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Contents

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Notifications

WIPO Convention

Accession

ANGOLA

The Government of Angola deposited, on January 15, 1985, its instrument of accession to the Convention Establishing the World Intellectual Property Organization, signed at Stockholm on July 14, 1967.

The said Convention will enter into force, with respect to Angola, on April 15, 1985.

WIPO Notification No. 131, of January 15, 1985.

Paris Convention

Accession

MONGOLIA

The Government of Mongolia deposited, on January 16, 1985, its instrument of accession to the Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Stockholm on July 14, 1967.

The said instrument of accession contains the following reservations:

"1. The Government of the Mongolian People's Republic considers that the provisions of Article 24 of the Convention are contrary to the Declaration on the Granting of Iodependence to Colonial Countries and Peoples (Resolution 1514/XV adopted by the General Assembly of the United Nations on 14 December 1960).

"2. The Government of the Mongolian People's Republic does oot consider itself bound by the provisions of paragraph (1) of Article 28 of the Convention."

Mongolia has not heretofore been a member of the International Union for the Protection of Industrial Property ("Paris Union"), founded by the Paris Convention.

The Paris Convention, as revised, will enter into force, with respect to Mongolia, on April 21, 1985. On that date, Mongolia will become a member of the Paris Union.

Mongolia will belong to class VII for the purpose of establishing its contribution towards the budget of the Paris Union.

Paris Notification No. 115, of January 21, 1985.

Madrid Agreement (Marks)

Accession

MONGOLIA

The Government of Mongolia deposited, on January 16, 1985, its instrument of accession to the Madrid Agreement Concerning tbe International Registration of Marks of April 14, 1891, as revised at Stockholm on July 14, 1967.

Mongolia bas not beretofore been a member of the Union for the International Registration of Marks ("Madrid Union"), founded by the Madrid Agreement.

The Madrid Agreement, as revised, will enter into force, with respect to Mongolia, on April 21, 1985. On that date, Mongolia will become a member of the Madrid Union.

The Government of Mongolia has also declared that the application of the Madrid Agreement, as revised, shall be limited to marks registered from the date on which the said Agreement enters into force with respect to Mongolia; however, the interested parties may make requests for extension of the protection resulting from the international registration to marks which have already been the subject of an earlier national registration still in force in Mongolia.

Madrid (Marks) Notification No. 35, of January 21, 1985.

Activities of the International Bureau

Paris Union

Committee of Experts on Biotechnological Inventions and Industrial Property

I. REPORT ADOPTED BY THE COMMITTEE OF EXPERTS

I. Introduction

1. Convened by the Director General of the World Intellectual Property Organization (WIPO), as part of the 1984/85 program of the International (Paris) Union for the Protection of Industrial Property (see document AB/XIV/2, Annex A, item PRG.03(3)), the Committee of Experts on Biotechnological Inventions and Industrial Property (hereinafter referred to as the "Committee of Experts") met in Geneva from November 5 to 9, 1984.[1]

2. The following States were represented at the session: Austria, Belgium, Brazil, China, Denmark, Dominican Republic, Egypt, Finland, France, Germany (Federal Republic of), Hungary, Indonesia, Italy, Japan, Madagascar, Netherlands, Saudi Arabia, Soviet Union, Spain, Sweden, Switzerland, United Kingdom and the United States of America (23).

3. Representatives of the United Nations Conference on Trade and Development (UNCTAD), the World Health Organization (WHO), the Commission of the European Communities (CEC), the European Patent Organisation (EPO) and the International Union for the Protection of New Varieties of Plants (UPOV) and of the following international non-governmental organizations participated as observers: the Association of Plant Breeders of the European Economic Community (COMASSO), the Committee of National Institutes of Patent Agents (CNIPA), the European Federation of Agents of Industry in Industrial Property (FEMIPI), the Institute of Professional Representatives Before the European Patent Office (EPI), the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP), the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL), the International Association for the Protection of Industrial Property (AIPPI), the International Chamber of Commerce (ICC), the International Federation of Industrial Property Attorneys (FICPI), the International Federation of the Seed Trade (FIS), the Union of European Practitioners in Industrial Property (UEPIP), the Union of Industries of the European Community (UNICE) and the World Federation for Culture Collections (WFCC).

