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WORLD INTELLECTUAL PROPERTY ORGANIZATION GENEVA

ON THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

(April 23 to 26, 1974)

REPORT

I. Introduction

- 1. Pursuant to a decision taken by the Executive Committee of the Paris Union for the Protection of Industrial Property in the course of its eighth ordinary session (September 1972), and at the invitation of the Director General of the World Intellectual Property Organization (WIPO), a Committee of Experts on the Deposit of Microorganisms for the Purposes of Patent Procedure (hereinafter referred to as "the Committee of Experts") met in Geneva from April 23 to 26, 1974.
- 2. All the member States of the Paris Union for the Protection of Industrial Property had been invited. The following were represented: Algeria, Austria, Denmark, Finland, France, Germany (Federal Republic of), Hungary, Ireland, Netherlands, Norway, Soviet Union, Spain, Sweden, Switzerland, United Kingdom and United States of America (16).
- 3. Two member States of the Paris Union for the Protection of Industrial Property were represented by observers: Czechoslovakia and Indonesia.
- 4. Twelve 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), European Industrial Research Management Association (EIRMA), International Association for the Protection of Industrial Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Industrial Property Agents (FICPI), Pacific Industrial Property Association (PIPA), Union of European Patent Agents (UNEPA), Union of Industries of the European Community (UNICE) and World Federation for Culture Collections (WFCC).
- 5. The list of participants is annexed to this report.
- 6. The session was opened by Dr. Arpad Bogsch, Director General of WIPO.

- 7. The Committee of Experts unanimously elected Mr. E. van Weel (Netherlands) as Chairman and Mr. P. Guérin (France) and Mrs. E. Parragh (Hungary) as Vice-Chairmen. Dr. L. Baeumer (WIPO) acted as Secretary of the Committee of Experts.
- 8. Discussions were based on documents DMO/II/2 and 4, containing a survey of the systems existing at the national level with respect to the deposit of microorganisms for the purposes of patent procedure, and document DMO/II/3, containing a study of the possibilities of international cooperation with respect to the deposit of microorganisms for the purposes of patent procedure.

II. General Discussion

- 9. The Delegation of the UNITED KINGDOM referred to its Government's proposal made in 1972 for the study of the problems raised by the requirement of deposit of microorganisms for the purposes of patent procedure. The interest of the United Kingdom in the subject was first aroused by United States of America Bill No. 2504, which provided for the requirement of deposit in a culture collection located in the United States of America without permitting recognition of foreign deposits for disclosure purposes. The consequence of such a scheme, if it entered into force, would be that foreign inventors might be denied patent protection if there were restrictions on the import of microorganisms into, say, the United States of America. The idea of the United Kingdom proposal was therefore to examine the possibility of concluding an international convention providing for recognition of deposits of microorganisms which had been effected abroad and thus avoiding multiple deposits of the same microorganism.
- 10. The Delegation of the UNITED STATES OF AMERICA, while generally acknowledging the desirability of an international convention for the recognition of deposits of microorganisms, said that the Bill referred to by the Delegation of the United Kingdom was pending, and that there was not yet any determination as to a particular solution. The competent authorities maintained an open mind and were ready to study the question further. Moreover, the Delegation of the United States of America explained that in its country two types of depositories existed: on the one hand, a governmental institution, ARS Culture Collection, which did not make any charge for the deposit or release of microorganisms; on the other hand, the American Type Culture Collection, which charged depositors for maintenance until the grant of the patent and required payment of a nominal charge for release of deposited microorganisms. The present practice of the US Patent Office was based on guidelines issued by the Patent Office. Those guidelines required in particular that the depository afford permanence of the deposit and ready accessibility thereto by the public.
- 11. The Delegation of SWITZERLAND stated that efficient protection of inventions involving the use of microorganisms raised some new problems in the field of patent law. Those problems resulted mainly from the fact that in general it was not possible, by means of a written description, to describe an invention in a sufficiently complete manner for an expert to be able to perform it. Any performance presupposed access to the microorganisms which constituted, in a manner of speaking, the key to the invention. For that reason, several States required the deposit of a strain of a microorganism in order to complete or even replace its description. It was essential for interested circles filing patent applications for microbiological inventions that multiple deposits in various countries should be replaced by a system of recognition of one single deposit in all countries in which protection was sought. Such a solution would be simple and would have some chance of success. In that context, there should be no attempt at the outset to harmonize the provisions of substantive law and, in particular, the conditions of the grant and validity of patents relating to microbiological inventions. It was essential to concentrate on administrative and technical questions relating to the deposit of microorganisms with institutions recognized internationally; the conditions of access to the deposited microorganism might also be considered. In the latter connection, reference should be made to Rule 28 of the European Patent Convention, which contained certain elements of harmonization and which, for instance, served as a model for the revision of the Swiss Patent Law.

