

PART I: GENERAL REQUIREMENTS FOR DEPOSIT  
AND FURNISHING OF SAMPLES

Section A: Making the Original Deposit

(a) Obligations of the Depositor

(i) Universal Requirements

11. When making an original deposit under the Budapest Treaty, the depositor must comply with Rules<sup>1</sup> 6.1(a) and 6.3(a). Rule 6.1(a) specifies the minimum information which the depositor must supply to the IDA when he sends his microorganism for deposit; Rule 6.3(a) lists the additional requirements which the IDA may ask the depositor to meet in respect of its own administrative procedures.

12. According to Rule 6.1(a):

“The microorganism transmitted by the depositor to the international depositary authority shall...be accompanied by a written statement bearing the signature of the depositor and containing:

(i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;”

The period specified in Rule 9.1 is five years after the most recent request for a sample, and in any case at least 30 years. It is important to realize that a deposit made under the Treaty cannot be cancelled during this period, either by the depositor or the IDA, regardless of whether a patent is eventually granted. This applies even if patent applications relating to the deposit are abandoned or withdrawn.

13. Rule 6.1(a) continues:

“(ii) the name and address of the depositor;

(iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;”

This provision ensures that the IDA is given sufficient information to enable it to handle the microorganism correctly. The instructions referring to mixed cultures are intended to ensure that a positive viability statement (see paragraphs 33 to 39) is not issued unless all the components of the co-culture have been shown to be viable.

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<sup>1</sup> Whenever the words “Article(s)” or “Rule(s)” are used in this Guide, they mean Article(s) or Rule(s) of the Budapest Treaty, unless otherwise specified.

14. Rule 6.1(a) continues:

“(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;”

The wording of this clause is sometimes misinterpreted. It does not mean that the depositor should have identified his microorganism in a taxonomic sense; it simply means the designation by which he refers to the organism. The “identification reference” may be a name, of course, but equally it may be merely a strain designation or even just a laboratory code number.

15. Rule 6.1(a) concludes:

“(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.”

The provisions of Rule 6.1(a) are fairly obvious requirements which are intended to ensure that the IDA is aware that the deposit is being made under the Budapest Treaty and is able to deal with the microorganism in the laboratory correctly and safely. Nevertheless, the requirements of Rule 6.1(a) are mandatory and may not be varied either by the depositor or the IDA. Indeed if the depositor does not comply with them all, the IDA is obliged by Rule 6.4(b) (see paragraph 29) to ask him to do so before it can accept the deposit.

16. Scientific description and/or taxonomic designation. Whereas Rule 6.1(a) lists the indications that must be contained in the written statement sent by the depositor to the IDA, Rule 6.1(b) states:

“It is strongly recommended that the written statement...should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.”

Since this Rule is not a requirement but an exhortation, compliance with it is not mandatory. Moreover, if the depositor does decide to submit a scientific description and/or proposed taxonomic designation, he need not do so at the time of deposit. Rule 8.1(a) permits the communication of this information at some later date, and also provides for the amendment of any description/designation indicated previously. The contents of such a communication are regulated by Rule 8.1(b), which states:

“Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:

- (i) the name and address of the depositor;
- (ii) the accession number given by the said authority;

(iii) the scientific description and/or proposed taxonomic designation of the microorganism;

(iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.”

When making such a communication, the depositor may ask the IDA to provide him with an attestation containing the information referred to in Rule 8.1(b)(i) to (iv) and the date on which the IDA received the communication (Rule 8.2). The IDA is obliged to meet such a request, but is entitled to charge a fee for so doing (Rule 12.1(a)(ii)).

(ii) Requirements of IDAs

17. As well as the foregoing requirements, the Regulations permit the IDA to impose on the depositor certain conditions of its own. The extent of these conditions is governed by Rule 6.3(a), which states:

“Any international depositary authority may require:

(i) that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations;”

This provision allows the IDA to require that cultures of microorganisms are submitted to it in a particular state, e.g., on agar slants, in liquid suspension, lyophilized, etc.; that a specified number of replicates is provided; that cultures should not be below a specified minimum titre; and so on.

18. Rule 6.3(a) continues:

“(ii) that a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority be furnished;”

This means the accession form and any other form routinely used by the IDA and obtainable from it.

19. Rule 6.3(a) continues:

“(iii) that the written statement referred to in Rule 6.1(a) or 6.2(a) be drafted in the language, or in any of the languages, specified by such authority, it being understood that such specification must at least include the official language or languages indicated under Rule 3.1(b)(v);”

This is a provision permitting a Japanese IDA, for example, to ask for information to be supplied to it in Japanese. Rule 3.1(b)(v) refers to the official language(s) of the institution specified in the communication required under Article 7(1) of the Treaty from the Contracting State or intergovernmental industrial property organization nominating that institution for the acquisition of IDA status. Rule 6.2(a) refers to the statement required from the depositor in the event of a new deposit, and is dealt with in Section B of this Guide.

20. Rule 6.3(a) continues:

“(iv) that the fee for storage referred to in Rule 12.1(a)(i) be paid...”

Rule 12.1(a)(i) permits the IDA to charge the depositor for storing his microorganism in accordance with the Treaty. However, Rule 12.1(b) requires this fee to cover the whole duration of storage; thus it must be a once-and-for-all payment.

21. Rule 6.3(a) concludes:

“(v) that, to the extent permitted by the applicable law, the depositor enter into a contract with such authority defining the liabilities of the depositor and the said authority.”

This provision allows the IDA to make the kind of contractual arrangements with the depositor that would be usual under the laws of contract of the IDA’s own country.

22. The provisions of Rule 6.3(a) allow the IDA to apply its normal in-house administrative and technical requirements to the internal processing of deposits. It is entirely a matter of choice for the IDA whether it demands any or all of the requirements permitted under Rule 6.3(a), but if it does, then it must so inform the International Bureau of WIPO (Rule 6.3(b)). The depositor must comply with any such requirements to ensure acceptance of his microorganism. These requirements are dealt with in Section D of this Guide.

(b) Obligations of the IDA

(i) Kinds of Microorganisms Accepted

23. The communication to the Director General of WIPO from a Contracting State or an intergovernmental industrial property organization, referred to in Article 7 and Rule 3, nominating a culture collection for the acquisition of IDA status must specify the kinds of microorganisms that the culture collection will accept for deposit under the Budapest Treaty (Rule 3.1(b)(iii)). From the time of its acquisition of IDA status that culture collection is obliged to accept all such microorganisms for deposit (subject to Rule 6.4(a)(ii) and (iii) - see paragraphs 26 and 27).