4. The list of participants is reproduced in the Annex to this report.[2]

5. Dr. Arpad Bogsch, Director General of WIPO, opened the session and welcomed the participants. He drew attention to the need for protection of biotechnological inventions, which in the future are likely to represent a high percentage of all inventions, and to the desirability of achieving harmonization in the approach taken by countries and regional organizations on this matter.

6. The Committee of Experts unanimously elected Mr. J.-L. Comte (Switzerland) as Chairman and Messrs. I. Ivanyi (Hungary) and P. Verdoux (Madagascar) as Vice-Chairmen. Mr. F. Balleys (WIPO) acted as Secretary of the Committee of Experts.

7. Discussions were based on a memorandum prepared by the International Bureau of WIPO, entitled "Industrial Property Protection of Biotechnological Inventions" (document BioT/CE/I/2, hereinafter referred to as "the memorandum"). The Secretariat noted the interventions made and recorded them on tape. This report summarizes the discussions and does not reflect all the observations made, but the main observations and principal conclusions of the discussions are reported below.

II. General Observations

8. The Delegation of the Federal Republic of Germany pointed out that biotechnology today was one of the focal points on which the interest of the public in many countries was concentrated. From the point of view of the protection of industrial property, it was essential to investigate how inventions in the field of biotechnology could be protected in the most appropriate manner and to ascertain the extent to which existing patent systems granted sufficient protection to the results of biotechnological research. On the other hand, ethical and moral considerations relating to those inventions were to be examined on the basis of the cultural, political and social traditions of each country. Certain questions relating to the industrial property protection of biotechnological inventions, for example, the question of

[1] For the Note on this session see *Industrial Property*, 1984, p. 413.

[2] See *Industrial Property*, 1984, p. 414.

deposit of microorganisms for the purposes of patent procedure, had already been discussed at the international level and were covered in the European Patent Convention and in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. More recently, problems inherent to the protection of biotechnological inventions were examined by a number of international organizations and, in this connection, it appeared very important to avoid fragmentation and duplication of efforts. Therefore, the initiative of WIPO to convene a Committee of Experts to study the industrial property protection of biotechnological inventions was particularly welcomed. The task of the Committee of Experts was that of identifying, in particular, the problems which would result from patent protection of biotechnological inventions and of making recommendations for appropriate solutions. Such a task would assure the necessary dialogue between legal practitioners and scientists involved in biotechnological research.

9. The Delegation of the United States of America pointed out that WIPO's study on the protection of biotechnological inventions came at a most opportune time and expressed the hope that the discussions within the Committee of Experts would lead to greater recognition of the importance of such inventions and make it possible to afford them adequate protection in a greater number of countries.

10. The Delegation of the Netherlands stated that most of the countries had a patent system that applied simple basic principles interpreted by the patent offices and courts and that that system had given good results. Subsequent to the adoption of those principles, which, for many countries, occurred a long time ago, important technological developments had taken place. While those developments required some adjustments to be made, the system itself did not have to undergo any profound changes. In the case of protection for biotechnological inventions, solutions should likewise be sought not necessarily in the law but rather in the regulations and through court decisions. It appeared preferable to maintain the existing simple legislative system and to leave to the patent offices and courts the task of taking decisions and of giving guidance in the interpretation of the law.

11. The Delegation of Sweden felt it of advantage, with a view to future work, to deal with the matter of protection for biotechnological inventions within an international framework and thought the time well chosen for undertaking work in this most important field. It further considered that the WIPO study should cover the entire field of biotechnological inventions and should not be limited to microorganisms, despite the fact that it was not certain that one single concept could cover the whole of the subject. The study should endeavor to highlight the difficulties met with respect to certain fields. While hoping that an attempt would be made to harmonize legislation, the Delegation of Sweden stated, with reference to a report which the Organisation for Economic Co-operation and Development (OECD) will publish shortly, that care would have to be taken that the major principles of patent law, particularly the distinction between inventions and discoveries, did not become too vague.

