advantages of making a deposit must be weighed against certain distinct disadvantages.

Uncertainty as to whether an examiner in a reviewing country will require a deposit compels many applicants to routinely make deposits even though they may be unnecessary. For example, the United States

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3. With very few exceptions (e.g., the Netherlands), industrial property offices do not view deposits and (taxonomic) descriptions as alternatives, but rather as complements. A deposit without a description is not satisfactory. The written description should provide enough information to ensure that the specification actually refers to the deposited material and that a skilled reader can ascertain that he or she has the required microorganism. A written description should also provide enough information to reduce the danger of the invention being lost if the deposit mutates or otherwise becomes unavailable after expiration or lapse of the patent. Just how much written information should be provided to satisfy these objectives must be determined separately in each case; however, some taxonomic description is required by the large majority of patent offices. In most instances where a deposit is required, it is to the applicant's advantage to provide a taxonomic description as it may permit the courts to employ the doctrine of equivalents.

4. CHARACTERIZATION OF MICROORGANISMS, at 16-17 (1989) (paper written by the Biotechnology Committee of the New Zealand Patent Office). This paper discusses what types of microorganism inventions may require deposits and what types can be adequately described by means of full written descriptions:

[i]t is clear that it is at best very difficult, and in practice virtually impossible, to define a pure strain of algae, bacteria, blue-green algae, fungi, lichens, viroids, or viruses, to a universally acceptable standard, without a reference strain (or "deposit") being provided.

On the other hand, when the organism under consideration is not limited to a particular strain, such as when all members of a new species are covered or when its "identity" is actually dependent on its properties, method of manufacture, or the products produced from it, then it would normally be possible to define it adequately by means of a full written description.

"Cell lines" are nearly always considerably more complex than the prokaryotic cells of most microorganisms and there is little visual, or morphological, distinction between cell cultures. It seems, therefore, that, as with prokaryotic organisms, it would be virtually impossible to adequately characterize a particular cell line without a deposit being provided.

On the other hand, when the "cell line" under consideration is a mixture of cell lines or a cell line whose "identity" is actually dependent on its properties, method of manufacture, or the products produced from it, then it would normally be possible to define it adequately by means of a full written description.

Plasmids are usually much simpler than living cells and it would normally be possible to define them with a written description, particularly if a complete base sequence is given. In most cases, a deposit should not be necessary, unless the description is clearly inadequate, for example when a complete base sequence is not available for a totally new plasmid.

5. See K. MURASHIGE, *Biotechnology Deposit Requirements*, in *INTELLECTUAL PROPERTY COUNSELING AND LITIGATION* 8-8 (1988) (identifying a set of questions for analyzing whether to make a deposit: Could one of ordinary skill practice the invention based on a written description along with materials available to him? Or would the practitioner actually need the specific physical embodiment of biological material described in the application, but unavailable to him?).

6. If a deposit must be made, it is generally preferable to deposit only the starting materials, and not the microorganism claimed, if the steps for producing the claimed microorganism from these starting materials can be adequately described in words.

patent examiner informs the applicant if a deposit is required and allows him to make a deposit during pendency of the application.<sup>7</sup> However, the European Patent Office (EPO) examiner does not follow this procedure; if a deposit is not made, but later deemed necessary, the applicant will not have the opportunity to make a deposit and the patent will not issue.

Applicants may be obliged to make deposits prior to their United States filing date even though this is not required under United States Patent Law in order to ensure granting of priority rights in other countries.<sup>8</sup> Certain countries will not allow priority unless a deposit was made before the filing date of the priority application. For example, when a deposit is required by the EPO, Japan and many other countries, the claimed priority date relying on a United States filing will be valid only if a deposit was made on or before that date in a recognized depository, and only if the original United States application made reference to the deposit.

In some countries a requirement to disclose the "best mode"<sup>9</sup> of an invention may also compel the making of deposits. For instance, even though an invention may have applicability to many different strains of a microorganism, and can be described in a fashion that enables others to make and use the microorganism, information may be lacking to enable the specific embodiment which represents the best mode. In these cases, a separate claim to the embodiment is desirable, and a deposit is required. From the inventor's point of view, a deposit of the best mode, or specific embodiment, may be desired when broad coverage for an invention or process is hoped for, but it is not known whether such coverage will be allowed. When a specific embodiment of an invention exists (which cannot be completely described in a written description), if nothing else, it may be entitled to patent protection. Consider, for example, a screening process which isolates bacteria with certain properties. Such a process, any time it works, may be proved to isolate bacteria with these properties, but it is not guaranteed to always isolate the same strain of bacteria. The inventor may or may not be able to get broad coverage for the process and all strains of bacteria that can be isolated from it, but he will desire and should be expected to get coverage for those strains that he has isolated and preserved. Thus, there are compelling reasons for applicants to deposit samples of their microorganisms.

Unfortunately, there are several undesirable consequences to mak-

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7. *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985).

8. International Convention for the Protection of Industrial Property (The Paris Convention), March 20, 1883, Paris, art. 4, 25 Stat. 1372. The first filing date in any member country (priority date) is the filing date for purposes of evaluating novelty and nonobviousness over the prior art. To be awarded this priority date, however, the application must be filed in the foreign country within one year of filing in the priority country.

9. 35 U.S.C. § 112 (1988). "The specification shall contain a written description of the invention, and of the manner and process of making and using it . . . and shall set forth the best mode contemplated by the inventor of carrying out his invention."

ing deposits. For example, reliance on a deposit may unnecessarily narrow the scope of a patent. Should there be an infringement action, a court may narrowly interpret the claims to cover only the actual deposit.<sup>10</sup> The potential for severe reduction in the scope of claims for an invention is worrisome and must be carefully analyzed. In addition, relying on a deposit that later mutates or becomes non-viable (and which can not be replaced) may lead to invalidation of the patent.<sup>11</sup>

Another practical problem involves the cost of establishing and maintaining microorganism deposits. Depending on the type of protection sought, this fee can run anywhere from \$570 to over \$970 in one of the major depositories in the United States,<sup>12</sup> and may be even higher in foreign countries.<sup>13</sup> When inventors need to make several deposits to ensure broader scope of their patents, these costs can multiply.

In many countries which have deposit requirements, deposits become accessible to the public upon issuance of the patent. In others, however, the public may have access during pendency of the application. When samples become available before the granting of patent rights, it is very difficult for the depositor to charge infringement. Moreover, the option of keeping the invention a trade secret should the patent not issue is markedly impaired.

Finally, when microorganism samples are made generally available, third-party requesters are not limited to a recipe or written description, but are essentially provided with the actual, complete invention. This serious drawback has several ramifications: it may significantly reduce the research and development efforts required by a competitor to develop improved, non-infringing strains; it becomes very difficult to police infringement of the patent because in many instances these parties may make the microorganism available to other, unknown third parties; and it is almost impossible to assure that the biological material is not exported to a country for which a relevant patent has not been granted.<sup>14</sup>

For obvious reasons, applicants will usually wish to limit public access to deposits. When applying for international patents, applicants should be aware of the policies and practices that may motivate patent office requirements for deposits and affect the availability of their microorganism inventions.

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10. This issue has not yet been tested in United States courts.

11. This issue has not yet been tested in United States courts.

12. As of 1987, the American Type Culture Collection (ATCC), Rockville, Maryland, charged \$570 for 30 years maintenance, \$300 to inform depositors for 30 years of all recipients of deposits, and \$100 for viability testing.

13. China's depository, the Chinese Center for Type Culture Collections (CCTCC), wanted to charge one of our clients \$36,000 for the deposit of 82 plasmids which were considered one deposit in a United States depository.

14. These issues have been considered in the United States, but no safeguards have yet been put into the rules. "A restriction against exports could be considered to be violative of 35 U.S.C. 112 since foreign requesters would be denied access to deposits where a patentee had never sought foreign patent protection." 54 Fed. Reg. 34,873 (1989) (comments).

## II. DEPOSITS

In most countries, when patents are sought for biological materials which are not known and readily available to the public, or cannot be made without undue experimentation, deposits of the materials are required. Depository institutions have been established to accept, maintain, and furnish samples of organisms to authorized parties for the purposes of fulfilling patent requirements. To make a deposit, a depositor provides the depository with sample cultures of the organism along with detailed information about how to maintain them and test for their viability. This information is specified on a standard contractual form which is sent to the depository along with the samples. Upon receipt of the deposit, the depository will assign it an accession number.<sup>15</sup> The applicant uses this number to reference his deposit in the written patent specification.