(ii) Extension or Limitation of the Kinds of Microorganisms Accepted

24. If the IDA subsequently wishes to limit or extend the list of kinds of microorganisms it accepts, it must do so by notifying the modified list to the Contracting State or intergovernmental industrial property organization under whose assurances it has acquired IDA status. That State or organization in turn must formally notify the Director General of WIPO of the withdrawal of its declaration of assurances either entirely or in respect only of certain kinds of microorganisms (Article 8(2)(a), Rule 4.2(a) and (b)) or of the extension of the list of kinds of microorganisms accepted (Rule 3.3). The changes then come into effect at the earliest three months from the date of notification in the case of a limitation of the list of

the kinds of microorganisms accepted (Rule 4.2(c)) and immediately after publication by the International Bureau of WIPO in the case of an extension (Rule 3.3, Article 7(2)(b)) of such list. In either case, the State or organization may specify a later effective date than that just mentioned.

(iii) Refusal to Accept a Microorganism

25. An IDA may refuse to accept a microorganism sent to it for deposit only in certain circumstances, which are specified in Rule 6.4(a). This Rule states:

“(a) the international depositary authority shall refuse to accept the microorganism and shall immediately notify the depositor in writing of such refusal and of the reasons therefor:

(i) where the microorganism is not of a kind of microorganism to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend;”

Although the reason for this provision may appear self-evident, it is important to note that the IDA is not merely entitled, but is obliged to refuse such a microorganism.

26. Rule 6.4(a) continues:

“(ii) where the properties of the microorganism are so exceptional that the international depositary authority is technically not in a position to perform the tasks in relation to it that it must perform under the Treaty and these Regulations;”

This provision covers the situation where, on the face of it, the microorganism should be of a kind which the IDA accepts, but where in fact the IDA clearly is unable to handle it. An example would be a strain of an otherwise “acceptable” species, which either naturally or because of genetic manipulation was too difficult for the IDA to cultivate.

27. Rule 6.4(a) concludes:

“(iii) where the deposit is received in a condition which clearly indicates that the microorganism is missing or which precludes for scientific reasons the acceptance of the microorganism.”

This provision again relates to a microorganism that in normal circumstances would be accepted by the IDA. It would apply, for example, where the receptacle containing the culture had been broken in transit, thereby making recovery of the microorganism in an uncontaminated state impossible.

28. Rule 6.4(a) specifies the only circumstances in which an IDA may legitimately refuse to accept a microorganism for deposit, other than by virtue of continued non-compliance by the depositor with the requirements for deposit. Refusal by the IDA in any other case is in contravention of its obligations under the Treaty and could lead to its losing its status as an IDA (Article 8, Rules 4 and 5).

(iv) Acceptance of the Original Deposit

29. The requirements which the IDA must observe when accepting a microorganism for deposit are laid down in Rule 6.4(b), (c) and (d). Rule 6.4(b) and (c) states:

“(b) Subject to paragraph (a), the international depositary authority shall accept the microorganism when all the requirements of Rule 6.1(a) or 6.2(a) and Rule 6.3(a) are complied with. If any of those requirements are not complied with, the international depositary authority shall immediately notify the depositor in writing of that fact and invite him to comply with those requirements.

“(c) When the microorganism has been accepted as an original or new deposit, the date of that original or new deposit, as the case may be, shall be the date on which the microorganism was received by the international depositary authority.”

Thus the IDA is obliged to ensure that the depositor has met all the mandatory requirements for deposit (see paragraphs 11 to 22) before it can accept the microorganism. However, deferment of formal acceptance (as opposed to refusal) pending the depositor’s compliance with all his obligations does not prejudice the date of deposit. Except in the case of a conversion of a deposit made outside the Budapest Treaty under Rule 6.4(d) (see paragraphs 30 and 31), the date of deposit is held to be the date on which the IDA physically receives the microorganism, even though all procedural requirements for acceptance may not have been met on that date.

(v) Conversion of Deposits Made Outside the Budapest Treaty

30. Rule 6.4(d) allows for a deposit originally made outside the provisions of the Treaty and before the culture collection became an IDA to be converted to a deposit made under the Treaty. This Rule states:

“The international depositary authority shall, on the request of the depositor and provided that all the requirements referred to in paragraph (b) are complied with, consider a microorganism, deposited before the acquisition by such authority of the status of international depositary authority, to have been received, for the purposes of the Treaty, on the date on which such status was acquired.”

The requirements for converting an existing deposit into a “Budapest deposit” are essentially the same as those which must be met when making an original deposit under the Treaty, except that the microorganism itself, of course, will already have been sent and received. However, it must be realized that when a deposit is converted under Rule 6.4(d), for the purposes of the Treaty the date of deposit is held to be the date on which the culture collection acquired IDA status, not the earlier date on which the collection physically received the microorganism. It is important that this “artificial” date of deposit be borne in mind in relation to the filing dates of patent applications referring to the deposited microorganism. Following an “understanding” reached by the Assembly of the Budapest Union (in 1981 and in 1990), the depositor may request that a deposit made with an IDA, but outside the scope of the Budapest Treaty, be converted into a Budapest Treaty deposit. Furthermore, according to such “understanding” in such a case, the date recognized for the purposes of the Treaty as the date of deposit is determined by the applicable national law. In practice this means that

whereas some industrial property offices may recognize the date on which the IDA received the microorganism as the date of deposit, others may recognize only the date of receipt by the IDA of the request for conversion. Depositors should bear this in mind and consider any effects it may have on patent applications or patents referring to the converted deposit.

31. Conversion is a useful facility because it means that an earlier non-Budapest Treaty deposit can be accorded the international recognition which it might not otherwise command. Conversion, for example, is essential for the recognition by the Japanese Patent Office of any non-Budapest Treaty deposit made outside Japan, regardless of its previous availability. At present, however, only the original depositor (or his successor in title) can convert a deposit. In all other cases, a separate deposit of the same organism must be made under the Treaty. Moreover, some IDAs will not agree to the conversion of deposits previously made for purely scientific purposes because of the constraints which the Budapest Treaty system might impose on the hitherto unrestricted distribution of samples. In such cases, separate deposit of the microorganism under the Treaty is again necessary.

(vi) Issuance of Receipt

32. Having received and accepted a microorganism for deposit (or having converted an existing deposit), the IDA must notify the depositor of this fact by issuing to him an official receipt in respect of that deposit (Rule 7.1). The receipt must be made out on the so-called “international form” BP/4 (see Appendix 3). This form is one of four “international forms,” a model of which has been established by the Director General of WIPO and the Budapest Union Assembly (Rule 7.2(a)). Wherever the Regulations specify the use of an “international form” by IDAs, such use is mandatory. The receipt must be signed by an authorized representative of the IDA (Rule 7.2(c)) and must contain the specific information required by Rule 7.3 which states:

“Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date of the original deposit as defined in Rule 6.4(c);
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority to the deposit;
- (vi) where the written statement referred to in Rule 6.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact.”