12. The Delegation of Japan indicated that, in view of the general recognition of the need to further promote the development of biotechnology and taking into account the increasing number of patent applications in this field, the initiative of WIPO to undertake the study of the industrial property aspects of the protection of biotechnological inventions appeared significant and opportune. The impact of biotechnology was expected to be considerable in the coming years. A new wave of innovations was to be foreseen in areas like chemistry, protection of the environment, mining, energy and foodstuff. It was to be noted, in this connection, that inventions in the field of biotechnology were generally based on universally applicable concepts. For example, inventions bearing on genes, plasmids or cells could constitute fundamental achievements which could be applied for the development of new technologies in other fields. It was, therefore, highly important to consider biotechnology as a single technological field and to afford it uniform industrial property protection. The existing systems of protection differed from country to country and, as pointed out in the memorandum, harmonization in this field was urgent. One had to bear in mind firstly that only recently had this type of technology, due to its remarkable achievements, given rise to the question of an appropriate form of protection, for example, in the sectors of genetic engineering, microorganisms, plants, genes and cells. Secondly, to enhance biotechnological developments, it was necessary to devise means, including an adequate form of protection, which would ensure recoupment of investments in this field. Thirdly, in the present age of international interdependence, harmonization of different national systems of protection for this technological field appeared an urgent goal to achieve. In consideration of its institutional tasks in the industrial property field, WIPO should actively pursue the study of those problems in order to indicate the most appropriate way to provide for adequate industrial property protection for inventions in the field of biotechnology.

13. The Delegation of the Soviet Union approved the International Bureau's activities and plans concerning the protection of biotechnological inventions. It also pointed out that the Soviet Union had some experience in that field since, from 1958 onwards, over 600 titles of protection had been issued for inventions concerning new microorganisms.

14. The Delegation of Italy underlined the importance of biotechnological inventions and drew attention to the existing provisions at the national and regional levels, which had to be taken into account for the WIPO study,

although that study had to examine also the need for protection independently of any existing provisions.

15. The representative of UPOV stated that the Union for the Protection of New Plant Varieties was keenly interested in the work of the Committee of Experts. The drafters of the International Convention for the Protection of New Varieties of Plants had studied, more than twenty years ago, some of the basic questions raised in the memorandum. In the context of the work carried out by WIPO, sight should not be lost of the solutions found for those problems in that Convention, which, in some respects, afforded a more restrictive, more limited protection than that given to patents, because of the special nature of plants and the use made of them in agriculture and horticulture. The reasons which justify these limitations should be carefully considered in the study. He drew attention, furthermore, to two symposia held by UPOV in 1982 and 1984, the first one under the title "Genetic Engineering and Plant Breeding" and the second under the title "Industrial Patents and Plant Breeders' Rights—Their Proper Fields and Possibilities for Their Demarcation."

16. The representative of the EPO stated that her organization was fully aware of the importance of the work of the Committee of Experts. Within the framework of the European Patent Convention, practical experience had shown that a number of problems existed which had yet to be examined and for which solutions had to be found.

17. The representative of CNIPA, after having expressed his satisfaction with the memorandum, which identified the real problems that arose, commented that one of the problems to be considered in the WIPO study was the fact that, according to the decision in the Chakrabarty case of the United States Supreme Court, protection could be afforded to microorganisms as such whereas, according to the case law of the Federal Republic of Germany, protection was afforded to microorganisms as such only if the repeatability requirement was complied with.

18. The representative of ATRIP expressed his satisfaction at the activities undertaken by WIPO in the field of biotechnological inventions, a field in which, thanks to scientists and research workers, rapid progress had been made. He particularly mentioned the importance to be attached to the fact that the study dealt with the question of the borderline between inventions and discoveries and also with the problem of industrial applicability.