Once the deposit is made, the depository releases samples to requesting parties according to guidelines set out by the relevant patent office, and for a time period which usually covers, and extends somewhat beyond, the enforceable life of the patent. It is expected that the depository will check the viability of the samples periodically and require the depositor to replace them if they become non-viable. In some instances, the depository must maintain records detailing the parties to whom samples have been provided; the depository may be required to make this information available to the depositor. In exchange for a fee, the depository provides these services for the party on whose behalf a deposit is made.

In general, industrial property (patent) offices recognize as valid only those depository institutions which are independent of the parties applying for patent. Depositories should be "impartial and objective,"<sup>16</sup> and "[e]nsure the safe and reliable storage of a deposited biological material under circumstances that are free of the opportunity for intentional or negligent handling of the deposited material."<sup>17</sup> A depository institution recognized for patent purposes in a country must follow the rules and regulations established by that country's industrial property office.

## III. THE BUDAPEST TREATY COUNTRIES

To facilitate the filing of patent applications in foreign countries and obviate the need for making individual deposits in many depositories, a number of countries established a union, known as the Budapest Treaty, for the International Recognition of the Deposit of Microorga-

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15. Depositories will not accept samples under certain conditions, such as when they present a danger to the environment, or when the depository does not have the facilities to keep them viable. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1242, T.I.A.S. No. 9768 [hereinafter Budapest Treaty].

16. *Id.* at art. 6(2)(iii).

17. 54 Fed. Reg. 34,869 (1989) (advance notice).

nisms for the Purposes of Patent Procedure.<sup>18</sup> There are now twenty-two member countries of this treaty, including the United States, the European Patent Office, Australia, Japan, and the Soviet Union.<sup>19</sup> Depository authorities which acquire international status through the office of the Director-General of the World Industrial Property Organization<sup>20</sup> (WIPO) will be recognized as valid in all the member countries, and an industrial property office in any of these countries will be entitled to samples of a deposit when a patent application referring to the deposit has been filed in that country. When a deposit is made under the treaty, the depository will store and keep the samples viable and uncontaminated for a period of at least 30 years after the date of the deposit and for at least 5 years after the most recent request for furnishing of a sample was received.<sup>21</sup> The international depository authority will also notify the depositor of those parties to which it has furnished samples, the date, and the name and address of the industrial property office through which such release was effected.<sup>22</sup>

The Budapest Treaty stipulates that the industrial property offices in contracting states are entitled to samples provided that their requests are accompanied by a declaration affirming that:

- (i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject-matter of that application involves the said microorganism or the use thereof;
- (ii) such application is pending before that office or has led to the grant of a patent;
- (iii) the sample is needed for the purposes of a patent procedure having effect in the said contracting state or in the said organization of its member states;
- (iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure.<sup>23</sup>

Although the Budapest Treaty requires member countries and international depository authorities to be in conformity with these general provisions, it does not specifically identify the parties, besides the industrial

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18. Budapest Treaty, *supra* note 15, art. 1.

19. The following countries and organizations have ratified the treaty: Australia, Austria, Belgium, Bulgaria, Czechoslovakia, Denmark, the European Patent Organization, Federal Republic of Germany, Finland, France, German Democratic Republic, Hungary, Italy, Japan, Liechtenstein, the Netherlands, Norway, the Philippines, Republic of Korea, the Soviet Union, Spain, Sweden, Switzerland, the United Kingdom and the United States. Notably absent from the treaty are Canada, China, all the Latin American countries, New Zealand, South Africa, Taiwan and Thailand. Letter from A.J. Lyons, U.S. Dep't of Agric., to Thomas Denberg (May 4, 1990) (discussing the Budapest Treaty).

20. A complete list of recognized depositories is available from the Agricultural Research Service Patent Culture Collection, 1815 North University Street, Peoria, Illinois 61604.

21. Budapest Treaty, *supra* note 15, Rule 9. Budapest Treaty depository contracts require the depositor to keep the sample in the depository for this period of time, even if a deposit is not required for a patent issued by a signatory country.

22. *Id.* at Rule 11.4(g).

23. *Id.* at Rule 11.1.



property offices themselves, who will have access to deposits,<sup>24</sup> the conditions under which such access will be granted (e.g., requiring a requester to sign an undertaking not to infringe the patent), nor does it specify when such access will be granted. These details are determined by the individual patent offices and vary from country to country.<sup>25</sup> In most countries, certified parties will have access to deposits *after* publication,<sup>26</sup> which in most countries is *before* the grant of a patent.

#### A. *Australia*

"A microorganism must be deposited where a person skilled in the art could not reasonably be expected to perform the invention without having a sample of the microorganism before commencing to perform the invention and the microorganism is not readily available to a person skilled in the art."<sup>27</sup>

An applicant should be able to ask the examiner to determine if a deposit is necessary. If a specification refers to a deposit deemed unnecessary by the examiner, the reference may be deleted, thereby preventing public access.

As a member of the Budapest Treaty, Australia recognizes all international depository authorities, and apparently no others.<sup>28</sup> The Australian Government Analytical Laboratories (AGAL) in Sydney is the local Budapest Treaty depository.

The best mode known to the applicant must be disclosed at the date of filing the complete specification. The patentee must show good faith and describe the best mode in sufficient detail for a skilled worker to perform the invention. This may entail making the microorganism available to the public via a deposit.

The deposit must be made on or before the filing date of the patent specification. If a deposit is made after the priority date of the patent application, any claim based on the microorganism would not be accorded that priority date, and a new application for claims related to the microorganism would have to be filed.

Deposits become available to third parties only when specifications become open to public inspection. Generally, patent applications become public eighteen months after the priority date. Before this time,

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24. *Id.* at Rule 11.2. The Treaty stipulates that the depositor may authorize any "authority, natural person or legal entity" he chooses to be furnished with samples of his deposits at any time.

25. The Treaty provides that a "certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled . . . ." *Id.* at Rule 11.3 (a)(iii). Thus to whom, when, and under what conditions samples are provided is determined according to the "law governing patent procedure before that office." *Id.*

26. Budapest Treaty, Rule 11.3 (a)(ii). This is the case in the United States and Japan.

27. Letter from Louis C. Gebhardt to Thomas Denberg (Mar. 27, 1990) (discussing Australian patent law relating to microorganisms).

28. *Id.*

availability is limited to the patent office itself and to those authorized by the depositor.

Once the specification is open to public inspection, any person may request the Patent Commissioner to issue a certificate authorizing release of a sample of the microorganism. If granted, the certificate can then be presented to the depository authority, whether inside Australia or not, and the sample will be released. The issuance of the certificate by the Commissioner is discretionary, but the Commissioner is required to give all parties, including the applicant or patentee, an opportunity for hearing before a request to issue a certificate is granted. Presumably, the patentee is entitled to suggest certain conditions on release of the deposit (e.g., providing security for damages, signing an undertaking not to infringe the patent, and agreeing not to transfer samples to third parties).

If mention of an unnecessary deposit is not removed, denying access to the deposit would probably be very difficult since, by implication, the deposit is reasonably necessary to perform the invention. Nonetheless, during hearings, the patentee could still present counter arguments to the Commissioner concerning issuance of certificates. How much weight the Commissioner would give to such arguments would depend on the facts of the case.

#### B. *The European Patent Office*<sup>29</sup>

If an invention concerns a micro-biological process or the product thereof and involves the use of a micro-organism which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in article 83 if: (a) a culture of the microorganism has been deposited with a recognized depository institution . . . .<sup>30</sup>

Unfortunately, the applicant in the European Patent Office (EPO) must decide for himself whether a deposit is likely to be required. A patent examiner in the EPO will not make this determination and then allow the applicant to respond. If a deposit is required, but none has been made, the patent will not issue.<sup>31</sup>

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29. European Patent Convention, concluded Oct. 5, 1973, 13 International Legal Materials, No. 2,263 (Mar. 1974), U.K.T.S. 20 (1978) (entered into force Oct. 7, 1977) [hereinafter EPC]. Members include Austria, Belgium, Denmark, France, Germany (FDR), Greece, Italy, Luxembourg, the Netherlands, Spain, Sweden, Switzerland (together with Liechtenstein) and the United Kingdom. The treaty provides for a central examination in the European Patent Office with issuance and interpretation of patents in the designated countries. It will likely be some time before Ireland and Portugal join the EPC.