The receipt is a very important communication for it constitutes a written attestation by the IDA that the microorganism in question was deposited with it on a particular date, was accepted by it, and was assigned a particular accession number. Moreover, the receipt together with a positive first viability statement (see paragraphs 33 to 39) provide documentary evidence that a deposit meeting the requirements of the Budapest Treaty has been made. Also, by virtue of the obligations imposed on IDAs by the Treaty, these documents are a presumptive indication that the deposited microorganism will be kept in storage and samples thereof will be furnished according to the requirements of the Treaty. Any Contracting State may demand a copy of the receipt (Article 3(1)(b)). (It should be noted in this connection, however, that, notwithstanding the provisions of Article 3(2) and the assurances furnished under Article 7(1)(a) in respect of the IDA, certain industrial property offices may require an additional declaration from the IDA as to the permanence and availability of the deposit.)

(vii) Viability Testing and Statement

33. Viability Testing. As soon as possible after receiving a microorganism for deposit, the IDA must test the viability of the microorganism (Rule 10.1(i)) and must inform the depositor in writing of the results of the test (Rule 10.2(a)(i)), using mandatory “international form” BP/9. The obligations placed on IDAs in respect of the viability testing of an original deposit are laid down in Rule 10.1, which states:

“The international depositary authority shall test the viability of each microorganism deposited with it:

(i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;”

Rule 5.1 refers to the transfer of microorganisms from a defaulting to a substitute IDA and is dealt with in Section B of this Guide.

34. Rule 10.1 continues:

“(ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary, for technical reasons;”

This provision, while requiring the IDA to pay attention to the viability testing of a microorganism during the storage period, nevertheless leaves the frequency of such testing to the professional judgment of the IDA.

35. Rule 10.1 concludes:

“(iii) at any time, on the request of the depositor.”

This provision acknowledges the right of the depositor to demand on any particular occasion evidence of the viability of his deposit.

36. Viability Statement. The circumstances in which an IDA must provide a written statement in respect of an original deposit are given in Rule 10.2(a), which states:

“The international depository authority shall issue a statement concerning the viability of the deposited microorganism:

- (i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
- (ii) to the depositor, on his request, at any time after the deposit or transfer;
- (iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples.”

This provision entitles anyone who has received a sample of the microorganism also to receive a viability statement, if he so wishes. In such a case, and in the case of Rule 10.2(a)(ii), above, the viability statement must refer to the most recent viability tests (Rule 10.2(c)).

37. The contents of the viability statement are laid down by Rule 10.2(b), which states:

“The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain:

- (i) the name and address of the international depository authority issuing it;
- (ii) the name and address of the depositor;
- (iii) the date referred to in Rule 7.3(iii) or, where a new deposit or a transfer has been made, the most recent of the dates referred to in Rules 7.4(iii) and 7.5(iii);”

The two last mentioned dates are the dates of receipt by the IDA of a new deposit or transferred deposit, respectively.

38. Rule 10.2(b) continues:

- “(iv) the accession number given by the said authority;
- (v) the date of the test to which it refers;
- (vi) information on the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative.”

This last provision enables the recipient of the viability statement to check, in the event of a negative result, that the IDA has carried out the viability test correctly. The IDA is entitled to charge for viability statements issued in respect of an original deposit, except for that issued to the depositor immediately after deposit or where the recipient is an industrial property office (Rules 10.2(e) and 12.1(a)(iii)).

39. Viability testing is an extremely important part of the depositing procedure under the Budapest Treaty since the whole point of deposit is to ensure that viable samples of the microorganism are made available at the appropriate time and under the requisite conditions to those entitled. The test carried out immediately after deposit is particularly important because it determines in effect the validity of the date of deposit. Accordingly, the viability statement reporting the result of this test is a very important document. If it reports a negative result, and if all subsequent viability statements report similarly negative results, then even though all procedural requirements may have been met in respect of the deposit, the original date of deposit is lost (see paragraph 67). If, on the other hand, the first viability statement reports a positive result, then, in the event of the microorganism subsequently being lost and in the absence of any later positive statements, it is the key to the recognition of the original date of deposit *vis à vis* any replacement (Article 4(1)(d); see paragraph 66).

(viii) Storage of Microorganisms

40. Having accepted a microorganism for deposit, tested its viability and issued the receipt and viability statement, the IDA is obliged to maintain the microorganism according to the provisions of Rule 9, which states:

“9.1 Duration of the Storage

“Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.”

This provision is intended to ensure the permanence of the deposit and in effect simply obliges the IDA to do what would be expected of any culture collection in order to minimize the loss of deposited microorganisms.

41. Rule 9 continues:

“9.2 Secrecy

“No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule.”

This provision is intended to ensure that the deposit of a microorganism remains secret until any patent application referring to it has been published. However, by linking the furnishing of information to the provisions of Rule 11 (see paragraphs 87 to 96), which govern the furnishing of samples, Rule 9.2 relieves the IDA of any obligation to ascertain for itself whether publication has taken place. (In practice, there are certain exceptions to this; see paragraphs 92 and 104.)

(c) Guidelines for Making the Original Deposit

(i) General

42. Subsections (a) and (b), above, have listed and explained the general requirements, obligations and procedures which must be observed by the depositor and the IDA when an original deposit is being made under the Budapest Treaty. The purpose of this subsection is to offer practical guidance and suggestions to prospective depositors so that timely and trouble-free deposits may be ensured.

(ii) Problems to Be Avoided

43. Last Minute Deposits. Making a deposit under the Budapest Treaty should be quite straightforward, but problems can and do occur. Most of these arise because the depositor has not left enough time for any unexpected difficulties to be put right. It cannot be emphasized too strongly that however good the intentions of the depositor may be, the industrial property office will recognize only the actuality of the deposit. This actuality is the physical receipt by the IDA of a viable sample of the microorganism. Thus, although in principle a microorganism being sent for deposit need not in most cases reach the IDA until the filing date (or priority date, as the case may be) of the corresponding patent application, in practice the depositor should begin the depositing procedure soon enough to allow for any possible delays or mishaps. Some delays can be anticipated, of course. If, say, the deposit is to be made with a foreign IDA, any import or quarantine regulations should be borne in mind. For instance, it may take several weeks, or even months, to import certain cell-lines and viruses into the United States of America (see Section D of this Guide). However, it is the possibility of unexpected delays that makes depositing at the last minute a risk not worth taking in view of the likely consequence for the patent application itself. None of the following common situations causes a problem if the microorganism has been sent for deposit in good time; all pose a serious threat to the last-minute deposit.

