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## WORLD INTELLECTUAL PROPERTY ORGANIZATION GENEVA

# COMMITTEE OF EXPERTS ON THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Second Session Geneva, April 22 to 29, 1975

REPORT

#### I. INTRODUCTION

- 1. Convened by the Director General of the World Intellectual Property Organization (WIPO) in accordance with a decision taken by the Executive Committee of the Paris Union for the Protection of Industrial Property in the course of its tenth ordinary session (September 1974), the Committee of Experts on the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as "the Committee") held its second session in Geneva from April 22 to 29, 1975.
- 2. All member States of the Paris Union for the Protection of Industrial Property had been invited. The following were represented: Czechoslovakia, Denmark, Finland, France, Germany (Federal Republic of), Hungary, Ireland, Japan, Netherlands, Nigeria, Norway, Soviet Union, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States of America (18).
- 3. The following intergovernmental organizations had been invited but were not represented: United Nations, United Nations Industrial Development Organization, Food and Agriculture Organization, World Health Organization, Interim Committee of the European Patent Organisation, International Patent Institute.
- 4. Ten international non-governmental organizations were represented by observers: Committee of National Institutes of Patent Agents (CNIPA), Council of European Industrial Federations (CEIF), European Council of Chemical Manufacturers' Federations (CEFIC), European Federation of Agents of Industry in Industrial Property (FEMIPI), International Association for the Protection of Industrial Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Inventors' Associations (IFIA), Union of European Professional Patent Representatives (UNEPA), Union of Industries of the European Community (UNICE), World Federation for Culture Collections (WFCC).

- 5. The list of participants is annexed to this report.
- 6. Dr. Arpad Bogsch, Director General of WIPO, opened the session.
- 7. The Committee unanimously elected Dr. J.-L. Comte (Switzerland) as Chairman and Mr. V. Tarnofsky (United Kingdom), Mrs. E. Parragh (Hungary) and Mr. Owoyele (Nigeria) as Vice-Chairmen. Dr. L. Baeumer (WIPO) acted as Secretary of the Committee.
- 8. Discussions were based on documents DMO/III/2 and 3, which contain a draft treaty and draft regulations. After a general discussion (see Part II of this report), the Committee decided to accept those drafts as a basis for its deliberations and examined them Article by Article, and Rule by Rule, in the order in which the Articles and Rules appear in the documents. Part III of this report relates to those deliberations; it only indicates the amendments suggested, generally without identifying speakers; the International Bureau, however, is able to identify the speakers on the basis of the notes taken by the Secretariat and the tape recordings of the discussions. The fact that a number of provisions are not mentioned in Part III of this report means that the Committee, after examining the provisions in question, did not ask for any changes to be made; moreover, consequential changes which have to be made in certain provisions in view of amendments suggested by the Committee are not expressly mentioned. All references to Articles and Rules, unless otherwise specified, are references to Articles and Rules of the draft treaty and the draft regulations as appearing in documents DMO/III/2 and 3.
- 9. The Committee also considered document DMO/III/4, which presents an analysis of replies received from depositary institutions to the WIPO questionnaire on deposits of microorganisms for the purposes of patent procedure, and documents DMO/III/5, 6, 8, 10, 11 and 12, which contain observations and proposals by the Delegations of Sweden, France, Switzerland, the International Bureau and the Delegation of Czechoslovakia and, as a joint proposal, by the Representatives of UNICE, CEIF, CEFIC, ICC and FEMIPI.

#### II. GENERAL DISCUSSION

- 10. The Delegation of the UNITED KINGDOM recalled that the work of the Committee had started on a proposal made by the United Kingdom in 1972. The main concern of that proposal was to avoid multiple deposits of microorganisms in cases where protection for a microbiological invention was sought in several countries; in such cases, a single deposit with an approved depositary institution should suffice. The draft treaty and regulations prepared by the International Bureau fully reflected that proposal.
- 11. The Delegation of SWITZERLAND expressed its general agreement with the draft treaty and regulations and in particular with one of its guiding principles, namely that changes in substantive national law should not be required.
- 12. The Delegation of the SOVIET UNION underlined the importance of the work undertaken by the Committee. In its view, the draft treaty and regulations constituted a good basis for discussion. As far as the admission of international organizations was concerned, it was logical to continue the study, taking Article 19 of the Paris Convention into account.
- 13. The Delegation of SPAIN said that it had examined with interest the draft treaty and regulations and had found them in general acceptable. There was, however, the question whether the provisions on release were sufficient to prevent abuses.
- 14. The Delegation of JAPAN said that Japan had about ten years' experience in the deposit of microorganisms for the purposes of patent procedure and that an administration existed which acted as depositary institution. It expressed its agreement with the basic principle of the draft treaty, namely, that a deposit with an internationally recognized depositary authority would have effect in other States. It also declared that the competent Japanese authorities agreed with the principle that for an invention involving the use of a microorganism the deposit of a culture of that microorganism should be mandatory. In some respects, however,