30. EPC, Rule 28(1).

31. On the other hand, most European Patent Office examiners now accept that the majority of recombinant DNA inventions can be reproduced without the need for a deposit. Letter from Adrian Fisher to Thomas Denberg (Apr. 19, 1990) (discussing EPC patent rules relating to microorganisms).

Only deposits made in accordance with the Budapest Treaty are accepted by the EPO.<sup>32</sup> Therefore, only deposits made in recognized Budapest Treaty depositories will be valid.

There is no requirement under the European Patent Convention to disclose the most preferred embodiment of an invention. On the other hand, quite commonly the EPO will accept generic claims, but allow more specific claims only if the appropriate deposits have been made.

The microorganism must be deposited with a recognized depository institution no later than the date of filing of the application.<sup>33</sup> If priority rights are sought based on a foreign filing, a deposit must have been made before the claimed priority date. For example, if a priority date is claimed based on a United States filing, and a deposit is required, it must be made before the United States priority filing in order for priority rights to be granted.

If a deposit is necessary, the application must include relevant information such as the characteristics of the microorganism, the name of the depository, and the accession number of the culture on deposit. The name of the depository and accession number may be submitted within sixteen months after the priority filing date, up to the date of a request for early publication of the application, or within one month after the EPO has communicated its right to inspect files, whichever comes first.<sup>34</sup>

It is important to realize that if a deposit is made and referred to in an EPO application, it is automatically considered an immutable part of the patent application and will become publicly available upon issuance of the patent, even if the patent would otherwise have issued without reference to a deposit.<sup>35</sup> Thus, applicants should be careful not to make unnecessary deposits.

From the date of filing, the depositor agrees that the deposit shall be made available to any person having the right to inspect files<sup>36</sup> for the purposes of patent application examination. The depositor also agrees that once the application is published, any person shall have the right to access deposits unless the depositor specifically requests such access to be limited to "experts" during pendency of the application.<sup>37</sup> An expert includes any natural person who has the approval of the ap-

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32. *Id.*

33. EPC, Rule 28(1)(a).

34. EPC, art. 128, para. 2.

35. EPC, rule 28(2) (providing that communication of this information "shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited culture being made available to the public . . ."). At one time, the EPO allowed deposits to be made under non-Budapest Treaty conditions and to be referred to in applications. If the examiner determined that a deposit was unnecessary, reference to it could be deleted from the specification. If, on the other hand, a deposit was deemed necessary, the applicant could convert his deposit to a Budapest Treaty deposit in order to fulfill the EPO requirements for granting patents. This provided a way for the applicant to protect his deposits from access by the public if the deposit was ultimately not required. Since July, 1986, however, this situation no longer pertains. Letter from Adrian Fisher to Thomas Denberg (Apr. 19, 1990).

36. EPC, art. 128, para. 2.

37. EPC, Rule 28(4).

plicant, or any natural person recognized as an expert by the President of the EPO.<sup>38</sup> The purpose of this provision is to allow third parties to ascertain, through an expert, whether a deposit indeed possesses certain relevant properties. As in the United States, once the patent issues, the deposits become available to any person, without territorial restriction. Unlike in the United States, however, the EPO requires the requester to sign an undertaking not to infringe the patent. The EPO also requires that the deposit not be transferred to any third party before the expiration of the patent in the last state in which it expires, and that it be used for experimental purposes only during this time period.<sup>39</sup> To receive a sample of a deposit, a requester must go through the EPO. The EPO will then transmit a copy of the request, with certification, to the depository institution as well as to the applicant or proprietor of the patent.<sup>40</sup>

### C. *Japan*

The deposit of a microorganism is required any time a patent application for an invention involving or using the microorganism is filed, except when the microorganism is readily available to persons with ordinary skill in the art to which the invention pertains.<sup>41</sup>

As in the EPO, the depositor should be aware that if a deposit is not made by the filing date and is determined to be necessary, the patent will not be granted. The written specification must refer to the accession number of the deposit; it cannot be added after filing.

If a written specification refers to a deposit, but the Patent Office later determines the deposit to be unnecessary, reference to it may be deleted from the application to prevent access by the public.

As a party to the Budapest Treaty, Japan recognizes deposits made in any authorized international depository. Deposits may also be made with the Fermentation Research Institute (FRI) in Ibaraki-ken<sup>42</sup> if the applicant prefers not to apply under the provisions of the Treaty.

There is no requirement to disclose the most preferred embodiment of an invention under the Japanese Patent Law,<sup>43</sup> hence no deposits are required unless narrow claims are sought for a specific embodiment which is not readily available to routineers.

If a deposit is required, it must be made prior to the patent application priority date. If made after this date, the date is lost. When a de-

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38. EPC, Rule 28(5).

39. EPC, Rule 28(3)(a),(b). These provisions shall not apply insofar as the requester is using the culture under a compulsory license. The term "compulsory license" is defined as including *ex officio* licenses and the right to use patented inventions in the public interest. EPC, Rule 28(3).

40. EPC, Rule 28(8).

41. Letter from Shusaku Yamamoto to Thomas Denberg (Apr. 11, 1990) (citing Japanese Patent Law, rule 27-2(1)).

42. S. BENT, *INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE* 505 (1987).

43. Letter from Shusaku Yamamoto to Thomas Denberg (Apr. 11, 1990) (citing Japanese Patent Law, rule 36(3)).

posit is made after the priority date and on or before the Japanese filing date, only the Japanese filing date is retained.<sup>44</sup>

In Japan, normal patent procedure calls for two publications of an application. The first (Kokai or "laying-open") publication occurs after the complete application is received by the patent office. The applicant then has seven years in which to request examination of the application, after which time a second (Kokoku) publication takes place if a patent is granted.

The deposited material will become available to members of the public, both international and domestic, after the patent application has been published the second time, that is, after the Kokoku publication when the patent is granted.<sup>45</sup> Access to deposits before the Kokoku publication (and after Kokai publication) is limited to those who have been both approved by the Japanese Patent Office and issued an infringement warning by the applicant or to those who require a sample in order to respond to the Patent Office in other patent applications (e.g., to those who have received an Official Action for rejection of their applications filed after the subject application). If, for some reason, reference to an unnecessary deposit is not deleted from a specification, it may be possible to petition the Japanese Patent Office not to authorize its release.<sup>46</sup>

Individuals who request samples of a deposit are not required to sign an undertaking not to infringe the patent, but they must agree not to use the deposited material for any purpose other than tests and experimentation, and are prohibited from giving the material to third parties.<sup>47</sup> Furthermore, they are required to make direct contact with the depository. The depository, in turn, seeks authorization from the Japanese Patent Office. For example, if a Japanese patent relies on a deposit made in the ATCC (an American depository), a request should be presented to the ATCC for release of a sample of the deposit. The request is then forwarded to the Japanese Patent Office. The Japanese Patent Office grants approval according to the provisions established by that office, and then communicates this back to the ATCC. Assuming approval is granted, a sample is then made available to the requester.<sup>48</sup>

#### D. *The Philippines*

In the Philippines, requests for patents involving novel strains of microorganisms, or useful substances derived from them, require deposits in Budapest Treaty depositories. Furthermore, the deposit

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44. *Id.* (discussing Japanese patent law).

45. *Id.* (citing Japanese Patent Law, rule 27-3(1)).

46. Additionally, if an unnecessary deposit is made in the Japanese FRI depository, under non-Budapest Treaty conditions (all deposits made under Budapest Treaty conditions cannot be removed for at least 30 years, according the provision of the contract), the depositor can remove the deposit by written request or by ceasing to pay the yearly maintenance charges. Letter from Shusaku Yamamoto to Thomas Denberg (Apr. 11, 1990).

47. *Id.* (citing Japanese Patent Law, Rule 27-3).

48. *Id.*

must be referenced in the written specification.<sup>49</sup> Thus, even if a written specification alone provides enough information for enabling others to make and use a microorganism, a deposit must still be made in order to meet the requirements of Philippine patent law.<sup>50</sup> In addition, the best mode devised by the inventor for carrying out his invention must be set forth.<sup>51</sup>

The Philippines does not currently have a depository of its own. Nationals typically make deposits in Japan, but any depository of recognized standing is valid. Applicants, however, have the burden of showing that a depository should be recognized. All Budapest Treaty depositories are considered valid.