- 12. The Delegation of the NETHERLANDS, referring to the information on national systems with respect to the deposit of microorganisms as outlined in documents DMO/II/2 and 4, expressed the view that in the area in question difficult problems of a complicated nature had to be solved. The establishment of one single international patent culture collection with its own building would seem to be the ideal solution, but like most ideals it could not be fully implemented, at least not at short notice. It was essential to have a realistic approach in the matter: only solutions which could be reached without considerable difficulties should be examined. Thus, an improvement of the nomenclature of microorganisms would be difficult and would in any case go beyond the competence of patent experts. For the time being, one could not do without the cooperation of existing culture collections. All efforts should be concentrated on such cooperation. For that reason, the Delegation of the Netherlands was inclined to support WIPO's suggestion that several countries recognize a number of existing culture collections. The avoiding of multiple deposits was mainly in the interest of industry, and the Netherlands Patent Office was ready to consider any relevant suggestions from industrial circles and to cooperate as far as possible.
- 13. The Delegation of SWEDEN stated that the solution to the problem of avoiding multiple deposits was the conclusion of an international convention on the recognition of foreign deposits for the purposes of patent procedure. The problem of the deposit of microorganisms had already been studied in Sweden for some considerable time. As regards the national law of Sweden, its revision was envisaged along the lines of Rule 28 of the European Patent Convention.
- 14. The Delegation of the SOVIET UNION indicated that the competent Soviet authorities were interested in the problem under discussion and were ready to study the possibilities of international cooperation with respect to the deposit of microorganisms for the purposes of patent procedure. The Soviet Law on Inventions provided for the protection of inventions involving microorganisms; for such inventions the State Committee for Inventions and Discoveries of the Council of Ministers of the USSR required that the microorganisms be deposited in the national culture collection. The number of the deposit in the culture collection had to be indicated in the application for protection. If a microorganism had first been deposited abroad, the applicant had to furnish, for the purposes of the subsequent application in the Soviet Union, a sample of a deposited microorganism to the USSR State Committee for Inventions and Discoveries in order to enable it to be deposited in the USSR collection. With respect to the Paris Union priority, it was required that the deposit should already have been effected on the date of the first filing invoked for the purposes of priority.
- 15. The Soviet Union was interested in working out international standards which could permit a more effective use of the Paris Convention for the purposes of microbiological inventions. In that context, however, the setting up of a centralized international collection was not called for. The best course of action seemed to be to deposit the microorganism in a collection in the country where the first application was made which was supervised and guaranteed by a State institution such as the Patent Office or the Academy of Sciences. The fact also had to be taken into account that not all countries were able to keep national culture collections and that therefore it would be appropriate to establish collections for a group of countries; such a collection should meet the requirements of international standards. Thus, an international collection in the form of a decentralized collection based on existing national or regional collections could be taken into consideration. The international standards with respect to the deposit of microorganisms should be adopted either in the form of an amendment to the Paris Convention or in the form of a separate protocol to it.
- 16. The Delegation of FRANCE, while in favor of setting up a system which would avoid multiple deposits, pointed out that so far there did not seem to exist a generally accepted opinion on the problem of the deposit of microorganisms and that a number of questions required further study. If provisions had been adopted on the matter within the framework of the European Patent Convention, such provisions were contained only in the Regulations of that Convention so that they could be modified by a decision of the Administrative Council of the European Patent Organisation. Further study of those questions should also include the financial aspects of the deposit of microorganisms.