the present situation in Japan differed from the system proposed by the draft treaty, in particular as regards the conditions for the release of a sample of the culture, the duration of storage and the conditions for recognition as a depositary authority. It expressed the hope that the problems resulting from those differences could be solved.

- 15. The Delegation of the FEDERAL REPUBLIC OF GERMANY welcomed the system proposed and stated that the drafts were in general acceptable.
- 16. The Delegation of FRANCE, referring to its observations contained in document DMO/III/6, declared that it had no general objection to the proposed treaty, which followed the recommendations adopted by the Committee at its first session in 1974. However, it felt that the conclusion and implementation of the treaty and regulations might require considerable time, which could justify the consideration of an emergency solution to come into effect more rapidly, such as that proposed by France. In France, there was as yet no regulation on the matter, nor was there an established depositary institution. Many questions of a technical nature still required further examination and therefore it was difficult to take a position on them at the present stage of the discussion.
- 17. The Delegation of CZECHOSLOVAKIA stated that an international system for the recognition of deposits of microorganisms would be useful but that such a system would not require the adoption of a new treaty; a protocol to the Paris Convention for the Protection of Industrial Property appeared to be the right form. International recognition of depositary authorities should be based on examination by the industrial property office of the country in which the institution was located. Particular care should be taken with respect to the provisions on the release of microorganisms.
- 18. The Representative of AIPPI, CEIF and ICC, speaking also for FEMIPI, said that the drafts were a useful basis for discussion.
- 19. The Representative of CNIPA expressed the view that the principle of a single deposit, provided for in the draft treaty, was most important and that such deposit should be made with a recognized depositary authority. Some further work on the clarification and unification of definitions might be required.

#### III. DRAFT TREATY AND DRAFT REGULATIONS

#### Article 1: Establishment of a Union

20. The majority of the Committee expressed itself in favor of allowing intergovernmental organizations to become party to the treaty on the understanding that, as already stated in Article 14 of the draft treaty, such organizations had been entrusted with the task of granting patents. For the next session, the question of any implications arising from Article 19 of the Paris Convention with regard to this problem and the question whether precedents existed for such a solution should be studied.

#### Article 2: Definitions

- 21. Ad (i) and (ii): These definitions should be re-examined by the International Bureau, and new proposals should be presented in the next draft. In particular consideration should be given to the possibility of deleting the definition of "strain of microorganism." Furthermore the definition of "culture of microorganism" should be redrafted. For the new draft of the latter definition, several proposals were made which should be considered by the International Bureau when preparing the next draft. One of those proposals was the following: "'culture of microorganism' means a viable population of microorganisms, in a given place and at a given time; such a population may or may not consist of similar individuals." Another proposal was to draft the latter part of that definition in a more specific way, to read as follows: "which is rigorously identical with respect to its morphological, physiological, genetical and serological behavior."
- 22. The term "microorganism" should be the subject of an explanatory note in the observations on the treaty; it could possibly be worded along the following lines:

"The term 'microorganism' is to be understood in a broad sense and, taking into account the purposes of the treaty, need not necessarily correspond to usage in some scientific circles. In particular, the following entities should be considered microorganisms for the purposes of the treaty:

(i) organisms which can be maintained by a depositary institution, such as  $% \left( 1\right) =\left( 1\right) +\left( 1\right)$ 

bacteria yeasts some algae protozoa some fungi mycoplasma rickettsiae viruses;

- (ii) killed entities derived from the foregoing, provided the living precursor is deposited;
- (iii) cells derived from the bodies or the embryos of higher organisms maintained and propagated in undifferentiated form in artificial culture, e.g., cell lines."

As regards the above text, the question should be studied in particular whether killed entities ought to be included, having regard to the need to provide for the possibility of release, which normally required reproduction of the organisms.