The best time to make a deposit is before or at the time of filing. If no deposit is made by the time of filing, the patent examiner will require one. Presumably, this means that an application will not be rejected if a deposit is not made by the time of filing; the patent examiner will simply issue a reminder to make a deposit before examination of the application.

Philippine law is not clear as to whether a priority date can be based on the date of an original filing if a deposit was made after this date. Likewise, it is not apparent what happens when no deposit was required in the priority filing. However, if an applicant seeks to base his priority date on a filing in another country, the priority date actually assigned will not be any later than the date the original deposit was made. In this case, the applicant must certify that the taxonomic information in the application corresponds to that of the deposit.

Deposits are made available to the international public at the time the patent is issued. Prior to issuance, the application and the deposit are confidential. There are no regulations regarding restrictions on access to deposits, such as undertakings not to infringe. The Bureau of Patents, Trademarks and Technology Transfer may notify the depository to release deposits to the public, but ordinarily it is the responsibility of the party obtaining the patent to do so.

#### E. *South Korea*

Deposits should be made if an invention cannot be easily worked by a person skilled in the art, however there is no special requirement to disclose the best mode of an invention under Korean Patent Law.<sup>52</sup>

Korea is a member of the Budapest Treaty, thus any recognized Budapest Treaty depositories are valid. In addition, Korea has two internal depositories, the Korean Collection for Type Cultures and the Korean

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49. Letter from Llewellyn L. Llanillo to Thomas Denberg (July 17, 1990) (citing to BUREAU OF PATENTS, TRADEMARKS AND TECHNOLOGY TRANSFER, MEMORANDUM-CIRCULAR TSE/73-1 (1973)).

50. Philippine Patent Law § 14-(d).

51. Letter from Llewellyn L. Llanillo to Thomas Denberg (July 17, 1990) (citing to Rules of Practice in Patent Cases, rule 62(b)).

52. Letter from Kim Myung Shin to Thomas Denberg (June 12, 1990).

Federation of Culture Collection of Microorganisms. Although these are not currently Budapest depositories, they are expected to be designated as such within the year. If the first filing occurs in Korea, the microorganism must be deposited with one of the Korean domestic depositories designated by the Commissioner of the Korean Patent Office no later than the filing date. The specification must include the accession number. If priority is claimed based on a foreign filing, the depositor need only submit the Deposit Certificate from that depository to the Commissioner of the Korean Patent Office at the time the application is filed in Korea. Presumably, in the course of prosecution, it should be possible to inquire as to the necessity of making a deposit. If a deposit is not required, any reference to it should be deleted from the specification.

If a specification refers to a deposit, the deposit must be made available upon publication of the application, which normally occurs eighteen months after the filing date in Korea (or eighteen months after the priority date if priority is claimed). The depositor or applicant for the patent should notify the depository, or confirm, that deposits are available at this time. If the deposit is not available at this time, an interested party may demand a trial, through the Korean Patent Office, calling for invalidation of the patent. The depositor and depository agree, at the time of deposit, that samples shall be furnished to the Commissioner of the Korean Patent Office, to the depositor or any person approved by the depositor, or to anyone, as long as: (a) the furnishing of samples of the microorganism is restricted to within the national territory; (b) the purpose of furnishing a sample is clearly for experiment or research; and (c) the microorganism furnished is not refurnished to a third party. Furnishing of a microorganism is made by contract between the depository and the person requesting a sample. The person seeking the sample must sign an agreement not to infringe the patent.

#### F. *The United States*

According to the United States statutory requirements, an application for a patent must include a specification which contains:

a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.<sup>53</sup>

In addition to the written specification, actual biological material must be deposited if it is not known and readily available to the public or cannot be made or isolated without undue experimentation.<sup>54</sup> Unlike mechanical inventions, a person with ordinary skill in the art may have

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53. 35 U.S.C. § 112 (1988).

54. 37 C.F.R. § 1.802(b) (1990).

insufficient knowledge about the particular biological material to enable him to make or use the invention solely from a written description.

The necessity of making a deposit is decided on a case-by-case basis by the patent examiner.<sup>55</sup> Reference to a deposit of biological material in a specification does not create any presumption that a deposit is required.<sup>56</sup> Thus, if the examiner decides that a deposit is unnecessary, reference to it may be deleted from the disclosure, preventing public access.

In the United States the best mode of an invention must be disclosed.<sup>57</sup> Whether an actual deposit is required to disclose the best mode will be decided on a case-by-case basis by the patent examiner according to the inventor's claims.<sup>58</sup> In some instances, deposits not required to broadly enable an invention may still be required to enable the specific, preferred embodiment. As most patent applications present both broad and narrow claims, the patent examiner may determine that a deposit is necessary for the latter if the best mode cannot be described in words alone.

The United States honors deposits made in any recognized Budapest Treaty depository.<sup>59</sup> In the United States, the principal depository agencies are the Agricultural Research Culture Collection (NRRL) in Peoria, Illinois, the American Type Culture Collection (ATCC) in Rockville, Maryland, and the In Vitro International, Inc. depository in Linthicum, Maryland. Each is recognized as an authorized international depository under the Budapest Treaty. If the depositor wishes, deposits may be made under the provisions of the Treaty.

Deposits not made in Budapest Treaty depositories may be made in other depositories, such as university laboratories, as long as the depository is independent of the assignee or inventor, and complies with the requirements for acceptable depositories as determined by the Commissioner of Patents and Trademarks.<sup>60</sup> Deposits made in these institutions will be valid for United States patent procedures only, and will not be honored in Treaty countries.

A deposit needed to satisfy statutory requirements can be made at any time before filing the application for patent, or any time during the pendency of the application.<sup>61</sup> If made during pendency, the deposit must be made no later than the time period set by the examiner at the time the Notice of Allowance and Issue Fee Due is mailed.<sup>62</sup> The time

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55. 37 C.F.R. § 1.809(a) (1990).

56. 37 C.F.R. § 1.802(c) (1990).

57. 35 U.S.C. § 112 (1988).

58. 37 C.F.R. § 1.809(a).

59. 37 C.F.R. § 1.803(a)(1) (1990).

60. 37 C.F.R. § 1.803.

61. *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985).

62. 37 C.F.R. § 1.809 (1989). But note that "[w]hen the original deposit is made after the effective filing date of an application for patent, the applicant shall promptly submit a verified statement from a person in a position to corroborate the fact, and shall state that the biological material which is deposited is biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice



period is normally three months although petition for extension can be made.<sup>63</sup> If a required deposit is not made according to these provisions, the application will be abandoned for failure to prosecute.<sup>64</sup>

As mentioned above, applicants who plan to rely on a filing date in the United States for claiming priority rights in foreign countries need to be aware of those countries' requirements regarding deposits. In certain countries, if a deposit is not made before the original filing date in the United States, the claimed priority date may not be honored.

The depositor may, at the time of making a deposit, elect to either make the deposit available to any bona fide requester from the international public as of the date of deposit or, more commonly, elect to limit access until a patent issues. In any event, during pendency of an application the depositor agrees to make the deposit available to anyone entitled to it, as determined by the Commissioner of Patents. In this way, the deposit is afforded the same confidentiality as the written patent application.<sup>65</sup> Once a patent issues, all restrictions regarding access to the deposit will be removed<sup>66</sup> and the depository will release the deposit to any bona fide requesters.<sup>67</sup> The depositor may, however, require the depository to notify him in writing of the date, name, and address of the parties to whom samples are furnished.<sup>68</sup> These provisions are automatic for deposits made under the Budapest Treaty<sup>69</sup> and the depositor is not required to make special arrangements with the depository. In the case of the NRRL, the depository will notify the depositor when strains are distributed to third parties if the strain was deposited under the Budapest Treaty. Otherwise, it is the depositor's responsibility to request this information, as is necessary.<sup>70</sup>

Notification presumably gives the depositor an idea of who might be infringing his patent. Parties receiving deposits, however, are not specifically required to sign an undertaking not to infringe, and may give samples to any third party they wish. Further, there is no requirement that an obtained deposit be used for experimental purposes only. In order to receive a sample of a deposit kept in the ATCC or NRRL, the

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before the Office, in which case the statement need not be verified." 37 C.F.R. § 1.804(b) (1989).

63. 37 C.F.R. § 1.136 (1989).

64. 37 C.F.R. § 1.809(c) (1990).

65. 35 U.S.C. § 122 (1988).

66. 37 C.F.R. § 1.808(a)(2) (1990).