- 17. The Delegation of GERMANY (FEDERAL REPUBLIC OF) indicated that the German Law would be revised, in the light of the solution adopted in Rule 28 of the European Patent Convention, after ratification of that Convention. It expressed support for the conclusion of an international agreement for the recognition of deposits of microorganisms effected abroad in order to avoid multiple deposits, provided that the date and conditions of release were governed by national law.
- 18. The Delegation of SPAIN said that so far its country had no experience in connection with deposits of microorganisms and that it could express only its own personal views. Under the Spanish Law, a patent was invalid if the description was not sufficient to enable an expert to perform the invention. In the case of microbiological inventions, a mere taxonomic description did not appear to be sufficient. It might therefore be advisable to effect a deposit of a microorganism in a culture collection—which, in view of the fact that no such collection existed so far in Spain, would have to be a foreign collection—in order to make sure that the patent was not invalid because of insufficient disclosure. Moreover, in Spain a new strain could not be protected per se, and a Spanish application could be filed only for the related process. In any case, third parties should have the best possibilities for access to deposited microorganisms, as, for example, under the European Patent Convention. However, those questions would still require further study and it would be interesting to note the views expressed by other delegations.
- 19. The Delegation of DENMARK referred to the negotiations between the Nordic countries in 1959 concerning the adoption of uniform patent laws and indicated that at that time it was not considered necessary to provide for the requirement of deposit. However, in Denmark almost all patent applications for inventions involving the use of microorganisms were made by applicants who for the purposes of procedure in other countries had already deposited the microorganism, and, if requested, information on the foreign deposit was supplied to the Danish Patent Office. In a scheme of future international cooperation, which could be envisaged within the framework of an international convention, deposits of microorganisms should be made in internationally approved culture collections, whether inside or outside the country. Moreover, it should be required that the microorganism be always deposited not later than the date of the first filing, even if the country of the first filing did not require deposit.
- 20. The Representative of CEIF expressed sympathy with the objectives and motives so far expressed by members of the Committee of Experts. He underlined the importance of microbiological inventions for industry. In the area under consideration, there were particular considerations with respect to disclosure. If a written description was not considered to be sufficient and therefore the deposit of microorganisms was required, a considerable financial burden was thereby placed on industry. Thus, it was important to avoid multiple deposits if protection in several countries was sought. In order to avoid multiple deposits, a system of international work-sharing could be devised along the lines of the system of the Patent Cooperation Treaty. In such a context, one should not only strive for international harmonization, but should also take care that the system be enforceable. Instead of merely a loose cooperation, a system of centralized steering should be provided for. Moreover, it was important to find an appropriate solution to the problem of the control over the release of the deposited microorganisms. Premature release would be dangerous since the microorganism embodied the necessary know-how for performing the invention in question. Therefore, it appeared to be appropriate to permit release in principle only after the grant of a patent or, in other words, once there existed an enforceable right.
- 21. The Representative of WFCC described the work of his Federation, which is a member of the International Association of Microbiological Societies (IAMS) and cooperates with various United Nations bodies, in particular Unesco, and hopes to cooperate in the United Nations Environment Programme (UNEP). Cooperation with Unesco related to the storage, retrieval and classification of data of microorganisms, while the proposed cooperation with UNEP would be concerned with the possibility of setting up regional culture collections, in particular in developing countries, with a view to the conservation of microbial genetic resources. Moreover, the Board of WFCC was working on the setting up of standards for affiliated membership of WFCC which would establish technical and administrative criteria for qualifying as an affiliated culture collection. In addition, a World Directory of Collections of Cultures of Microorganisms had been published under the auspices of WFCC. Attention was also drawn to the work of the International Committee on Systematic Bacteriology, also a member of IAMS, on the preparation of revision of the International Code of

Nomenclature of Bacteria, which involved the establishing of guidelines for new names, minimal standards and tests. The Representative of WFCC stressed his Federation's readiness to cooperate in a scheme of international recognition of deposits of microorganisms for the purposes of patent procedure.