- 23. Ad (iii): It was suggested that the possibility should be considered of adding a definition of "sample" which would cover a viable subculture prepared by the depositary institution and destined for release as well as a culture held in reserve by the depositary institution.
- 24.  $\underline{\text{Ad (iv)}}$ : After the words "patents for inventions," the following text should be inserted: "[and other titles for the protection of inventions, including]..."
- 25. Ad (v): The new draft should give a broader definition, comprising any kind of administrative and judicial procedure, thus covering, for example, a procedure for the grant of a compulsory license or for the invalidation of the patent. Moreover, the questions should be examined whether the words "or result" should not be deleted.
- 26. Ad (vi): The expression "internationally recognized depositary authority" should be maintained even if the French version has to continue to use the shorter expression "autorité de dépôt." Several delegations, however, expressed the wish that two texts be harmonized.
- 27. Ad (vi-bis (b)): The question should be studied whether, after the words "office, authority or court of such State," the text should be clarified to show that this is a mixed reference, for instance by adding "as the case may be."
- 28. Ad (viii): The question should be examined whether, after the word "transmittal," the following words should be added: "(sending and receipt), as provided in this Treaty and the Regulations." The definite article "the" before "internationally recognized depositary authority" should be replaced by the indefinite article "an."
- 29. Ad (ix): This subparagraph should be deleted.

#### Article 3: Recognition of the Deposit of Microorganisms

30. Ad paragraph (1)(a): Views differed on the question whether a definition of the words "recognize as valid" should be given, covering in particular the fact of the deposit, its date and its identity. The question should be examined whether the next draft should contain such definition in square brackets.

- 31. Ad paragraph (1)(b): "Viability" should not be expressly defined. No provision should be made to the effect that the receipt should in all cases include the certificate of the first viability test.
- 32. Ad paragraph (2): The Committee accepted the principle of permitting new deposits in the cases and with the consequences referred to in this provision. It asked the International Bureau to redraft the provision, taking into account the following considerations in particular.
- 33. The principle of retroactivity contained in paragraph (2)(c) should be maintained, depending on the identity of the microorganism which is redeposited with the microorganism originally deposited. The question of proof of that identity should be left to the national law; the treaty, however, could require that in any case a declaration by the depositor alleging the identity should be filed when making the new deposit. Moreover, it should be required that the new deposit would have retroactive effect only where a viability certificate had been issued for the culture originally deposited. A general reference should be made to the provisions of the regulations.
- 34. The identity should be defined by an expression such as "another culture of the originally deposited microorganism having the same essential characteristics and properties as those of the culture originally deposited" or by using the term "duplicate culture," which would require a special definition.
- 35. In the case of paragraph (2)(a), the possibility might be considered of requiring that the new deposit be made with the same internationally recognized depositary authority unless the non-availability is due to a fault on the part of that internationally recognized depositary authority. In the case of a new deposit in a different internationally recognized depositary authority, there should be an obligation to communicate the number of the new deposit to the industrial property offices with which patent applications had been filed with a reference to the original deposit.
- 36. In the case of paragraph (2)(a), and possibly also in the case of paragraph (2)(b), the depositor should be notified of the fact that the culture is no longer available for release. In paragraph (2)(c), Alternative Y should be adopted; the period for making the new deposit should start on the date of receipt of the notification of non-availability or, if no such notification was made, on the relevant (earlier) one of the dates provided for in the draft.
- 37. As regards the questions raised in the observations, the treaty should not oblige Contracting Parties to admit several deposits; whether several deposits could be relevant for patent purposes should be left to the national law. The question should be studied whether and under what conditions and with what effects the treaty might provide for the possibility of the transfer of a deposit.

#### Article 4: Export and Import Restrictions

38. The question should be studied to what extent this Article could be made applicable to intergovernmental organizations party to this treaty. The new draft of this Article should no longer contain the part within square brackets in lines 3 and 4. The Delegation of JAPAN, while stating that only a few export and import restrictions existed in its country, reserved its position on this Article.

## <u>Article 5: General Conditions of the Status of Internationally Recognized Depositary Authority</u>

39. As regards (iii), it was preferred to restrict the possibility of the location of an internationally recognized depositary authority to Contracting States. The DIRECTOR GENERAL remarked in this context that this would mean that, in the case of a regional patent organization, not only that organization but also all its member States on the territory of which a prospective internationally recognized depositary authority is located would have to accede to the treaty.

#### Article 6: Guarantees

40. The question should be studied whether the guarantees could be given only by the Contracting Party or also by the depositary institution itself (see also the discussion on Article 7).