67. A. LYONS, PROCEDURES AND POLICIES FOR DEPOSITION OF STRAINS OF MICROORGANISMS FOR PATENT PURPOSES IN THE AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL) 1 (1989). Note, however, that where a deposit is not required but mentioned in a specification, public access becomes a requirement of the depository but not the Patent and Trademark Office. If a deposit made and referred to in an application is deemed unnecessary, its lack of availability will not affect the validity of the patent. This is illustrated in circumstances where a deposit becomes non-viable: the depositor will not have to replace the sample in the depository. Statutory law states that "in no case is a replacement or supplemental deposit of a biological material necessary where the biological material . . . need not be deposited." 37 C.F.R. § 1.805(g) (1989).

68. 37 C.F.R. § 1.808(b)(3).

69. Budapest Treaty, *supra* note 15, at Rule 11.4(d),(g).

70. A. LYONS, *supra* note 67, at 5.

requester may go directly to the depository with a copy of the issued patent. Other depositories may require the depositor to notify them when a patent has issued and authorize them to release samples in order to fulfill the requirements for patent.

### G. *The USSR*

Any invention which "is a microorganism or the use of said microorganism"<sup>71</sup> requires a deposit in a depository within Russia or in a depository recognized under the Budapest Treaty. There are no Budapest Treaty depositories within the USSR. Deposit is not obligatory if the applicant can prove that the microorganism has been previously available to the public, provide the deposit access numbers from recognized depositories, or show that the organism is widely used in a scientific practice, such as taxonomic standard, model, or neomodel strains.

Members of the public may be given access to the deposit after publication of a report about the issuance of a patent if the Patent Office certifies that the particular person requesting the deposit has a right to obtain the organism and specifies the registration number of the deposit.<sup>72</sup> However, the depository is not bound to make samples of microorganisms which have properties harmful to humans and the environment available to a person who is considered to be unable to handle the microorganisms with proper care.

It is recommended that deposits be made prior to filing a patent application. The certificate proving deposit can be filed with the Patent Office up to two months after the filing date of the application, however the date of receipt of the certificate will be regarded as the application priority date.

There is no "best mode" requirement for patent applications in the USSR, however, if a preferred embodiment is claimed, such as in a dependent claim, it must be supported by deposit.

## IV. THE NON-BUDAPEST TREATY COUNTRIES

### A. *Argentina*

Although Argentina has not adopted the Budapest Treaty,<sup>73</sup> it permits microorganisms to be patented and ascribes to the conditions of the Treaty, namely that a deposit is required when a written specification alone is not enabling, or the materials are not available to the public. If the examiner determines that a deposit is not necessary, reference to such may be deleted from an application. If a deposit is necessary, however, it must be made before the Patent Office examines the application to avoid compromising the filing date. Only Budapest Treaty depositories are recognized; Argentina does not have a depository of its own.

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71. USSR Regulations under the Budapest Treaty, §§ 11.1, 11.3.

72. *Id.* § 11.3(c).

73. Letter from Hausheer, Belgrano & Fernandez to Thomas Denberg (May 2, 1990).

Further, there is no requirement to disclose the best mode of an invention. Finally, there are no rules governing public access to the deposits.

### B. *Brazil*

While patenting microorganisms has been the object of study of the Brazilian Patent Office, universities and research institutes, Brazil has not accepted the Budapest Treaty<sup>74</sup> and currently has no regulations regarding this matter. The studies have focused on defining the best manner of protection, rather than raising the threshold issue of whether microorganisms should be patented. Thus, one may conclude that, in Brazil, microorganisms *per se* are patentable. The only prohibition for patenting microorganisms relates to inventions involving foodstuffs and medicines. These are not patentable.<sup>75</sup> Conversely, inventions involving microorganisms that are *processes* are patentable.

Presently, no deposit is required to support the description of biotechnological inventions. Nonetheless, it is recommended that the applicant refer to deposits made in Budapest Treaty depositories in his specification.

### C. *Canada*

Canada is not a member of the Budapest Treaty and there are no statutory provisions in the Canadian Patent Act regarding the deposit of microorganisms.<sup>76</sup> A recommendation that Canada accede to the Treaty is under consideration,<sup>77</sup> but no bill has been introduced into the House of Commons. There has been a precedent, however, for allowing deposits of microorganisms to satisfy the disclosure requirements of the Patent Act.<sup>78,79</sup>

To satisfy the requirements of the Canadian Patent Act an applicant must, in the specification of his invention, correctly and fully describe the invention and its operation or use, as contemplated by the inventor.<sup>80</sup> In practice, this means that a specification must be enabling in and of itself. One case,<sup>81</sup> however, established a precedent for allowing deposits of microorganisms to fulfill description requirements, although

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74. Letter from Carlos C.C. Pires to Thomas Denberg (May 3, 1990).

75. Brazilian Patent Law, art. 9.

76. Letter from Cynthia J. Ledgley to Thomas Denberg (May 8, 1990).

77. "Canada should sign and ratify the Budapest Treaty." TASK FORCE ON THE STATUS OF CULTURE COLLECTIONS IN CANADA, REPORT TO THE MINISTER OF STATE (SCIENCE AND TECHNOLOGY), Recommendation 26 (1988) [hereinafter TASK FORCE].

78. *In re* Application of Abitibi Co., 62 C.P.R.2d 81 (1982) (holding that a mixed yeast culture was patentable *per se* and that a deposit of the culture in a culture collection would enable reproduction of the invention by the public).

79. Note that this applies to microorganisms only. Plants are not included as has recently been emphasized by the Supreme Court of Canada in *Pioneer Hi-Bred v. Commissioner of Patents*, 25 C.P.R.3d 257 (1989), in which a seed deposit was not accepted to fulfill the description requirements for a soya-plant line cultivated naturally but resulting from artificial cross-breeding of three known varieties to produce a new hybrid, because the court did not feel such a deposit supported the case.

80. Patent Act, CAN. REV. STAT. ch. P-4, § 34(a) (1985).

81. *Abitibi*, 62 C.P.R.2d at 81.

current practice regarding deposits is not codified in any written document.

Apparently, deposits would be allowed in instances where a written description alone is not enabling, as in the United States and EPO. In *Pioneer Hi-Bred v. Industrial Commissioner of Patents*,<sup>82</sup> Judge Lamer notes in dicta that "the practice of a deposit is simply intended to require the applicant submitting a process involving a microorganism unknown and inaccessible to the public as a *necessary part of reproducing* the invention to deposit a culture of the microorganism with the authorities.<sup>83</sup> The language "microorganism unknown and inaccessible to the public" is very similar to that of other countries, such as the United States,<sup>84</sup> which have specific requirements regarding deposits. It seems that deposits in Canada should be made for the same reasons they would be made in these countries; namely, to complete the description insofar as the deposit provides a specific embodiment of the invention and enables the invention to be reproduced.<sup>85</sup> To meet the requirements of the Canadian Patent Act, however, a written description should be as complete as possible; a mere reference to a deposit will be rejected.

Since there are no provisions for requiring deposits, the Canadian Patent Examiner will not automatically issue a determination regarding the necessity of a deposit. The applicant must decide whether a deposit is required for the granting of a patent. The Canadian Patent Office will accept deposits made in any Canadian tissue culture collection,<sup>86</sup> as well as deposits made in the ATCC, but again, there is no law addressing this point.

The Act is silent with respect to best mode requirements for inventions involving microorganisms. An applicant must determine independently whether a deposit would be helpful for getting broad coverage of claims for an invention or narrow coverage for a specific embodiment.

It is recommended that deposits be made before filing the application. Alternately, a deposit may be made before the patent issues, if it can be established that the deposited material is the same as that on hand at the time of filing.<sup>87</sup> Presumably, if an examiner determines that a written description alone is enabling, an amendment can be made to the specification, within one year of the date of filing,<sup>88</sup> to eliminate

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82. 25 C.P.R.3d 257 (1989) (emphasis added). Judge Lamer refers here to the *Abitibi* case but erroneously limits the *ratio decidendi* in *Abitibi* to "a process." That case also allowed claims to the cell line *per se*.

83. *Id.* at 272.

84. 37 C.F.R. § 1.802(b) (1990). "Biological material will need to be deposited if it is not known and readily available to the public or cannot be made or isolated without undue experimentation." *Id.*

85. There is a recommendation under consideration that Canada should require both a description and a deposit of the organism in order to meet the disclosure requirements. If adopted, deposits would be required in all instances. See TASK FORCE, *supra* note 75, Recommendation 24.