- 22. The Representative of AIPPI referred to the recommendation recently adopted by his organization with respect to the conclusion of a new special agreement under Article 19 of the Paris Convention for the Protection of Industrial Property. In accordance with that recommendation, the deposit in a culture collection of the microorganism described in a patent specification and not available to the public should be a condition for the grant of a patent; moreover, the deposit in one culture collection approved under the special agreement should be sufficient to meet the requirements of all States party to the agreement; finally, the deposit should take place on or before the filing of the first patent application, with the possibility of formal details of deposit being furnished later within a prescribed period. In addition, the Representative of AIPPI believed that such an agreement could also improve the nomenclature of microorganisms.
- 23. The Representatives of UNICE and CEFIC, while supporting international cooperation in order to avoid multiple deposits, emphasized that microbiological inventions were different from normal inventions. In the case of microbiological inventions, a written description normally did not allow experts to perform the invention. Therefore, it was required that the microorganism used for the invention should be made available in order to permit the invention to be performed. Making the microorganism available, however, meant that the inventor would give more than the description of the invention since he would provide the material itself that had been used for the working of the invention. In the case of all other inventions, the inventor was under no obligation to make available the material used for the working of the invention. For example, if a chemical invention was based on the use of a particular catalyst for producing a compound, it was sufficient for the obtaining of the patent if the inventor fully described his invention, indicating what catalyst had to be used for the purpose; however, he was not obliged also to furnish the catalyst itself. In the case of microbiological inventions, however, the inventor, through the requirement of deposit, was obliged to make available not only the knowledge but also the material itself used for the working of the invention. Therefore, it was important to examine carefully under what conditions a deposited microorganism should be released. The Representatives of UNICE and CEFIC also drew attention to the question whether, if a system of internationally approved culture collections were to be set up, there should be any control of those collections in order to check whether they complied with the international standards to be fulfilled so as to qualify for approval. That question and also the question of the legal relationship between the depositor and the culture collection would require further study.
- 24. The Representative of EIRMA was also in favor of the plan to avoid multiple deposits of microorganisms through a system of international recognition of deposit. He emphasized the importance of the provisions on the time and the conditions of release of a deposited microorganism. He expressed concern as to the measures to be taken in order to avoid premature release.
- 25. The Representative of UNEPA also supported the idea of recognizing one single deposit of a microorganism as a sufficient basis for patent applications in all countries. The Patent Office could designate the depositories qualifying for deposit of microorganisms for the purposes of patent procedure, and the decision could be recognized also by other countries. He doubted whether the setting up of an international deposit center would be useful and feasible. The recognized culture collections would have to observe certain rules. The system of international cooperation through recognition of foreign deposits would avoid duplication of work. He expressed support for AIPPI's recommendation and the hope that it would be possible rapidly to find an appropriate solution.
- 26. The Representative of CNIPA drew attention to the fact that so far there existed no clear definition of a microorganism. The expression covered bacteria but was used also for yeasts, viruses, and possibly even cell lines which might be developed exclusively for the purposes of new inventions. Descriptions of microorganisms should be made in accordance with internationally accepted methods; merely local rules should be avoided. He strongly supported a system involving a single deposit in an internationally recognized culture collection both for priority purposes and for sufficient disclosure of inventions in member countries.