- 41. Ad paragraph (1)(i): The question should be studied whether, in view of the discrepancy between "continued existence" in the English text and "existence permanente," in the French text, it was not necessary to use a more appropriate wording in the next draft.
- 42. Ad paragraph (1)(iii): It was suggested that this provision should be deleted or at least redrafted, taking into account the wording used in document DMO/II/16, paragraph 35(a), and possibly using the terms "impartial and objective."
- 43. Ad paragraph (1) (viii): The next draft should offer alternatives with respect to the questions whether the responsibilities of an internationally recognized depositary authority should be limited and/or whether the proposing or certifying Contracting Party should hold that authority immune from claims. In particular, the question should be studied whether the matter should be entirely left to the national law or whether the treaty should contain provisions, for example, limiting the amount of liability or excluding, under certain conditions, the liability for cases of damage occurring because of the release of samples by an internationally recognized depositary authority. One of the possible solutions to be studied would consist in differentiating between a mistaken release of a sample with the express authorization of an industrial property office and such a release without such authorization. In this context, solutions adopted in other areas, for example, in existing or proposed conventions on carrier liability, might be taken into consideration.

#### Article 7 (Alternatives A and B)

- 44. Opinions in the Committee were equally divided on the question whether Alternative A or B should be adopted. Therefore, the new draft should again contain both Alternatives. One delegation suggested combining both Alternatives by providing that the decision to grant the status of internationally recognized depositary authority should be taken by the Director General.
- 45. The new draft should limit the right to propose or certify to a Contracting Party which is a State, and only with respect to depositary institutions located on its territory. The question should be studied whether the proposal or the certification should be made not by the State but by the depositary institution, the State, however, endorsing the relevant declarations.
- 46. Ad paragraph (1): The right to ask for further information from the certifying State should be provided for.
- 47. The proposing or certifying State should have the right to indicate a date before which the grant of the status of an internationally recognized depositary authority should not take effect. In paragraph (1)(b), Alternative B, the effective date should be the date of receipt of the communication, unless a later date had been indicated by the certifying State.

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- 48. Ad paragraph (2): It should be possible for any Contracting Party (whether a State or an intergovernmental organization) to make the request under paragraph (2)(a); the next draft should make it clear that such requests cannot be made by the State on whose territory the internationally recognized depositary authority is located. Before making the request, the requesting Contracting Party should, through the intermediary of the Director General, bring the reasons for the request to the attention of the latter State, thus giving an opportunity to that State to take appropriate action which would obviate the need for making the request, such as a withdrawal of the declaration of guarantee under paragraph (3) or elimination of the reason for the request; a time limit for such action might have to be specified.
- 49. Ad paragraph (4): In Alternative A, paragraph (4)(a), the majority required should be three-fourths. For the decision to withdraw or terminate the status of internationally recognized depositary authority, a simple majority should suffice in both Alternatives. The Delegation of the SOVIET UNION reserved its position on this matter.

#### Article 8: Committee of Experts

50. The next draft should not provide for a Committee of Experts as an institution. This, however, would not preclude the Assembly from establishing, under Article 9, committees or working groups, which would prepare its decisions. Reference was made to the possibility of convening extraordinary sessions of the Assembly and to the further possibility that the rules of procedure of the Assembly could provide for a written procedure.

#### Article 9: Assembly

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- 51. The status of international non-governmental organization (paragraph (2)(a)(vi)) should be clarified. The question should be studied whether the Assembly should admit internationally recognized depositary authorities to its meetings as observers.
- 52. In paragraph (1)(c), the word "(Paris)" should be inserted between "International" and "Union."
- 53. Paragraph (6) (a) should also refer to Article 7(4).

#### Article 11: Regulations

54. The possibility of a veto against the amendment concerning the release of samples should be maintained.

#### Article 13: Amendment of Certain Provisions of the Treaty

55. The observations on the next draft should mention that paragraph (1)(a) follows the precedent of other Conventions administered by WIPO and is to be understood in the sense that it cannot be amended under Article 13.

#### Article 16: Denunciation of the Treaty

56. The consequences of denunciation by a State on whose territory an internationally recognized depositary authority is located should be studied, and the next draft should contain a proposal on this matter, taking into account, in particular, the possibility of a new deposit.

#### Article 17: Signature and Languages of the Treaty

57. The Delegation of the SOVIET UNION, referring to WIPO's recently acquired status of specialized agency of the United Nations, proposed that the original of the treaty to be signed should also be in Russian. The Delegation of SPAIN made the same proposal with respect to the Spanish language. The DIRECTOR GENERAL stated that the specialized agency status agreement did not contain any provision changing the present practice of WIPO with respect to languages of treaties, documents, etc; in any case, that was a question which should more appropriately be considered by the Diplomatic Conference.