44. Postal Delays. Sometimes the microorganism sent for deposit simply fails to arrive at the IDA in time, either because the package has been mailed too late or because of abnormal delays in the postal system. It should also be noted that the postal authorities in some countries will not accept packages containing certain classes of microorganisms transmitted by airmail and will destroy them on receipt. Usually, an IDA is able to advise a prospective foreign depositor whether it can accept his microorganism sent by airmail.

45. Customs Delays. Microorganisms sent for deposit in IDAs abroad often must be transmitted by air freight. Delays frequently occur because depositors have provided insufficient shipping information to allow the smooth passage of the package through the customs authorities in the country of destination.

46. Damaged Packages. Sometimes depositors do not pack the vessels containing their microorganisms adequately, with the result that the vessels may be broken in transit, rendering the microorganism irrecoverable from the package in an uncontaminated state. In such a case, the IDA will refuse to accept the deposit (Rule 6.4(a)(iii)). If the deposit has been made at the last minute, it may be too late to send a replacement. Prospective depositors should note that the packaging of microorganisms for transmission through the overseas mail and by air freight is governed by the regulations of the Universal Postal Union and the International Air Transport Association, respectively.

47. Non-Viability. Sometimes a microorganism sent for deposit proves to be non-viable when tested by the IDA, necessitating the depositor to send a replacement sample. Such a replacement cannot be treated as a new deposit under the provisions of Article 4 because a positive viability statement was not issued in respect of the original sample (see paragraphs 67 and 68). Thus the replacement must be treated as an original deposit in its own right, which means that the earliest date of deposit is the date on which the IDA receives the replacement sample, not the date on which it received the first sample. If the first sample was sent for deposit at the last minute, the replacement sample may not reach the IDA in time. (It should be borne in mind in this connection that, depending on the kind of microorganism, viability testing may take some time. Thus for most bacteria, fungi, yeasts, algae and protozoa, viability testing usually takes two to five days, for animal cell-lines a week or slightly longer is normal and for animal viruses and plant tissue cells, up to a month is not unusual (see Section D of this Guide).)

48. It is essential to recognize the difference between a new deposit in the sense of Article 4 (see paragraphs 65 to 68) and a replacement deposit as described above, and to realize that if a microorganism is found by the IDA from the outset to be non-viable, the original date of deposit cannot be applied to any replacement.

49. Unacceptable Microorganisms. Occasionally an IDA finds that a microorganism sent to it is not one of the kinds which it accepts under the Treaty, and thus it refuses the deposit (Rule 6.4(a)(i)). Again, if the deposit is being made at the last minute, it may be too late to send the microorganism to another IDA that will accept the deposit.

50. Lack of Communication. Last-minute deposits usually occur through lack of forethought on the part of the depositor or his patent agent, or through lack of communication between the two. And even when the microorganism itself is sent in good time, lack of communication between depositor and agent can cause confusion and delay. In such cases, the date of deposit is not usually jeopardized, but the depositing procedure is made unnecessarily complicated and time-consuming. Thus, for example, the depositor (who is often a scientist with little knowledge of patent procedure) may be told simply to ensure that he sends his microorganism to the IDA by a certain date, without being adequately briefed about the relevant administrative and legal requirements. Consequently, deposits sometimes arrive not only late but also lacking sufficient information to enable the IDA to process them. Furthermore, it is often forgotten that the Treaty speaks always of the depositor and that, unless instructed otherwise, the IDA will communicate only with him. If requested, most IDAs will send copies of receipts and viability statements to both the depositor and his agent, which avoids the common problem of depositors not realizing the importance of the receipt and viability statement and the need to furnish them as evidence of deposit.

51. Problems can also arise when patent agents are inadequately briefed by depositors about possible technical or legal difficulties with their microorganism, with the result that IDAs may be confronted with situations about which they should have been forewarned. There has been at least one case where the patent agent had all the administrative procedures in hand, only to find that the depositor had told neither him nor the IDA that the microorganism had to be handled under special conditions to which the IDA did not have immediate access.

52. Communication between a patent applicant and his patent agent is always considered vital in the drafting of the patent application and in its filing. It is equally essential in the depositing of microorganisms for patent purposes.

(iii) Guide to Procedures

53. The problems and pitfalls described in paragraphs 43 to 52 can largely be avoided if prospective depositors adhere to the following three simple guidelines:

- start the deposit procedure in good time;
- ensure that adequate briefing is received from the patent agent about administrative and legal requirements;
- ensure that the patent agent is briefed about the kind of microorganism and about any possible technical problems there may be with it.

This being said, the following points about practical procedures should be observed.

54. Acceptability of the Microorganism. The depositor should ensure that the IDA he has chosen is able and empowered to accept for deposit the kind of microorganism to be submitted. If there are likely to be technical problems, he should advise the IDA in advance.

55. IDA Requirements and Forms. The depositor should check the administrative and technical requirements of the IDA (Rule 6.3(a)) and should ask for the appropriate forms.

56. Information. The depositor should give all the information asked for on the forms and should ensure that it is correct, and that it is expressed in one of the official languages of the IDA. It is generally recognized that many depositors will not be familiar with the details of the Budapest Treaty and Regulations and thus may not be fully aware of all their obligations in respect of them. Therefore, the forms which the depositor is asked to fill in are so designed that, by completing them correctly, he automatically provides all the information required of him by the Regulations (in particular, Rule 6.1(a)) and by the IDA itself. These forms vary to some extent between IDAs but they all follow a similar general pattern.) Nevertheless, deposit forms are not infrequently returned to IDAs only partially completed or containing incorrect information, thus leading to unnecessary delays.