III. Conclusion of an International Treaty and Possible Features of Such Treaty

- 27. After the general declarations reported upon above, the Committee of Experts considered the report of the International Bureau entitled "Possibilities of international cooperation with respect to the deposit of microorganisms for the purposes of patent procedure" (document DMO/II/3).
- 28. The discussions were very thorough, lasting for almost three days. Practically all participants, whether appointed by governments or by non-governmental organizations, took a very active part in it. Although the discussions generally dealt with the various questions in the order in which they were presented in the said document, the present report deals with them in a slightly different order, which seems to be the logical one in the light of the outcome of the discussions.
- 29. <u>Basic Features</u>. There was general agreement that, in order to avoid unnecessary duplication and in order to economize costs both for governments and for patent owners and applicants, the possibilities of concluding a treaty should be further explored. The essence of the obligations which the countries party to such a treaty would assume under the said treaty would consist of the recognition of the validity, for the purposes of patent procedure in <u>all</u> the member countries, of the deposit of cultures of strains of microorganisms in respect of which patent applications have been filed, in <u>one</u> of the institutions, located in <u>one</u> of the member countries, provided that a certain number of conditions are fulfilled. However, the Delegation of the United Kingdom qualified its views on the matter, as reported in paragraph 62.
- 30. Other possibilities—existing at least theoretically—such as the establishment of a single, internationally owned or controlled institution in which all deposits would have to be made, even if such institution had branches in several countries, were expressly discarded by the Committee of Experts for several reasons, primarily because they would be extremely costly both in money and manpower.
- 31. The Committee of Experts then considered the conditions which the solution based on the recognition principle would have to fulfill. They might be grouped under the following headings: matters which should not be regulated by the treaty (paragraphs 32 and 33); recognition of depositary authorities (paragraphs 34 to 37); receiving (paragraphs 38 to 40), maintaining (paragraphs 41 to 44) and releasing (paragraphs 45 to 58) of the deposited cultures; export and import restrictions (paragraph 59); conclusion of a treaty (paragraphs 60 to 63).
- 32. Matters Which Should Not Be Regulated by the Treaty. It was agreed that any international agreement which might be considered on the subject of the deposit of microorganisms should not deal with any of the following matters: (i) whether a deposit is required, (ii) when the deposit, if one is required, must take place, (iii) what the physical requirements of the deposit should be, (iv) the manner of describing the microorganism. Those were matters which had to be left to the national laws and international treaties other than the one under consideration.
- 33. Furthermore, it was generally thought that there were no difficulties in the definition of the word "microorganism" but that no attempt should be made to define that word in the treaty. It would be sufficient if the recognized depositary authorities would be required to publish from time to time information on which kinds of microorganisms they were able and ready to accept for deposit and also, in particular, on which kinds they were unable or unwilling to accept for deposit. Moreover, the possibility of enumerating the relevant taxa of living and possibly living organisms should be studied by experts.
- 34. Recognition of Depositary Authorities. It was generally agreed that each Contracting State should have the right to propose one or more institutions located in its territory and qualifying as depository under the domestic procedure for recognition by the Assembly of the Contracting States as an internationally recognized depositary authority of cultures of strains of microorganisms. The decision of the Assembly should be preceded by a detailed examination of and report on the proposal, such examination and report being made by a committee of experts appointed by the Assembly. Alternatively, some Delegations proposed that a committee of experts should establish a list of conditions to be fulfilled by institutions in order to qualify as depositories, and the Contracting States would then announce those institutions which they guaranteed as observing such conditions.

- 35. In order to be recognized, the institution would have to fulfill certain conditions:
- (a) It would have to be independent of any influence on the part of actual or prospective depositors and their actual or potential competitors. The fact that industry might lend its support to an institution would not necessarily mean that its independence would thus be affected. It might be a public or a private institution but it would have to be available, for the purposes of deposit, to anyone and on the same conditions for everybody.
- (b) The institution would have to have a generally recognized, high scientific standing.
- (c) The government proposing the recognition of any institution would have to vouch for its continued existence and availability for the purposes of deposit. For cases where any recognized depositary authority would, in the future, cease to exist, the proposing government would have to guarantee that the cultures deposited with such authority would be transferred to another recognized depositary authority for further maintenance.
- (d) The institution would have to have the specialized staff and equipment necessary to carry out viability checks, to maintain the cultures, and to deliver samples of them when so required.
- 36. A question that should be further studied is whether depositories should be required to store, for safety purposes, samples of the same culture at least in two, geographically distant places.
- 37. Naturally, each depository would have to comply with the rules and regulations which the treaty or the organs created by the treaty would prescribe in respect of the acceptance of the cultures, their maintaining and the release of samples. The government proposing the recognition of any institute would have to accept the obligation to control and enforce the compliance, by the institute, with such rules and regulations.
- 38. Receiving of Cultures. It was generally agreed that, when depositing cultures of microorganisms, the depositor should indicate his own name and address and the strain's "culture conditions" (medium in which and temperature at which the microorganism grows, any atmospheric or other conditions required for its growing). (Those culture conditions would be intended solely for the purposes of the depositary authority. They are not to be confused with any information or description that is required under the patent laws by way of disclosure or claiming.) Furthermore, the depositor should indicate his own identification reference or, where the depositary authority gave the prospective depositor an accession number in advance of the deposit, the accession number of the depositary authority. Finally, the depositor should be strongly recommended also to indicate the scientific designation of the strain, that is, the group to which the microorganism belongs and the genus and species (and, where applicable, the subspecies and the infra subspecific designation) of such microorganism.
- 39. Receipt. The depositary authority should give the depositor a receipt showing the depositor's name and address, the identification reference indicated by the depositor, the date of the receipt of the deposit, the depositary authority's accession number and the scientific designation, if any was given by the depositor, of the strain.
- 40. <u>Certificate</u>. The question should be studied whether, in addition to the receipt, each deposit should, as soon as possible, be tested for viability and confirmation of the viability of the culture and the fact that it is suitable for maintenance in the depository should be stated in a certificate which would also contain the same data as the receipt. The content of the certificate and the language in which it was drafted would have to be provided for in the Regulations. The treaty would not require filing of the certificate with the industrial property offices requiring the deposit.
- 41. Maintenance of Cultures. Opinions were divided on the question of the length of time the depositary authority should be obliged to maintain the culture. Some were of the opinion that it should be maintained without any time limit since it was an indispensable element for ascertaining prior art even without the existence of any valid patent.