#### Article 18: Depositary Functions

- 58. In view of the subject matter dealt with by the treaty, the new draft should modify the title of this Article.
- 59. As regards the transmittal of copies under paragraph (2), the DIRECTOR GENERAL stated that on request more than two copies would be transmitted.

#### Article 19: Notifications

60. The next draft should provide for a notification of any amendment of the regulations.

61. As regards amendments of the treaty by a revision conference, no obligation for notification should be included in Article 19 since this matter would have to be decided by the revision conference.

#### Financial Questions

62. On discussing the proposal of a delegation to include a system of contributions in the treaty, the Committee was of the opinion that the next draft, like the present draft, should not contain any provisions on finances, and that there should be no observations on the matter. The Committee's conclusion was reached on the understanding that the administration of the new Union to be created would not cause very considerable expenses and that most probably the computing and collection of contributions and the auditing of such a system would be more expensive than the administration of the Union itself; in view of those facts, it was more appropriate that the expenses caused by the administration should be borne by the budget of the Paris Union.

#### General Remark on the Regulations

63. Throughout the regulations, references to "the International Bureau" should be replaced by references to "the Director General."

#### Rule 2: Internationally Recognized Depositary Authorities

- 64. Ad Rule 2.1: This Rule should be redrafted, harmonizing the English and the French versions and making it clear that public institutions attached to any public administration other than the central government of the State concerned were covered as well.
- 65. Ad Rule 2.2(i): This Rule should be deleted.
- 66. Ad Rule 2.2(iii): This Rule should be redrafted, by making it less specific and stating, for example: "provide for sufficient safety measures."
- 67. One delegation proposed that a rule be provided which would oblige internationally recognized depositary authorities to publish at regular intervals catalogues of deposited microorganisms. Other delegations stated, however, that such an obligation would be a heavy burden on the depositary institutions and that the possibility might be considered of publishing in the Gazette lists of new deposits made.

#### Rule 3 (Alternatives A and B)

- 68. Ad Rule 3.1(a): The next draft should no longer specify the language of the proposal or the communication. It should require that the proposal or the communication be transmitted to the Director General through diplomatic channels. The signature requirement as now provided for in the draft would consequently be omitted. The Delegation of the SOVIET UNION reserved its position on this provision.
- 69. Ad Rule 3.1(b) (ii): This Rule should be redrafted, deleting in particular, at the end, the words "sources of revenue and methods of management." One delegation proposed the deletion of the end of this provision, commencing with the word "including."
- 70. Ad Rule 3.1(b) (v): This Rule should be harmonized with the recommendation concerning Article 7.1(b) (see paragraph 47).
- 71. Ad Rule 3.2(Alternative B): This Rule should refer also to compliance with Article 7 (1)(a) (Alternative B).

- 72. Ad Rule 3.2(c) (Alternative A): It should be stated whether instead of "six months" there should be a more flexible time limit, for instance "between four and eight months." The next draft should provide for the possibility of a decision of the Assembly by correspondence. The observations on the next draft should make it clear that, where the decision by correspondence is negative, the Assembly could, as always, reverse that decision at one of its following sessions.
- 73. Ad Rule 3.2(d) (Alternative A): This Rule should be harmonized with the recommendation contained in paragraph 47.
- 74. Rule 4 (Alternatives A and B): The question should be studied whether the next draft should contain provisions concerning possible consequences of a decision under Rule 4 with respect to deposits which have been made with the internationally recognized depositary authority concerned, taking into account the provisions on new deposits contained in Article 3(2)(b) and Rule 7.2.
- 75. Ad Rule 4.1(a): The language requirement should be deleted.
- 76. Ad Rule 4.2(b) (Alternative A) and Rule 4.2(d) (Alternative B): The question should be studied whether a shortening of the time limit should be provided for and, if so, under what conditions.
- 77. The question should be studied whether and to what extent the public should be informed about requests made under Rule 4.