86. *The Directory of Canadian Culture Collections 1986* lists 140 collections in Canada.

87. This is in line with United States policy. See *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985).

88. See Patent Act, CAN. REV. STAT. ch.33, § 27(1.1) (Supp. 1989).

references to the deposit. The applicant should be aware of the danger of the deposit being considered new subject matter in instances where the written description cannot be proved to correspond to the deposit. In this case, the filing/priority date may be lost. No statutes or other written policies address the question of to whom, when and under what conditions deposits are released. At the present time, it appears that a depository will not release a deposit without written consent from the patent applicant.

#### D. *China*

China is not presently a member of the Budapest Treaty,<sup>89</sup> however, Chinese patent law stipulates that:

[i]n the case of microorganisms, including various bacteria, actinomycetes, yeasts, filamentary fungi, higher fungi, cell lines, viruses, plasmids existing in the above host cells, and strains of unicellular algae, which are essential in the embodiment of the subject invention, are not available to personnel of this area of technology (in the People's Republic of China), and are involved in the applications in China for patents, the subject microorganisms are deemed to be essential components of application specifications, and must be submitted in the form of two samples to the China Center for Type Culture Collection (CCTCC), designated by the Chinese Patent law, for deposit, prior to, at least not later than the date of filing of the subjected applications with the C[hina] P[atent] O[ffice].<sup>90</sup>

Thus, deposits are mandatory and only the CCTCC is a recognized depository. The period of deposition of a culture is thirty years, with an extension of five years if the applicant makes a request before expiration of the patent. Additionally, the specification of the patent application must describe in detail the best mode contemplated by the applicant for carrying out an invention.<sup>91</sup>

According to the law cited above, deposits must be made no later than the filing date. Moreover, the applicant must determine independently if a deposit is likely to be required for complete disclosure. Failure to submit the necessary strains in a timely manner may cause the examiner to reject the application on the ground that the specification is insufficient.

If priority is based on a foreign filing, deposits must be made in China before the Chinese filing date. Even though China is not a member of the Budapest Treaty and recognizes only its own depository, it appears that China will grant priority rights based on foreign filings, even if the granting of the priority patent did not rely on a deposit and none was made.

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89. Letter from Xu Yiping to Thomas Denberg (Mar. 28, 1990).

90. Regulations for the Implementation of the Patent Law of the PRC, STATUTES AND REGULATIONS OF THE PEOPLES REPUBLIC OF CHINA, vol. II, § 850119, art. 25 (University of East Asia Press 1987).

91. *Id.* at art. 18(8).

After the pre-examination publication of an application, but prior to the granting of a patent right, anyone wishing to use the microorganism in question must file a request with the Chinese Patent Office. This request must include: (a) an undertaking by the entity or individual making the request not to make the microorganism available to any other person; and (b) an undertaking to use the microorganism for experimental purposes only before the grant of the patent right.<sup>92</sup>

After the granting of the patent right, deposits are released only to those parties authorized by the owner of the patent. In negotiating contracts with other parties, the patentee can place any restrictions he wishes on the release of the deposit. A requester must go through the patentee to access a deposit.

#### E. *Colombia*

In principle, microorganisms are not patentable in Colombia.<sup>93</sup> The issue, however, of whether a particular microorganism is patentable seems to be decided on a case-by-case basis by the patent examiner. It does not appear that Colombia is considering becoming a member of the Budapest Treaty, and there is no legislation related to the issue of deposits.

#### F. *Costa Rica*

Costa Rica has not ratified the Budapest Treaty and there is no indication that it will do so.<sup>94</sup> Although Costa Rica does not allow patenting of microorganisms *per se*, nor of processes that involve microorganisms,<sup>95</sup> their Supreme Court is currently hearing arguments against this policy.

#### G. *Ecuador*

Like Costa Rica, Ecuador does not currently allow microorganisms to be patented. Certain reforms, however, are under consideration.

#### H. *Egypt*

The question of becoming a member of the Budapest Treaty is not under consideration in Egypt.<sup>96</sup> Patent applications with claims related to strains or species of microorganisms *per se* are not allowed. Inventions related to foodstuffs, new substances, medicinal drugs and pharmaceutical compounds are not patentable,<sup>97</sup> but the processes for

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92. *Id.* at art. 26.

93. "Patents shall not be granted for: . . . b) Vegetable varieties or animal breeds, or essentially biological procedures for obtaining vegetables or animals." The Andean Pact, art. 5, Decision 85.

94. Letters from Hugo Jimenez Gutierrez to Thomas Denberg (May 1990).

95. Law Governing Patents for Inventions, Industrial Drawings and Models, and Improvement Models, COSTA RICA LAW 6867, art. 1, § 3(b) (1983).

96. Letter from Moufid El Dib to Thomas Denberg (Apr. 21, 1990).

97. Patents Act of Egypt, art. 2B.

making such materials may be patentable if they are new. If a process relies on the use of microorganisms, the specification must contain a complete scientific description and taxonomic information concerning the microorganism used in the production. Since the situation has yet to arise, it is not known whether Egypt would accept deposits to supplement incomplete written descriptions when it is impossible to provide the necessary additional information in written form.

### I. *India*

India does not permit patents for processes or substances involving microorganisms. Further, there is no indication that India will accede to the Budapest Treaty in the near future.<sup>98</sup>

### J. *Ireland*

Ireland has no present plans to become a member of the Budapest Treaty. The Irish Government, however, intends to ratify the European Patent Convention before 1992, and it is expected that ratification of the Budapest Treaty will follow.<sup>99</sup>

While it has no specific legislation regarding the deposit of microorganisms, Ireland will most likely adopt the policy of the United Kingdom<sup>100</sup> and require deposits where a written specification alone is not enabling or where the relevant materials are not available to one skilled in the art.

Since specific legislation regarding deposits does not exist, it is unlikely that a patent examiner would require a deposit. It appears, though, that where a written specification alone is insufficient, the Irish Patents Office will honor a deposit. Deposition in a recognized Budapest Treaty depository is recommended. Further, there is a requirement to disclose the best mode of an invention.

A deposit should be made as of the filing date of the patent application or by the priority date in the case of a European Patent Convention application. It is not clear whether the Patent Office will allow a late deposit if the specification is deemed insufficient. All provisions for the release of deposits should be negotiated by the depositor with the relevant depository since Ireland, not a member of the Budapest Treaty, has no formal agreements with these institutions. It is unclear as to when a deposit is made available to the public.<sup>101</sup> It appears that Ireland would prefer to follow the provisions of the EPO with respect to matters such

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98. Letter from Pravin Anand to Ellen P. Winner (June 1, 1990).

99. Letter from Don McAleese to Thomas Denberg (May 2, 1990).

100. *Id.* McAleese believes that the Irish Court would follow the decisions of the English Court of Appeal and the House of Lords in *Dann's Application* 1966 R.P.C. 532, 1971 R.P.C. 425 (holding that a specification was not insufficient for lack of a deposit since it was sufficiently identified in the specification).

101. In *American Cyanamid (Dann's Patent)*, 1971 R.P.C. 425, the court states in dicta that public access need not be granted until publication of the application following acceptance. In *American Cyanamid v. Berk*, 1976 R.P.C. 231, however, the court suggests that the relevant date is the filing date of the complete specification.

as timing, authorization and restrictions placed on making deposits available.

#### K. *Israel*

Although Israel has signed the Budapest Treaty, it has not yet been ratified by the Israeli government. A committee is currently reviewing Israeli Patent Law, and, if the law is amended, it is expected that the provisions of the Budapest Treaty will be incorporated, and the Treaty ratified.<sup>102</sup>

Currently, Israel has no legislation regarding deposits. Accordingly, it does not require deposits of microorganisms in any particular instance. If a written description alone is not enabling, it may honor deposits to supplement the written description. Presumably, one may ask the examiner if a written specification is sufficient and, if so, delete any unnecessary reference to deposits. Further, it is sufficient that the specification indicates how the invention can be carried out. There is no stipulation that the best mode must be disclosed.

Deposits should be made prior to filing the first application. Deposits made after this date may necessitate postdating of the application if they are required for enablement. Israel has no recognized depository of its own. Any authorized collection in the United States, Europe or Japan will be recognized.