- 42. Others were of the opinion that, for practical purposes, maintenance ad infinitum was neither necessary nor feasible, and the suggestion was made that maintenance should be obligatory until the expiration of a time limit of X (e.g., 30) years after deposit, or until the expiration of a time limit of Y (e.g., five) years during which the depositary authority has not received any request for a sample, whichever of the two periods expires later.
- 43. The question was raised whether the depositary authority should at certain intervals (e.g., during the first, fifth, tenth, fifteenth, etc., years after deposit) check the continued viability of the deposited culture. The question was reserved for further study.
- 44. There was general agreement that, as long as no application or patent concerning the deposited culture was published—but not thereafter—, the depositor could withdraw his deposit or instruct the depositary authority to destroy such culture.
- 45. Release of Samples. The Committee of Experts discussed in great detail the question of the conditions that should be applied in a scheme of international recognition of one single deposit with respect to the release of samples of the deposited culture to interested third parties. After the discussion and in order to allow delegations and observers to make written proposals, the session was interrupted for twenty-four hours.
- 46. The following delegations and organizations filed written proposals which were submitted to the Committee of Experts as working documents:
- (a) AUSTRIA, FRANCE, GERMANY (FEDERAL REPUBLIC OF), NETHERLANDS, SWITZERLAND, UNITED KINGDOM and UNITED STATES OF AMERICA (document DMO/II/7);
 - (b) ALGERIA (document DMO/II/11);
 - (c) IRELAND (document DMO/II/12);
 - (d) HUNGARY (document DMO/II/13);
 - (e) WFCC (document DMO/II/8);
 - (f) UNEPA (document DMO/II/9);
 - (g) AIPPI, CEFIC, CEIF, EIRMA, FEMIPI, ICC, PIPA, UNICE (document DMO/II/14).
- 47. Resuming the discussion, the Committee of Experts considered the proposals referred to in the preceding paragraph. Each proposal was introduced and, in reply to questions raised, explained by the proposing governmental delegation(s) or organization(s).
- 48. In introducing the proposal contained in document DMO/II/7, the Delegation of the UNITED KINGDOM pointed out that an agreement (which after all had as its sole objective assistance to industry and practitioners in their prosecution of multiple applications) could be quickly reached if it required no changes in national laws. However, it was always open to States to work towards harmonization and any such efforts would be welcome. Suggestions had been made by others which would require changes in national laws or in Rule 28 of the European Patent Convention. Industry in particular had criticized the latter, but they should remember that it was a compromise that had been made with their interests very much in mind. It was understood that the proposal contained in document DMO/II/7 might impose administrative burdens on the collections: one could, however, be confident that those burdens would be reduced to mere formalities.
- 49. The Delegation of SWEDEN, speaking on behalf of the Nordic countries, declared that they supported the requirements concerning time and other conditions of release laid down in the European Patent Convention, especially in Rule 28 of that Convention. Those countries intended to change their present patent rules to meet the said requirements. They were looking forward to an international agreement on the matter based on the principles laid down in the European Patent Convention. However, in order to reach as fast as possible an international agreement to which the greatest number of countries could accede, the time and conditions of release should, in the view of the Nordic countries, remain a matter for the national laws for the time being.