#### Rule 6: Defaults by the Internationally Recognized Depositary Authority

- 78. Ad Rule 6.1(a)(ii): Files and all other relevant information relating to deposits should be transferred from the defaulting authority to the substitute authority.
- 79. Ad Rule 6.1(iii): The drafting should be harmonized with (i) and should not refer to the obligations of internationally recognized depositary authorities since this follows from the requirement that the substitute authority must be an internationally recognized depositary authority. The question should be studied whether any provisions on financial implications should be contained in the next draft, for instance to the effect that the transfer is made free of charge in so far as the depositor and the industrial property office are concerned.
- 80. Ad Rule 6.2: This Rule should be re-examined. In particular, the question should be studied whether it should not be supplemented by a provision obliging the State on whose territory the internationally recognized depositary authority is located to make sure that all the kinds of microorganisms to which the status of recognized depositary authority applies can be deposited. This would imply, where the internationally recognized depositary authority would not accept certain kinds of microorganisms to which the guarantee applies, the obligation for the said State to ensure the possibility of deposit for such kinds of microorganisms within another internationally recognized depositary authority.

#### Rule 7: Making the Original Deposit or New Deposit

- 81. Ad Rule 7.1(a): The new draft should provide for an obligation to include in the written statement an indication that the deposit is made under the treaty.
- 82. Ad Rule 7.1(a)(ii): This provision should be redrafted, for instance on the following lines: "details of the conditions necessary for the cultivation of the deposited culture and, in so far as they may differ from the foregoing, details of the conditions suitable for testing the viability and/or purity of the culture; if a mixed culture is deposited, descriptions of the components of the mixture and methods for checking their presence and/or viability should also be supplied." The question should also be studied whether a supplement to the description should be admitted.

- 83. Ad Rule 7.1(a)(iii): The words within square brackets should be deleted.
- 84. Ad Rule 7.1(b): The next draft should use the terms "scientific description and/or taxonomic designation." Several delegations suggested that the furnishing of those indications be made mandatory—at least by adding "in so far as such a designation and description exist"—but others objected on legal grounds (such indications might conflict with the description in the patent application, which alone should count) and/or practical grounds (not all depositors are equipped to ascertain the indications; in any case, it frequently involves loss of time, additional cost and possibilities of error). The question should be studied whether the existence of such indications in connection with the originally deposited culture (even if made later than at the time of the original deposit) could not be made a condition of any new deposit. The possibility could be considered of adding before the words "taxonomic description" the word "proposed." One delegation proposed that the taxonomic designation should be required to be in harmony with the international codes on plants and bacteria in force on the date on which the deposit was made or the designation was supplied. Consideration should also be given to the possible legal consequences of an incomplete or incorrect designation or description.
- 85. Ad Rule 7.1(c): The payment of the fee should not be a condition of the validity of the deposit. The fact should be taken into account that not all existing depositary institutions charge fees for acceptance and maintenance of deposits. It could possibly be left to the internationally recognized depositary authority to make the issuance of a receipt contingent upon the payment of a fee, thus leaving it to that authority to decide whether it was ready to issue a receipt even without payment of a fee.

#### Rule 8: Receipt

- 86. Ad Rule 8.2(a): The model of the form should be established by the Director General.
- 87. Ad Rule 8.2(b): One delegation proposed that receipts in languages other than English or French should be allowed. The DIRECTOR GENERAL stated that the forms would have to be used in many countries and should therefore be in either English or French. They could, however, as already provided in the draft, also include the language used by the internationally recognized depositary authority.
- 88. Ad Rule 8.2(c): The next draft should provide for the possibility of using a seal instead of a signature.
- 89. Ad Rule 8.3: The words "except where Rule 8.4 applies," should be deleted.
- 90. Ad Rule 8.3(iii): This provision should be redrafted in such a way as to make it clear that the date of deposit was the date of receipt of the deposited culture by the internationally recognized depositary authority (irrespective of the date on which the fee, if any is due, was paid).
- 91. Ad Rule 8.3(iv) and (vi): These provisions would have to be harmonized with the amendments made in Rule 7.1.
- 92. Ad Rule 8.4(i): There should also be a reference to Rule 8.3(v).

#### Rule 10: Storage of Cultures

93. Ad Rule 10.1: Notwithstanding the proposal of one delegation that "30," in square brackets in the last line, be replaced by "20," the Committee was of the opinion that the periods of five and 30 years should reappear in the next draft without brackets.

- 94. Ad Rule 10.2: The new draft should provide for an alternative under which no restitution or destruction may occur before a certain period of time has elapsed after deposit, in order to provide for the case of usurpation. A period of three years was proposed, to appear in square brackets in the next draft.
- 95. The text contained within square brackets should be presented in the next draft without brackets, but the words "and shall publish it in the Gazette" should be deleted.
- 96. Ad Rule 10.3: The next draft should add the words "subject to Rule 12."