57. Identity of Depositor. It should be made clear whether the person sending the microorganism is himself the depositor or whether he is acting on behalf of the organization employing him. In the case of the latter, the deposit form should be signed by an authorized official of that organization and it should be made clear to whom the IDA should send any official notifications.
58. Patent Agent. If the depositor's patent agent is likely to be communicating with the IDA, the depositor should inform the IDA, otherwise it may withhold information until it has ascertained the agent's right to receive it. In particular, the depositor should tell the IDA if he wishes copies of the receipt and viability statement to be sent to his patent agent.
59. Form and Quantity of the Microorganism. The depositor should ensure that he meets the requirements of the IDA as to the form and quantity of the microorganism to be deposited (Rule 6.3(a)(i)).
60. Advance Information. Although Rule 6.1(a) states that the microorganism should be accompanied by a written statement (the completed deposit form), in practice it is often helpful to an IDA to receive information in advance of the microorganism itself, so that arrangements can be made to deal with the deposit promptly. This is particularly helpful if, say, a special growth medium containing unusual ingredients has to be prepared by the IDA.
61. Date of Deposit. Notwithstanding paragraph 60, the depositor should bear in mind that the date of deposit is the date on which the microorganism is actually received by the IDA. Therefore, in an emergency (which should not arise, of course, if the depositor is following these guidelines), priority should be given to ensuring that the IDA receives the microorganism itself. However, in such a case the depositor should remember that without the written information, the IDA may not be in a position to test the viability of the microorganism.
62. Authenticity Checks. Depending on its policy and on the kind of material being deposited, an IDA may or may not prepare subcultures for eventual distribution as samples of the deposited microorganism. Thus in the case of cell-lines and naked plasmids, for instance, the depositor is usually required to supply sufficient material for the IDA to distribute direct (see also paragraph 59). On the other hand, for bacteria, yeasts, moulds, etc., it is more usual for the IDA to distribute its own preparations. In this case, many IDAs will ask the depositor to check the authenticity of their preparations (a normal practice of culture collections). The depositor is not obliged by the Treaty to check these preparations, but he is well-advised to do so to ensure that the material sent out by the IDA will in fact correspond to the claims in the patent application.
63. Official Communications. The depositor should expect to receive an official receipt and viability statement from the IDA and should be aware of their importance and of the fact that he may be required to furnish them as evidence of deposit. Technically, the receipt should be issued first but in practice, where the viability test takes only a few days, many IDAs find it more convenient to await the result of this test and then send out the receipt and viability statement together. If asked, most IDAs will communicate the accession number and date of deposit when they have accepted the deposit. However, it must be remembered that these communications are unofficial and have no standing under the Treaty.

64. Conversions. If an existing deposit is being converted to one made under the Budapest Treaty (Rule 6.4(d)), the depositor should first inform the IDA of the accession number of the microorganism and obtain confirmation that the conversion is, in fact, permissible (if it is not, he will have to make another deposit). He should then attend to the points contained in paragraphs 55, 56, 58, 62 and 63, above).

### Section B: Making a New Deposit

#### (a) Circumstances in Which a New Deposit May Be Made

65. Article 4 of the Treaty states:

“(1)(a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,

(i) where such microorganism is no longer viable, or

(ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions, that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

“(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:

(i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority or discontinues the performance of its functions in respect of deposited microorganisms;

(ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii).”

These provisions are intended to ensure, as far as possible, the continued availability of a deposited microorganism in the event of the IDA not being in a position to furnish samples. In this way, the depositor's patent rights are not jeopardized by circumstances that are not of his making and which are beyond his control. It should be noted, however, that according to Article 4(2) these provisions cannot be applied to microorganisms previously transferred to another IDA, unless that IDA is also unable to furnish samples.

(b) Requirements to Be Met(i) Statement by the Depositor

66. Article 4(1) continues:

“(c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law.”

The contents of the signed statement which the depositor must submit with his new deposit are laid down in Rule 6.2, and may be summarized thus (the following is a summary, not a quotation, of Rule 6.2):

(i) where the new deposit is being made with a different IDA, all the indications required under Rule 6.1(a) (see paragraphs 12 to 15);

(ii) the reason for making the new deposit, a statement alleging that the microorganism being submitted is the same as that deposited previously, and an indication of the date on which notification was received from the IDA of its inability to furnish samples (or, as the case may be, the date of publication of the fact that the IDA has lost its status or discontinued its function--Article 4(1)(e); see paragraph 70);

(iii) the most recent scientific description and/or proposed taxonomic designation submitted to the IDA in respect of the previous deposit. (Rule 6.2(c) defines “previous deposit” as either the latest of a succession of earlier new deposits, or the original deposit, as the case may be.)

This signed statement must be accompanied by a copy of the receipt of the previous deposit and a copy of the most recent positive viability statement.

(ii) Date of Deposit

67. Article 4(1) continues:

“(d) Subject to subparagraphs (a) to (c) and (e), the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph (a).”

This subparagraph is central to the concept of continuity of deposit in that it allows the original date of deposit to stand, regardless of the actual date of the new deposit, provided that this latter date falls within the stated three-month time limit.

68. It should be noted that, as mentioned earlier (see paragraphs 39 and 47), the original date of deposit can be applied to a new deposit only if at least one positive viability statement had been issued in respect of the previous deposit. Article 4 does not apply to replacements for deposits that have never been shown to be viable.

(iii) Time Limit

69. The exact dates that circumscribe the three-month time limit are calculated according to Rule 12**bis**.2, which states:

“When a period is expressed as one month or a certain number of months, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.”

Thus if the depositor receives notification from the IDA on, say, January 15, he must make his new deposit no later than April 15; or if he receives notification on, say, January 31, the new deposit must be made no later than April 30. (The same formula is applied, mutatis mutandis, when calculating time periods expressed in years (Rule 12**bis**.1).)

70. This three-month time limit does not begin until the depositor has received notification from the IDA of its inability to furnish samples, except where the IDA has ceased to function as such or has lost its status (Article 4(1)(b)(i)) and has not notified the depositor of this fact. In this case, Article 4(1)(e) states that if the IDA has not notified the depositor within six months of the publication by the International Bureau of WIPO of its loss of status, the three-month time limit starts from the date of that publication. However, in practice Article 4(1)(e) should not need to be invoked since, in the event of loss of status or discontinuance of function by the IDA, the Contracting State is required to ensure the transfer of all deposits to another IDA and to ensure that the defaulting IDA notifies depositors (Rule 5.1; see paragraph 84).

(iv) Receipt and Viability Statement

71. Having received and accepted a new deposit, the IDA must test its viability and must issue to the depositor a receipt and viability statement. The latter is identical with that which would be issued in the case of an original deposit (see paragraphs 36 to 38), but the receipt (Rule 7.4), which must be made out on “international form” BP/5, is not. Indications in Rule 7.4(i) to (v) are the same as in the receipt for an original deposit (see paragraph 32), except that they refer instead to “new deposit,” but Rule 7.4 goes on to state:

“(vi) an indication of the relevant reason and the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);”

This refers to the reason for making the new deposit and the date on which the depositor received notification of the inability of the IDA to furnish samples.

72. Rule 7.4 continues:

“(vii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;”

Rule 6.2(a)(iii) refers to the last description/designation submitted in respect of the previous deposit.

73. Rule 7.4 concludes:

“(viii) the accession number given to the previous deposit...”

Unless the new deposit is being made with another IDA, the accession number is likely to be the same as that accorded the previous deposit.

74. If the new deposit is being made with another IDA, the receipt must also give the name and address of the IDA with which the previous deposit was made, although Rule 7.4 does not mention this. When the IDA issues a receipt for a new deposit it must send with it to the depositor copies of the receipt and of the last positive viability statement issued in respect of the previous deposit.