- 50.1 The Representative of ICC stated that document DMO/II/14 contained the ad hoc observations of the representatives of the organizations mentioned. They could not be looked upon as being endorsed by those organizations; however, in as much as it emerged from document DMO/II/14 that the system of Rule 28 of the European Patent Convention was not entirely satisfactory to the legitimate interests of industry or even to the public interest, the thinking of all organizations representing industrial circles was reflected. Furthermore, it was evident, in view of the short time available and the complexity of the matter, that those observations, especially in so far as they took the character of specific proposals, were of a preliminary character and might need further reflection and study. The view had been put forward by many speakers that the problem of disclosure in patent applications concerning microbiological inventions using new strains put the applicant in a very peculiar and disadvantageous position.
- 50.2 In the field in question—in contrast to other fields—the material property in the starting material and its immaterial definition and disclosure could unfortunately not be separated in most cases. Therefore, full disclosure and identification could only be reached in those cases by submitting the material strain to direct observation and experimental identification.
- 50.3 Secondly, the know-how usually connected with the preparation of the starting material -- and particularly large amounts of it -- was given away free in the form of the strain and its conditions of growth, whereas such specific know-how in other fields was preserved by applicants and formed a valuable financial asset. Finally, a strain released might easily be changed in unessential aspects of its genetic material, thus inviting circumvention of the invention while using the gist of it. Adequate protection against such acts depended on a broad-minded interpretation of the scope of the claims and their wording, which unfortunately was not often the case. Summing up, the Representative of ICC said that a new field of technology had evolved where under the conventional regulations of the patent system the patentee had to give much more away for the benefit of the public and in return received much less than in other technical fields. To say that it was just bad luck for the inventor and the industry involved would be short-sighted. A rigid application of existing concepts of patent law which forced applicants in the field in question to give away their invention before knowing whether they had obtained or very probably would obtain a patent would force many inventors in the field to keep their inventions secret. Such a state of affairs was not in the public interest nor could it be the purpose of a patent system. The patent system should not be static but should be flexible enough to advance and cope with new technical developments.
- 50.4 It was in the light of the foregoing remarks that the observations contained in document DMO/II/14 should be read. The proposal of the Director General, which left an applicant with at least some control over his strain at his own risk, found under the prevailing circumstances the support of the organizations that had presented the observations contained in document DMO/II/14, but it seemed necessary to try to avoid some of the objections raised against it. The said observations showed how that could be done. However, it should be made clear that the proposal, inasmuch as it forced in any country those who refused to release their strains prior to full protection to abandon their patent rights, still fell short of what the said organizations considered a really satisfactory solution.
- 51. The International Bureau also presented a proposal on the release of samples by the depositary authority, contained in document DMO/II/10, which reads as follows:
 - "l. The following solution is offered for the consideration of the Committee of Experts.
 - 2. The proposed Treaty should provide as follows:
 - "(a) Samples of the deposited culture shall be given by the depositary authority to any authority, natural person or legal entity (hereinafter referred to as "party"), on the request of such party, provided that the request is accompanied
 - (i) either by a written authorization of the depositor, or

(ii) by a declaration of the requesting party to the effect that it has made a serious but unsuccessful attempt (as specified in the Regulations) to obtain the authorization of the depositor and

by a declaration of the Patent Office of a Contracting State certifying that the application or the patent concerning the deposited culture has been published by such Office and that, under the national law of the said State, the requesting party has a right to receive such a sample.