#### Rule 11: Viability Test and Viability Certificate

- 97. Ad Rule 11.1: The question should be studied whether the new draft should maintain (ii) and (iii) and, if (ii) were to be maintained, whether the words "each interval not exceeding [five] years" should not be replaced by "depending on the microorganism and the possible storage conditions, or at any time, if this is necessary for technical reasons."
- 98. Ad Rule 11.2: The drafting of this provision should be reviewed to make it clear that a statement would issue from the depositary authority also where the test showed that the culture was not or no longer viable. The title of the statement and of the rule should be modified accordingly.
- 99. Ad Rule 11.2(e): The question should be studied whether industrial property offices would have to pay a fee for a viability certificate.

#### Rule 12: Release of Samples

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- 100. Ad Rule 12.1(a): It was suggested that the possibility of release not only to an industrial property office but also to a competent court should be provided for. It was considered, however, that this proposal might not be necessary in view of Rule 12.2, since the depositor could be forced to provide a sample in a court procedure.
- 101. The observations on the next draft should contain an explanatory note on the word "use" in (ii), to the effect that use as an inoculating material, in a process of propagation to obtain more cells constituting the end product, was also covered.
- 102. Ad Rule 12.1(b): The reference to the owner of the patent should be replaced by a reference to the original applicant, which would be safer in the event of assignment of the patent.
- 103. Ad Rule 12.2: The question should be studied whether provisions should be included in the next draft to cover the case of a depositor having a successor in title.
- 104. Ad Rule 12.3: In addition to the proposals for amendment of this Rule contained in documents DMO/III/5, 8, 11 and 12, further proposals were made by the Delegations of JAPAN, the SOVIET UNION and the UNITED KINGDOM, as well as by the Representative of UNICE.
- 105. The Delegation of JAPAN proposed that
- (i) the person requesting the release would have to be a resident of the country in which the depositor's patent application had been made, and that the use of the sample should be restricted to the territory of that country,
  - (ii) the sample should not be transmitted to any third party,
- (iii) the use of the released sample should be restricted to testing and research,

- (iv) after testing or research, the sample should be returned to the internationally recognized depositary authority.
- 106. The Delegation of the SOVIET UNION proposed that the request for release should be accompanied by a declaration issued by the industrial property office of the Contracting State with which the depositor's patent application referred to in the request, has been filed and on whose territory the requesting party was domiciled or had a real and effective industrial or commercial establishment, certifying that the requesting party undertook not to transmit the microorganisms to third parties, to export them from the said Contracting State or to use them for industrial purposes.
- 107. The Delegation of the UNITED KINGDOM, referring to Rule 28 of the Regulations under the European Patent Convention, proposed that any intergovernmental organization party to the treaty should have the right to waive the requirement of a declaration, and that, in the case of such a waiver, it should simply be required that any internationally recognized depositary authority should release a sample of any deposited culture to a third party if that third party gave an undertaking to that authority, vis-à-vis the applicant or the owner of the patent, complying with any requirements of the said organization, and if the relevant application or patent granted thereon had been published.
- 108. The DIRECTOR GENERAL suggested that a distinction be made between requests for "routine" and requests for "extraordinary" release to a third party. A "routine" release would be a release effected once the relevant patent application had been published or the relevant patent had been granted. An "extraordinary" release would be a release before such publication or grant. In either case, the depositary authority would require the requesting third party to fill in a form the model of which it would receive in advance from each industrial property office, and which would contain all the statements required by the law (or treaty) applicable in proceedings before that office. In the case of a routine release, the fact that the publication or grant had occurred would be established from lists furnished by the industrial property offices to the depositary authorities; the release could thus take place without delay, on the same day as the publication or grant. In the case of an extraordinary release, the requesting third party would have to produce a statement from the industrial property office to the effect that he had a right to the sample. This would apply, for example, in the case of interference procedures under the law of the United States of America.
- 109. The Representative of UNICE proposed that a study be made of the question whether a Contracting State could refuse the grant of a patent for a microbiological invention in a case where the applicant agreed to make the microorganism involved available on the territory of that State but did not agree to export the said microorganism to other States. The various States would have to clarify that question before their industrial property offices were in a position to issue a declaration according to Rule 12.3(iii) stating expressly or implicitly that the certified party had the right to receive a sample without any territorial restrictions.
- 110. The Committee first considered the question of principle, namely, whether the treaty should oblige Contracting States to adopt in their national laws provisions of substantive law with respect to release and to refrain from adopting provisions on release that were contrary to the treaty. All the delegations replied to this question in the negative and the Chairman stated, by way of a conclusion drawn from the discussion, that the treaty should not provide for any such obligation. The representatives of several international nongovernmental organizations did not agree with the foregoing conclusion of the Committee. The Chairman added that, as a consequence of the Committee's conclusion, in particular all proposals for the introduction of the condition that release may be made only to residents of the country in which the depositor's patent application, referred to in the request for release, had been filed, and of the further condition that released samples might be used only for certain purposes and in particular might not be exported to other countries, were to be regarded as rejected. The Delegation of the SOVIET UNION reserved the right to revert to its proposal in due course.