(c) Guidelines for Making a New Deposit

75. If the original date of deposit is to be retained, a viable sample of the newly deposited microorganism must have been received by the IDA no later than the last day of the three-month time limit referred to in Article 4(1)(d) (see paragraph 69). If a viable sample is not received until later, the earliest date of deposit that can be applied to the new deposit is the date on which it was actually received by the IDA. Since loss of the original date of deposit can have serious implications for any patents or applications relating to the particular microorganism, timely action by the depositor when making a new deposit is just as important as when making an original deposit. New deposits made at the last minute are subject to the same risks as are last-minute original deposits (see paragraphs 43 to 49).

76. Most of the suggestions and guidelines discussed in Section A in respect of original deposits are equally applicable to new deposits, but the depositor should also bear the following points in mind when making a new deposit.

77. Notification from the IDA. The depositor should be aware of the significance of a notification from the IDA that it can no longer furnish samples and he should act promptly when he receives it. He should, of course, immediately note the date on which he received the notification and from it calculate the latest date by which any new deposit must be made.

78. Possibility of Transfer. If the IDA is unable to furnish samples because of loss of status or discontinuance of function, the depositor should ascertain (if the IDA has not so informed him) whether his deposited microorganism(s) will be transferred under the aegis of the Contracting State to another IDA in accordance with Rule 5.1(a)(i) (see paragraph 54). If this is to be the case, the right to make a new deposit under Article 4 does not exist (Article 4(2)).

79. Deposit with a Different IDA. If the new deposit is to be made with another IDA, the depositor should ensure that the IDA he chooses will accept his microorganism and he should determine its administrative and technical requirements (see Section D of this Guide), since they may differ from those of the original IDA. However, the depositor has the right to make a new deposit in another IDA only in the case of discontinuance or loss of status (Article 4(1)(b)(i)) or because of export/import restrictions (Article 4(1)(b)(ii)).

80. Identity of the New Deposit. The depositor should take care to ensure that the microorganism he is submitting as a new deposit is the same as that deposited previously, since there is always the possibility of the allegation he makes under Article 4(1)(c) being contested.

81. Statement. Unless the forms from the IDA provide space for it, the depositor should ensure that he has appended a signed statement giving the reason for making a new deposit, the date on which he received notification from the IDA of its inability to furnish samples, and a declaration that the microorganism he is submitting is the same as that previously deposited (Article 4(1)(c) and Rule 6.2(a)(ii)). Some IDAs use WIPO model forms BP/2 and BP/3 (see Appendix 3) for new deposits, which ask for these indications. In such cases, a separate statement is not necessary.

82. Additional Documentation. The depositor should remember that, in addition to the appropriate forms and declaration, he must also submit to the IDA (a) a copy of the receipt for the previous deposit, (b) a copy of the latest positive viability statement issued in respect of the previous deposit, and, if applicable, (c) the latest scientific description/taxonomic designation sent to the IDA in respect of the previous deposit.

(d) Transfer of Deposited Microorganisms

(i) Reasons for Transfer

83. Although they are not, strictly speaking, new deposits, it is appropriate to deal here with the case of deposited microorganisms which are necessarily transferred from one IDA to another. This situation can arise as a consequence of any of the following:

- the IDA temporarily or permanently ceases to carry out its functions in respect of the microorganisms deposited with it;
- the Contracting State or intergovernmental industrial property organization which originally furnished the assurances (Article 6(1)) leading to the IDA acquiring its status withdraws those assurances with the result that the status of the IDA is terminated (Article 8(2)).
- the IDA fails to meet its obligations under the Treaty and Regulations with the result that a Contracting State or intergovernmental industrial property organization successfully petitions the Budapest Union Assembly to terminate or limit the status of the IDA (Article 8(1));

– the IDA loses its status as a consequence of the Contracting State or intergovernmental industrial property organization which furnished the assurances in respect of it under Article 6(1) ceasing to be a party to the Treaty (Article 17(4)) or ceasing to recognize the provisions of the Treaty (Article 9(4)), respectively.

Except in the case of the last of these reasons, which inevitably must be absolute, the foregoing can apply either to all the microorganisms deposited with the IDA or only to certain kinds.

(ii) Obligations of the Contracting State

84. In the event of any of the foregoing, the Contracting State or intergovernmental industrial property organization which furnished the assurances under Article 6(1) is obliged by Rule 5.1 to ensure the prompt transfer of all affected deposits and all relevant files, etc., to another IDA. The State or intergovernmental industrial property organization must also ensure, as far as possible, that the defaulting IDA notifies all affected depositors of such transfers. In these circumstances, the State or the organization decides on the substitute IDA to which deposits are to be transferred, but the depositor may, if he so wishes, ask the defaulting IDA to send, in addition, a sample of any of his deposits and copies of any relevant files, etc., to another IDA. In this case, however, he must bear the expenses of any such additional transfer himself (Rule 5.1(e)).

(iii) Obligations of the Substitute IDA

85. The substitute IDA must issue to the depositor a receipt in respect of any microorganism transferred to it under Rule 5.1 and, after testing their viability, a viability statement. The viability statement is identical with that which would be issued in the case of the original or new deposit, but the contents of the receipt in the case of a transferred deposit (which must be made out on “international form” BP/6) are governed by Rule 7.5. This Rule requires the following particulars:

- “(i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date on which the transferred sample was received by the international depositary authority (date of transfer);
- (iv) the identification reference...given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority;
- (vi) the name and address of the international depositary authority from which the transfer was effected;
- (vii) the accession number given by the international depositary authority from which the transfer was effected;

(viii) where the written statement referred to in Rule 6.1(a) or 6.2(a) contained the scientific description and/or proposed taxonomic designation of the microorganism, or where such scientific description and/or proposed taxonomic designation was/were indicated or amended under Rule 8.1 at a later date, a reference to that fact.”

(iv) Position of the Depositor

86. Transfer of deposits in the case of loss of status or cessation of function of the IDA occurs in circumstances over which the depositor has no control, and, therefore, his active participation in the process is minimal. He should, however, be aware that it may be necessary, depending on the applicable patent procedure, for him to notify the new accession number to any industrial property office with which he has filed an application referring to the original deposit (Rule 5.1(c)). It might be prudent for him to do this in any case. Furthermore, it should be noted that Rule 5.1 requires the Contracting State or intergovernmental industrial property organization to ensure the transfer of deposits “to the fullest extent possible.” There is thus no absolute guarantee that transfer of a particular deposit would in fact be effected. Therefore, when the depositor is notified by the IDA of its inability to furnish samples (as he must be under Article 4) because of loss of status or cessation of function, it is in his own interest to ascertain from the IDA whether his deposits will be transferred according to Rule 5.1. If the answer is negative, he can exercise his right under Article 4(1)(b)(i) to make new deposits with another IDA.