Provisions for release of deposits must be made between the depositor and the depository. Deposits should be made available, at least to the public in Israel, when the complete specification has been published and the patent granted. Requiring undertakings not to infringe, not to give samples to third parties, and to use the material for experimental purposes only is most likely permitted in Israel.

#### L. *Mexico*

Biotechnological, genetic and chemical (pharmaceutical) inventions are not patentable in Mexico. Biotechnological processes are also not patentable at present.<sup>103</sup> A new patent law, currently being considered by the Mexican Congress, would allow patenting of such inventions. If approved, the law would be effective by June 1991.<sup>104</sup>

#### M. *New Zealand*

In 1988 the Industrial Property Advisory Committee (IPAC) of New Zealand strongly recommended that New Zealand accept the Budapest Treaty but, to date, this has not occurred.<sup>105</sup> New Zealand's law is unclear on the requirement for deposits and the release of deposits. Nothing in their Patents Act or Regulations specifically mentions deposits,

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102. Letter from Dr. Yitzhak Hess to Thomas Denberg (Mar. 22, 1990).

103. Letter from Jaime Delgado to Thomas Denberg (Mar. 26, 1990).

104. Letter from Oswaldo Pacheco to Dr. Donna M. Ferber (May 24, 1990).

105. Letter from D.C. Calhoun to Thomas Denberg (Mar. 22, 1990).



however, they can be used to complement written descriptions for patent applications involving microorganisms. At a meeting of the Committee of Experts on Biotechnological Inventions and Industrial Property convened by the New Zealand Patent Office in October, 1988,<sup>106</sup> a majority of delegates and representatives approved the following World Intellectual Property Organization suggestion regarding the requirement for deposits:

Where an invention concerns a microorganism, or involves the use of a microorganism, which is not available to the public and which cannot be described in a patent application in such a manner as to enable a person skilled in the art to carry out the invention, such an invention shall be regarded as having been sufficiently disclosed only if the microorganism has been deposited with a recognized depository institution and samples thereof are available according to the applicable law, and if the patent application contains such relevant information as is available to the applicant on the characteristics of the microorganism.<sup>107</sup>

Although this suggestion has not been enacted into law, it is very similar to legislation in the United States, EPO, and Australia, and will probably become the official policy of the New Zealand Patent Office. Case law affirms that a deposit is necessary, when there is insufficient information in a disclosure, to enable an invention to be performed or to enable microorganism strains to be identified.<sup>108</sup>

Since there is no formal statute governing deposits, a patent examiner will not issue an unsolicited opinion as to whether a deposit is required. Hence it is the applicant's responsibility to either make a deposit before filing an application or, if no deposit is made and an application is deemed non-enabling by an examiner, to make a deposit after filing and amend the specification accordingly.

Although not a signatory to the Budapest Treaty, New Zealand only accepts deposits made in Budapest Treaty depositories. There are no recognized depositories in New Zealand at present, and, according to the Assistant Commissioner of Patents, none will be recognized in the future unless they are able to meet the requirements of the Budapest Treaty.<sup>109</sup>

There is a requirement<sup>110</sup> to disclose the best method of putting an invention into practice, similar to the best mode requirements of the United States. In some instances, deposits not required to broadly enable an invention may still be required to enable the specific, preferred embodiment. As most patent applications present both broad and

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106. Letter from D.C. Calhoun to Thomas Denberg (Apr. 23, 1990) (referring to a discussion paper prepared by the Biotechnology Committee).

107. INTERNATIONAL BUREAU OF WIPO, WIPO DOCUMENT BioT/CE/IV/3: REVISED SUGGESTED SOLUTIONS CONCERNING INDUSTRIAL PROPERTY, PROTECTION OF BIOTECHNOLOGICAL INVENTIONS (1988).

108. See American Cyanamid (Dann's Patent), 1971 R.P.C. 425.

109. Calhoun, *supra* note 103.

110. New Zealand Patents Act, § 10(3)(b) (1953).

narrow claims, the applicant may decide that a deposit is necessary if the best mode cannot be described in words alone.

The recommended time for making a deposit is before filing of the priority application. If a deposit is made after this date, the difficulties encountered are much the same as those discussed above for Canada. There is always some danger that a deposit made after the filing date could constitute a new matter giving rise to postdating of the application. If it can be shown, however, that the organism was held by the applicant on the filing date and subsequently deposited, then the deposit and reference to it is considered to have been disclosed in the original description. This is the principle of inherent disclosure, and in instances where it can be shown to apply, filing/priority dates should not change.<sup>111</sup>

There are no formal provisions governing public access to deposit samples. Presumably, the Patent Office has access to deposits during pendency of an application. It should be noted, however, that the New Zealand Patent Office has no written agreement with Budapest Treaty depositories. Accordingly, Treaty depositories will not release samples without written consent of the depositor. It is recommended that samples be made available, at least to bona fide requesters in New Zealand, at the time the complete specification is published. According to the recommendations made by IPAC, failure to make a deposit publicly available by this date would invalidate the patent. Interested third parties can oppose the granting of a patent within three months from the date of acceptance and publication. In order to present counter arguments, these parties should have access to the complete description, including deposits if these are required for enablement.

If a deposit is made and referenced in a specification which is later determined to be enabling by itself, reference to the deposit can be deleted during prosecution in order to prevent public access. If reference to a deposit is not deleted, it is unclear whether the deposit would have to be released. Not releasing the deposit could give rise to an action for revocation on the grounds that the patent was issued under false pretenses, namely that the culture would be available.

There are no provisions in New Zealand regarding what type of restrictions may be placed on the release of deposits, however, the IPAC recommends following the practice of the United Kingdom which requires undertakings that samples be used in a non-infringing manner. Currently, the means of preventing the misuse of a sample obtained by a third party is to start an infringement action.

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111. Calhoun, *supra* note 103. According to this source, there is a decision before the Assistant Commissioner in the New Zealand Patent Office which supports this principle. In that case a description was made of a chemical compound whose formula was not known at the date of filing of the complete specification. The applicant was allowed to enter the chemical formula into the specification without postdating. This would appear to be the same in principle as the entry of details of a deposit made after the date of filing. *Id.*

To obtain a sample, a member of the public must have the depositor's authorization and go through the depository since the New Zealand Patent Office has no formal agreements with international depository authorities.

N. *Paraguay*

In Paraguay, there is no legislation referring to the patentability of microorganisms or biotechnology.<sup>112</sup>

O. *Peru*

In Peru there is no special legislation covering the patentability of microorganisms or biotechnology.<sup>113</sup>

P. *South Africa*

Suggestions that South Africa become a member state of the Budapest Treaty have met with opposition.<sup>114</sup> The issue has yet to be fully addressed and no steps have been taken to achieve membership status. It is expected that South Africa will adopt the EPO legal and procedural requirements relating to microorganism deposits. Thus, where no specific statutes exist regarding microorganism deposits, it is safest to refer to EPO policy.

The South Africa Patents Act states:

If a complete specification claims as an invention a microbiological process or a product thereof, and requires for the performance of the invention the use of a microorganism which is not available to the public on the date of lodging of the application and which cannot be made or obtained on the basis of the description in the specification, the microorganism shall before the acceptance of the application be dealt with in the prescribed manner.<sup>115</sup>

This section, which leaves the term "prescribed manner" undefined, is not yet in operation. Proposed regulation 28*bis* would provide clarification of this law. It states that a specification, in instances where a microorganism is not available to the public and cannot be obtained by the written description alone, will be regarded as fully describing, ascertaining and disclosing the invention if:

- (a) A culture of the microorganism has been deposited in a culture collection recognized by the European Patent Office for the purpose of Rule 28 of the implementing regulations to the Convention or the grant of European patents;
- (b) the complete specification gives such relevant information as is available to the applicant on the characteristics of the microorganisms; and

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112. Letter from Gladys Bareiro de Modica to Thomas Denberg (Mar. 26, 1990).

113. Letter from Alejandro Botto B. to Thomas Denberg (May 10, 1990).

114. Letter from G.L. Erlank to Thomas Denberg (Mar. 16, 1990).

115. South Africa Patents Act, § 32(6).

(c) the complete specification gives the date when the culture was deposited, the culture collection in which it was deposited and the file number of the deposit.<sup>116</sup>

These regulations have not been implemented, and the mode of deposit currently has no relevance as to the validity of a patent. It would be prudent to comply with the provisions of section 32(6) until South Africa adopts regulations because patents may be considered invalid on the ground of insufficiency of disclosure if the written description alone is not enabling.