- (b) Notwithstanding paragraph (a), a sample of the deposited culture shall be given by the depositary authority to any Patent Office of a Contracting State before which an application filed by the depositor and concerning the deposited culture is pending, on the request of that Office, provided that the said Office certifies in its request that such patent application is pending before it".
- 3. In respect of paragraph (a)(ii), it should be understood that, where the national law makes the right of the requesting party dependent on certain conditions (for example, an undertaking that the sample would be used by such party only for its own research purposes), the Patent Office could make the said declaration only after it is satisfied that such conditions have been fulfilled."
- 52. In introducing the above proposal, the DIRECTOR GENERAL said that the question of what provisions should go into a treaty and what provisions should go into regulations was naturally an open one and that the regulations should, among other things, provide that, whenever the depositary authority released a sample, it would have to notify that fact, its date and its recipient's name and address to the depositor.
- 53. Referring to the proposal of the International Bureau, the Delegation of the UNITED STATES OF AMERICA declared that it was based on a valid principle but that an authorization for the release by the depositor should not be required after the grant of a patent.
- 54. The Delegation of HUNGARY supported the proposals contained in documents DMO/II/7 and 10 and stated that it could accept the proposal contained in document DMO/II/10 provided that in paragraph 2(a)(ii), third line, the "and" be replaced by "and/or."
- 55. The Delegation of GERMANY (FEDERAL REPUBLIC OF) declared that it agreed with the principle of the proposal since it did not touch the national law; however, difficulties arose through the use of the concept of authorization of release, which could not be required after publication of a patent application since by then the invention had been fully disclosed. The problem might be solved by deleting in paragraph 2(a)(ii) the words before "and," including the word "and" itself in the third line. Moreover, the question might be considered of providing for the possibility that Patent Offices could notify the depositary authority mentioned in the patent application once the conditions for release under the applicable law had been fulfilled; the latter suggestion was also made by the Delegation of the NETHERLANDS.
- 56. The Delegation of FRANCE said that it could not take a position on the proposal. The question would have to be examined whether the proposal was compatible with Rule 28 of the Implementing Regulations to the European Patent Convention, a provision to which France had agreed at the Munich Diplomatic Conference. The Delegations of the NETHERLANDS, SWEDEN and the UNITED KINGDOM shared the view of the Delegation of France.
- 57. The Representatives of AIPPI, CEIF, CNIPA, FICPI, ICC, PIPA, UNEPA, UNICE and WFCC supported the proposal of the International Bureau as a possible basis for further study and discussions. The Representative of CEIF added that the applicant should be given the possibility of preventing release by withdrawing the patent application. The DIRECTOR GENERAL said that such a possibility was implicit in the proposal. The Representative of WFCC stressed that depositories would need to be protected from or not liable to legal action, in particular as regards the release of samples of a deposited culture. The Representatives of CNIPA and UNEPA wondered whether

Patent Offices would be in a position to issue the declaration referred to in the proposal of the International Bureau. The Representative of CNIPA added that at present the UK Patent Office could not issue such a certificate, and the same would appear to apply to a number of other countries, in particular those whose laws were based in principle on the United Kingdom law.

- 58. On a question from the Director General whether the proposal should be included in the report as a basis for further study, the Committee of Experts took an affirmative position.
- 59. Export and Import Restrictions. The Committee of Experts considered paragraph 31 of document DMO/II/3 and expressed the view that, although export and import restrictions seemed to exist at present only with respect to a few exceptional cases of species of particularly dangerous microorganisms, a recommendation should be included in the envisaged treaty to the effect that such restrictions should be applied in the case of microorganisms relevant for patents or patent applications only where it was absolutely necessary.
- 60. <u>Conclusion of a Treaty</u>. Subject to what is stated in the next paragraph, it was generally agreed that international recognition of deposits of microorganisms should be regulated in an international treaty which should be concluded as a special agreement under Article 19 of the Paris Convention for the Protection of Industrial Property.
- 61. The Delegation of the SOVIET UNION suggested that the new international provisions should have a closer link with the Paris Convention; for example, they could constitute a protocol to that Convention.
- 62. The Delegation of the UNITED KINGDOM said that, as a minimum, the treaty should provide that deposit with an internationally recognized depositary authority must be recognized for priority purposes and that each Contracting State should permit the import of microorganisms unless they were dangerous to health or to the environment. As a further possibility, the treaty should provide that the said deposit would fully replace the need of individual deposits in each Contracting State.
- 63. The Delegation of the UNITED KINGDOM asked whether the treaty could be acceded to by regional Patent Offices, such as the European Patent Office. The DIRECTOR GENERAL replied that, in any case, regional Patent Offices should, under the treaty, have the same standing and role as national Patent Offices. He would study the question whether international organizations, such as the European Patent Organisation, could become contracting parties, that is, have the same status as States. It was a question of treaty law. He expressed the hope that a solution could be found which would allow regional patent organizations to become contracting parties.

IV. Conclusion

- 64. The Committee of Experts noted the declaration of the Director General that the International Bureau would prepare the draft of at least the main provisions of a possible treaty and regulations and submit it, together with explanatory notes, to the member States and to interested international organizations and that he would propose to the competent organs of WIPO and the Paris Union that next year's program include the convening of a Committee of Experts to which at least the same States and organizations would be invited as to the present meeting; if his proposal was approved, such a meeting could take place next year. There would be approximately nine months between the publication of the preparatory documents and the date of the meeting so that governments and organizations would have sufficient time to study the proposals and formulate opinions.
 - 65. This report was unanimously adopted by the Committee of Experts at its meeting on April 26, 1974.

DMO/II/16 ANNEXE/ANNEX

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