Section C: Furnishing of Samples

(a) General Conditions for Requesting Samples

87. The whole point of depositing a microorganism for patent purposes is to make it available to entitled parties according to the requirements of patent law. The purpose of this section is to inform depositors of the general conditions under which samples of their deposit will be furnished under the Budapest Treaty and to advise third parties of the requirements they must comply with when requesting a sample. This section should be read with reference to Section E, which gives the requirements of individual countries as to the furnishing of samples of deposited microorganisms.

88. It is widely acknowledged that IDAs cannot be expected to be familiar with the patent laws of countries throughout the world. Thus to require an IDA to judge for itself whether a particular third party is legally entitled to receive a sample of a particular deposit is generally considered to be undesirable. Many industrial property authorities also consider it unreasonable to expect an IDA to ascertain from the relevant industrial property office (which it may not even know) the legitimacy of every request for a sample. Therefore, the solution provided by the Budapest Treaty is to permit an IDA to furnish a sample of a particular microorganism only if the request is accompanied by the written authorization of the depositor or by a certificate from a competent industrial property office indicating the legitimacy of the request, or, alternatively, if a competent industrial property office has already notified the IDA

that the microorganism may be distributed without the need for such authorization. These matters are governed by Rule 11, which recognizes three different situations in which samples may be furnished, viz. to interested industrial property offices (Rule 11.1), to or with the authorization of the depositor (Rule 11.2), or to parties legally entitled (Rule 11.3).

(b) Requests from Interested Industrial Property Offices

89. When the industrial property office of a Contracting State or an intergovernmental industrial property organization requests a sample of a deposited microorganism, Rule 11.1 states that the request must be accompanied by a declaration to the effect 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 or 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.”

This Rule clearly indicates that an “interested” industrial property office is one that either is processing a patent application or has granted a patent in respect of the deposited microorganism. The above provisions also prohibit such an office from using a sample of the microorganism (or information about it) for any purposes other than its own procedures.

(c) Requests from or with the Authorization of the Depositor

90. Rule 11.2 states:

“Any international depositary authority shall furnish a sample of any deposited microorganism:

(i) to the depositor, on his request;

(ii) to any authority, natural person or legal entity (hereinafter referred to as ‘the authorized party’), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample.”

These provisions recognize the right of the depositor both to obtain a sample of his own deposited microorganism whenever he wishes and to permit the furnishing of a sample to whomever he pleases, regardless of whether that person is otherwise “legally entitled.”

However, the depositor does not have the right to prevent the furnishing of samples to parties legally entitled, whatever his personal wishes may be.

(d) Requests from Parties Legally Entitled

(i) Requests Requiring Industrial Property Office Certification

91. The furnishing of samples in the vast majority of cases is governed by Rule 11.3, which provides two alternative mechanisms. The first of these is given by Rule 11.3(a), which states:

“(a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as ‘the certified party’), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

(i) that 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) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;

(iii) either that the 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 or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.”

These provisions are intended to protect both the depositor and the IDA from the danger of samples being furnished illegally or mistakenly. They ensure that not only must the requesting party obtain certification of entitlement from the industrial property office, but also that the industrial property office must effectively state that it is competent to provide such certification, i.e., that it is actually processing an application referring to the microorganism (either in its capacity as a national office or, in the case of an international application filed under the Patent Cooperation Treaty (PCT), as a “designated Office” within the meaning of that Treaty (Rule 11.5)), and that the requesting party meets all the conditions required by the applicable law. Moreover, where the requesting party is entitled to receive a sample before publication of the patent application, the industrial property office must refer to the actual provision of the law which grants such entitlement. Except where Rules 11.1, 11.2 or 11.3(b)

apply, any request not made out on the appropriate form or endorsed as above by the industrial property office will automatically be refused by an IDA. In the case of an international application filed under the PCT, the certification of publication required by Rule 11.3(a)(ii) can, at the option of the industrial property office, certify either international publication under the PCT or publication by that office in its own right (Rule 11.5). It should also be noted that some industrial property offices (see Section E of this Guide) may require a form additional to that just mentioned to be completed by the requesting party and may have to provide additional certification to comply with their own national law.

(ii) Requests not Requiring Industrial Property Office Certification

92. The alternative mechanism for the furnishing of samples to parties legally entitled is given by Rule 11.3(b), which states:

“(b) In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as ‘the requesting party’), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3(a).”

By notifying the IDA of the accession numbers of microorganisms cited in published patents, industrial property offices in countries whose laws require that such organisms must be available without restrictions to anyone once the relevant patents have been granted and published are able to circumvent the certification procedures of Rule 11.3(a). In practice, however, such notification is provided by very few industrial property offices and IDAs are often left to ascertain for themselves whether the relevant patents have been issued.

(e) Common Procedures

93. Procedures that must be followed in respect of all requests for the furnishing of samples are laid down in Rule 11.4(a) to (e). Rule 11.4(a) and (b) deals with the languages in which any request, declaration, certification or other communication referred to in Rules 11.1, 11.2 and 11.3 must be written. Such communications must be in English, French, Russian or Spanish where they are addressed to an IDA whose official language is or whose official languages include English, French, Russian and Spanish, respectively. However, where the official language of the IDA is Russian or Spanish, any communication addressed to it may still be in English or French, in which case the International Bureau of WIPO will provide, on request and free of charge, a certified translation into Russian or Spanish. Conversely, where a request for a sample is made by an industrial property office (Rule 11.1) whose official language is Russian or Spanish, the request may be made in Russian or Spanish regardless of the official language of the IDA. In this case, the International Bureau will provide, on request and free of charge, a certified translation into English or French.

94. Rule 11.4(c) requires any request, etc., made under Rules 11.1, 11.2 or 11.3 to be in writing and to be signed and dated. Rule 11.4(d) states that any request, etc., made under Rules 11.1, 11.2 or 11.3(a) (not 11.3(b)) must contain:

“(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;

(ii) the accession number given to the deposit;

(iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;

(iv) in the case of Rule 11.3(a), the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule.”

In the case of any request made under Rule 11.3(b), only the name and address of the requesting party and the accession number of the deposit need be given (Rule 11.4(e)). However, as already mentioned (paragraph 92), Rule 11.3(b) is rarely invoked and in practice delays can be avoided if the request is also accompanied by evidence of the issuance of a patent referring to the particular microorganism.