South Africa has no provisions for opposing patent applications. An application received by the Patent Office undergoes a formal examination in which the examiner verifies that the proper drawings accompany the specification and that the application is otherwise in proper form. Once the application is accepted and published, any party can go to the Court of Commissioner of Patents to apply for revocation of the patent. Apparently the examiner will not decide whether a deposit is required, hence the applicant carries the burden of deciding whether a deposit is necessary. It is also the responsibility of the applicant to make sure that the deposit is available to the proper parties or risk challenge and revocation of the patent on the grounds of insufficiency.

No depositories are officially authorized at present, but based on proposed regulation 28*bis*, it appears that South Africa will recognize the same depositories as the EPO. Since the EPO recognizes only Budapest Treaty depositories, this means that only international depository authorities of the Budapest Treaty will be recognized by South Africa, whether or not South Africa accedes to the Treaty. Since South Africa is not a member of the Treaty, and thus has no formal agreements with Budapest depositories, applicants must authorize the depositories to release samples to the proper parties after the patent has issued.

According to the Patents Act, a complete specification shall "disclose the best method of performing the invention known to the applicant at the time when the specification is lodged at the patent office."<sup>117</sup> The term "best method," as opposed to "best mode," presumably references inventions involving processes only. If narrow claims are sought for a specific embodiment, a deposit may be required even if none is required to broadly enable the invention.

It appears that the acceptance date, not the filing/priority date, is the deadline for deposits in South Africa. To comply as closely as possible with the EPO's legal and procedural requirements of deposit before the priority date, deposits should be made before the priority date in South Africa as well.

Proposed regulation 28*bis*, discussed above, also provides that the applicant must be able to prove to the satisfaction of the Registrar that samples of the microorganism in question are available to the public in

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116. Letter from G.L. Erlank to Thomas Denberg (Mar. 8, 1990).

117. South Africa Patents Act, § 32(3)(c).

the Republic of South Africa. Since there is no substantive review of patent applications by the South African Patent Office, this proof presumably would be required only if reference to a deposit is made in the specification. There is no provision or proposed provision that access to deposits will be required for members of the international public, as there is in the EPO.

There are no statutes or proposed statutes governing what kinds of restrictions can be placed on requesters for samples of deposits. In light of South Africa's intent to follow EPO practice and legislation as closely as possible, it would seem permissible for a depositor to require requesters of samples to sign an undertaking not to infringe the patent or transfer samples to third parties and to use the samples for experimental purposes only.

#### Q. *Taiwan*

The Taiwan Government (Republic of China) has not yet studied the possibility or necessity of becoming a member of the Budapest Treaty.<sup>118</sup> Presently, the National Bureau of Standards in Taiwan does not require microorganism deposits for patent-filing purposes. Although processes for creating new strains of microorganisms are eligible for patent protection, new species of microorganisms *per se* are barred from patent protection.<sup>119</sup>

This policy is currently under review. A proposed amendment to the patent law would allow new species of microorganisms to be eligible for patent protection. This amendment stipulates a deposit requirement for patent applications involving microorganism inventions. The following discusses what policies are likely to be adopted in the event the proposed amendment is enacted.

Presently, an invention must be described in a written specification such that those skilled in the art understand it and can put the invention into practice accordingly.<sup>120</sup> Under the new amendment, when microorganisms cannot be adequately described, a deposit will be required. It is expected that the National Bureau of Standards may require the patent applicant to provide proof of deposit if a deposit is deemed an essential element in identifying the objective, the technical contents, the characteristics and the effectiveness of the invention involved. The proposed amendment to the patent law will most likely allow deposits to be placed with any international depository authority recognized under the Budapest Treaty. The Culture Collection and Research Center (CCRC) is the first and most widely used depository in Taiwan, and it is expected to be one of the designated institutes recognized by the National Bureau of Standards.

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118. Letter from C.V. Chen to Thomas Denberg (Apr. 24, 1990).

119. ROC Patent Law, art. 4(2). "The following items shall not be granted a new invention patent: . . . 2. New species of animal, plant and microorganism, except the cultivating processes for the new species of plants and new strains of microorganism . . . ." *Id.*

120. ROC Patent Law, Enforcement Rules, art. 10(5).

Although the Republic of China's patent law does not contain any provision regarding the inclusion of the "best mode" in the patent specification, the National Bureau of Standards, under a draft Patent Examination Manual, requests patent applicants to describe the "best manner in which their inventions could be practiced" in the patent specification. Although the National Bureau of Standards uses this manual extensively, it is not considered to be binding regulation.

Since Taiwan is not a signatory to any international conventions or treaties concerning patent matters, no conventional priority can be claimed based on foreign filing. According to the proposed amendment, patent applicants must complete the deposit before filing patent applications. The National Bureau of Standards will not grant a filing date until it has received proof that the applicant has made the deposit.

During prosecution of an application it may be possible to ask the examiner to make a determination as to the necessity of a deposit. If one is required, but has not been made, the applicant may, prior to a final decision rendered on the application, file a request for amendment of the specification and submit a deposit. If the amendment causes "substantial changes"<sup>121</sup> to the application, the filing date may be affected. What constitutes a substantial change is not clear, but probably includes anything that could be considered to be a new matter. If the deposited material was on hand at the time of filing, however, a strong argument could be made that a late deposit is not really a new matter. Presumably, if a specification refers to a deposit that is ultimately not required, reference to it could be deleted.

It is expected that public access to the deposit will be granted after the patent application is approved and published in the Patent Gazette. As with patent specifications and drawings, it is likely that deposits will be available to the international public. It appears that the patent applicant will be required to authorize release of the deposit. The National Bureau of Standards and CRCC have not yet agreed upon what restrictions may be placed on accessing the deposits, but presumably they will take appropriate steps to avoid unwarranted public inspection that could lead to patent infringement.

#### R. *Thailand*

Animal, plant and biological processes involved in the production of animals or plants are not patentable. It is not known whether animals or plants may be interpreted to include microorganisms. The Patent Office has never required deposits of microorganisms to fulfill description requirements.<sup>122</sup>

#### S. *Turkey*

Turkey does not permit patents for microorganisms and has no

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121. ROC Patent Law, art. 18(1).

122. Letter from Chavalit Uttasart to Thomas Denberg (July 23, 1990).

legislation covering the patentability of microorganisms.<sup>123</sup>

#### T. *Uruguay*

Similarly, there is no legislation in Uruguay concerning the patentability of microorganisms or biotechnology.<sup>124</sup>

#### U. *Venezuela*

Venezuelan industrial property law does not specifically address the patentability of microorganisms or biotechnology. Venezuela is in the process of adopting a new industrial property law, which is expected to be enacted within two years. The proposed law does not expressly prohibit the patenting of plant and animal life or processes involved in the generation of such life.<sup>125</sup> Presumably, patenting these types of inventions will be permitted, although it is not known what, if any, provisions are being made for the deposit of microorganisms.

### V. CONCLUSION

As the preceding discussion illustrates, the rules governing deposits vary widely from country to country. Even in the Budapest Treaty countries, specific policies vary. Important differences include: (1) whether a reference to an unnecessary deposit can be deleted from the specification; (2) whether non-Budapest Treaty depositories are recognized for local patenting procedures; (3) whether the best mode must be disclosed; (4) whether the deposit must be made before filing the specification; (5) the stage at which deposits become publicly available; and (6) the conditions which can be imposed on the release of deposits. The policies of the non-Budapest Treaty countries are even more variable. For example, many South American countries do not allow the patenting of microorganisms at all, while countries such as Israel and New Zealand are on the verge of adopting the provisions of the Treaty and are operating as if they were member states.

The applicant who wishes to gain multi-national rights, without facilitating infringement by making his microorganisms publicly available, should pursue to have a detailed understanding of the patent procedures and deposit requirements in the patent offices of interest. Sometimes regulations in one country will nullify the effect of regulations in others. For example, the United States does not require deposits unless necessary, but the Philippines always requires deposits which are made available to the international public when the patent is granted. The applicant must consider all ramifications in determining the appropriate strategy and timing for filing in foreign offices.

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123. Letter from Ahmet Atalay to Greenlee and Associates (May 9, 1990).

124. Letter from Marcela Hughes to Thomas Denberg (May 21, 1990).

125. Letters from Sonia Lorenzo to Thomas Denberg (May 1990).

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