- 111. The Committee recommended that Rule 12.3 should be re-examined in the light of the proposal made by the Delegation of the United Kingdom--which could possibly be presented in square brackets in the next draft--making the proposed option for intergovernmental organizations available also to Contracting States. In particular, consideration was given to the possibility of providing for a system that would oblige industrial property offices to transmit to the internationally recognized depositary authority concerned forms containing the conditions of release which would have to be signed by the requesting party before the release was made. Furthermore, the question should be studied whether in (ii) the requirement of publication of the patent grant should not be replaced by the requirement that the patent should have been granted and the description made available for public inspection; the possibility of combining (iii) and (iv) should also be studied. Finally, an examination should be made of the question whether particular provisions were necessary for release in the case of an interference procedure taking place before publication of the application or before the grant of the patent.
- 112. The proposal contained in document DMO/III/8 was not supported.
- 113. The proposal contained in document DMO/III/12 for the introduction of a new Rule 12.4 was withdrawn.
- 114. The Committee replied in the negative to the question raised on page 20 of document DMO/III/2, namely, whether the depositor should be heard by the internationally recognized depositary authority before a certificate was issued under Rule 12.3.
- 115. Ad Rule 12.4(a): The question should be studied whether the next draft should contain a more precise expression than "all the indications necessary for identifying the deposit," or whether that expression should be specified by reference to the relevant provisions of the treaty and the regulations.

#### Rule 13: Fees

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- 116. It was proposed that a study be made of the question whether the system of a lump-sum fee for the whole duration of storage should be maintained without any reimbursements, or whether the fee paid for storage could be refunded in part if the depositor no longer had any patent or pending patent application involving the deposited microorganism, in which case the deposit would merely be serving public interest. It was further proposed that the question be examined whether, in addition to the fee for release, mailing costs should be charged separately. It was, however, agreed that a lump-sum fee system had definite administrative advantages and that it was also appropriate in view of the fact that the cost of storage was minimal. With respect to charges for mailing costs, the cost varied according to the country of destination and the method of transport, and therefore could not normally be levied in advance.
- 117. Ad Rule 13.1(c): It was agreed that the term "person" should be broadened so that patent offices, in particular, were also included.

#### Rule 14: Gazette

- 118. The provision contained in Rule 14.1(a) should be transferred from the regulations to the treaty.
- 119. Consideration might be given to providing for the possibility of publishing an extraordinary issue of the Gazette whenever new information on internationally recognized depositary authorities required urgent publication.

#### IV. OBSERVATIONS BY THE DELEGATION OF FRANCE

- 120. The Delegation of FRANCE, introducing its observations contained in document DMO/III/6, stated that its proposal should be considered as an emergency alternative for cases where the draft treaty and regulations considered by the Committee were found difficult to accept or would require a long period of time before they entered into force. The Delegation of France recognized, as a result of the discussions of this session, that its fears about the difficulties which the adoption of the system proposed by the International Bureau might encounter were somewhat dispelled. It was therefore ready to withdraw its proposal.
- 121. It was nevertheless agreed that the proposal of the Delegation of France might be discussed at a further session of the Committee if the need to revert to it was felt and if a request to that effect was made by the Committee.

#### V. FURTHER PROCEDURE

- 122. The DIRECTOR GENERAL said that he would consult the participants in writing on the proposed new drafts of at least the following provisions:
  - (i) certain definitions,
  - (ii) liability of internationally recognized depositary authority,
  - (iii) release of samples to third parties.
- 123. Thereafter, he might convene a small working group to discuss the first version of the next draft.
- 124. After that, the next draft would be released in preparation for the next session of the Committee, which would be convened in 1976.
- 125. The Committee endorsed these plans.

126. This report was unanimously adopted by the Committee in its meeting on April 29, 1975.

[Annex follows]

#### DMO/III/16 ANNEXE/ANNEX

#### LISTE DES PARTICIPANTS LIST OF PARTICIPANTS

(dans l'ordre alphabétique français des noms des Etats) (in the French alphabetical order of the names of the States)

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