(f) Procedures for Furnishing Samples

(i) Indications Provided by the IDA

95. Rule 11.4(f) to (h) deals with the procedures to be followed by the IDA when actually furnishing samples. Rule 11.4(f) states:

“The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7, an indication of any properties of the microorganism which are or may be dangerous to health or the environment and, upon request, an indication of the conditions which the international depositary authority employs for the cultivation and storage of the microorganism.”

Except for the requirement to supply a copy of the receipt, these are obvious provisions which most culture collections apply in any case when sending out cultures of microorganisms.

(ii) Notification of the Depositor

96. Rule 11.4(g) states:

“The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party or of the requesting party, to whom or to which the sample was furnished. The said

notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3.”

This Rule recognizes the right of the depositor to be informed in every case when, to whom and under what conditions samples of his microorganism have been furnished. In practice, however, some depositors indicate in writing to the IDA that they wish to waive their right to be so informed. In such cases, most IDAs will comply with the depositor’s wish; in fact, some charge a lower fee for storage if the depositor waives this right (see Section D of this Guide).

(iii) Fees

97. A fee may be charged by the IDA for the furnishing of samples (Rule 12.1(a)(iv)) in all cases except where the recipient is an industrial property office, in which case the sample must be supplied free of charge (Rule 11.4(h)).

98. Any party entitled under Rules 11.1, 11.2 or 11.3 to receive a sample of a deposited microorganism is also entitled to be supplied, on request, with a copy of the most recent scientific description and/or proposed taxonomic designation relating to the microorganism (Rule 7.6), provided, of course, that the IDA has previously received such information from the depositor under Rules 6.1(b), 6.2(a)(iii) or 8.1(b)(iii) (see Section A of this Guide). The IDA is permitted to charge a fee for the communication of the description/designation in such cases (Rule 12.1(a)(v)). This fee, like all fees charged by the IDA, cannot be varied according to the nationality or residence of the party paying it (Rule 12.1(c)).

(g) Guidelines to Making a Valid Request for a Sample

(i) General

99. Subsections (a) to (f) have detailed and explained the requirements that must be met to effect the furnishing of a sample of a microorganism deposited under the Budapest Treaty. The purpose of this subsection is to translate these requirements into the practical steps that a third party (other than an industrial property office) should take in order to obtain a sample of such a microorganism.

100. Except where Rule 11.3(b) applies, anyone making a simple request for a sample of a particular microorganism, without any authorization or certification, can expect the IDA to ask him to do one of the following:

- obtain the authorization of the depositor (Rule 11.2(ii); see paragraph 101);
- obtain certification from the appropriate industrial property office, in which case the IDA may or may not supply him with the relevant forms (Rule 11.3(a); see paragraphs 102 and 103);

– provide evidence of the issuance of a US patent. (This is necessary because samples must be available without restriction when a US patent has issued, but IDA may not be aware of the patent; see paragraph 105.)

(ii) Obtaining Samples with the Authorization of the Depositor

101. The procedure which the requesting party should follow to obtain a sample with the authorization of the depositor is self-evident. He should approach the depositor, ask him for a written, dated, signed declaration authorizing the IDA to furnish to him a sample of the microorganism in question (if he wishes, he can use form BP/11 for this, which can be obtained from the IDA, although it is not essential). He should then send this declaration along with his request (and a purchase order) to the IDA. However, Rule 11.2(ii) presupposes that the requesting party knows who the depositor is. If he does not, he cannot expect the IDA to divulge this information to him (Rule 9.2; see paragraph 41). Thus there is little point in anyone who does not already know the identity of the depositor attempting to obtain a sample by this route.

(iii) Obtaining Samples with Industrial Property Office Certification

102. A request for a sample with industrial property office certification must be made on a form corresponding to form BP/12 (see Appendix 3), which ensures that the indications required by Rules 11.3(a) and 11.4(d) are given. Commonly, form BP/12 itself is used, although certain offices may have their own version of it. For example, the European Patent Office uses a form which combines the requirements of Rules 11.3(a) and 11.4(d) of the Budapest Treaty with those of Rule 33 of the European Patent Convention. Also, some offices may require additional forms to be completed in respect of their own national procedures. The equivalent of form BP/12, and any other appropriate forms, obviously can be obtained from the relevant industrial property office(s). Also many IDAs (see Section D of this Guide) keep stocks of them and will supply copies on request. Rule 11.3(a) assumes, however, that the requesting party knows which industrial property offices are competent to provide certification (i.e., where applications have been filed) in respect of the particular microorganism being asked for. If he does not, he should not assume that because the IDA can provide him with form BP/12, it can also tell him where to send it. In many cases, IDAs do not know where applications have been filed in respect of microorganisms deposited with them.

103. To obtain a sample of a microorganism under Rule 11.3(a), the requesting party should:

(a) ask the competent industrial property office, or the IDA, for a copy of the form to be used for requesting samples of microorganisms according to Rule 11.3(a) of the Budapest Treaty;

(b) complete that part of the form to be filled in by “the requesting party;”

(c) send the entire form to the industrial property office, not to the IDA, along with any fee that may be payable;

(iv) Obtaining Samples of Deposits Cited in US Patents

104. In the United States of America, in general, after grant any microorganism referred to in the published patent must be available to the public without restriction.

105. Before the patent has been granted, however, access to the deposit will be available during the pendency of the patent application with the reference to the microorganism only to one determined by the US industrial property Office to be entitled to the deposit under U.S. law and regulations. Because of this, the certification procedures of Rule 11.3(a) are relevant to US practice to establish a right to access to the deposit before a patent has been granted. The IDA may not know that a particular microorganism is the subject of a US patent and hence freely available. Thus, anyone requesting a microorganism which is referred to in a published US patent should ascertain whether the IDA is aware of such publication. If it is not, he should accompany his request with the number and date of the patent, the name(s) of the applicant(s) and a copy of the page referring to the accession number of the microorganism as evidence of publication. If the requesting party is not able to supply such evidence, he must expect the furnishing of a sample to be delayed until the IDA has verified that publication has occurred (not all IDAs, however, do conduct this type of verification). If the IDA is already aware of such publication, however, it is likely to furnish the sample in accordance with Rule 11.3(b).

(v) Obtaining Samples under Rule 11.3(b)

106. To obtain a sample pursuant to Rule 11.3(b), a requesting party merely needs to give his name and address and quote the accession number of the microorganism. Some IDAs, however, request use of WIPO model form BP/13.

(vi) Health and Safety Requirements

107. It should be noted that the procedures described in this subsection relate only to the right to receive samples of microorganisms according to patent law. They do not override any requirements to be met in respect of import and quarantine regulations, health and safety procedures, plant disease regulations, etc. Thus as well as obtaining any certification required by the Budapest Treaty, anyone requesting a sample must ensure that he has obtained any permit or license and complies with any safety requirements necessary for handling the organism in question.