19. The representative of UNICE pointed out that considerable investment was frequently necessary for the creation of new plants and those who were willing to make such investment had to be fully informed of the protection they could enjoy.

20. The representative of ASSINSEL observed that making inventors aware of the protection to which they were entitled would constitute an encouragement to research. He also observed that relations between the UPOV Convention and the Paris Convention for the Protection of Industrial Property posed a number of problems and that it would be desirable for WIPO and UPOV to achieve harmonization.

21. The Director General of WIPO, replying to a question put by the Chairman of the Committee of Experts as regards the task of the Committee of Experts and the results that could be expected during its present session, stated that the International Bureau wished to know which questions could be given a reply at once and which would need more detailed treatment in the study. On the basis of the opinions expressed within the Committee of Experts, the International Bureau would submit proposals for future work to the 1985 session of its Governing Bodies. The final objective was to show that the international community was taking a firm attitude in respect of the protection of biotechnological inventions, with the conclusion that they had to be protected and generally recognized as patentable, taking into account the special situation as regards plants. In that respect, it had to be remembered that any system of protection for inventions would lose a considerable part of its significance if it did not apply to new types of inventions which, in some years' time, would represent a high percentage of all inventions. If protection were not rapidly afforded to such new types of inventions, there was a risk that the patent system in general would be undermined. The Director General of WIPO added that it was desirable, at the national level, to look for uniform and simple solutions in order to give inventors greater legal security and, at the international level, to ensure that the existing treaties were applied and to provide a form of internationally harmonized protection for biotechnological inventions that was as simple, as reliable and as inexpensive as possible. In conclusion, the Director General of WIPO stated that the International Bureau would examine, on the basis of the results of the current session of the Committee of Experts, whether it was necessary to call on the services of consultants in order to complete the WIPO study.

III. Discussion of Specific Questions

Scope of the WIPO Study, in Particular the Subject Matter of Biotechnology (Paragraphs 3 to 6 of the Memorandum)

22. As regards the term "biotechnology," it was agreed that, although various organizations had established definitions of that term which could be considered for the WIPO study, the coverage of that study would finally not depend on a precise definition. In any case, all technological developments concerning living organisms (which include animals, plants and microorganisms) and other biological material should be covered by the study.

23. It was pointed out that three categories of biotechnological inventions should be distinguished: inventions relating to a process for the creation of a living organism or the production of other biological material, inventions relating to an organism or a material *per se* and inventions relating to the use of an organism or a material. It was suggested to consider, in addition to the creation of an organism, also the multiplication of an organism. Not only organic changes, but also changes in inorganic material by means of biological material should be covered.

24. As regards the legal treatment of biotechnological inventions, it was stressed that there should not be any special treatment but that the generally applicable principles of protection of inventions should apply also to biotechnological inventions. All biotechnological inventions should be considered patentable inventions if they complied with those principles.

25. Attention was drawn to the problems which existed in respect of inventions concerning human beings. Such inventions should be referred to in the WIPO study because that study should cover all living organisms and the term "animals" is understood as including non-human and human beings. However, in view of the particular ethical problems that arise in respect of such inventions, which are outside WIPO's competence, it would not seem appropriate for the WIPO study to examine in detail questions concerning inventions relating to human beings. It was pointed out that, on the international level, the Council of Europe considered, *inter alia,* those ethical problems.

26. As regards the fields of application of biotechnological inventions referred to in paragraph 5 of the memorandum (agriculture, etc.), it was understood that not all inventions concerning those fields should be considered as biotechnological inventions but that, on the other hand, most biotechnological inventions would occur in these fields.

27. Attention was drawn to the need for patent offices to establish documentation on biotechnological inventions. This called for a further elaboration of the existing International Patent Classification, which was under preparation.

28. In conclusion, it was stated that the WIPO study should draw attention to the fact that it was generally agreed that, provided the requirements of patentability were fulfilled, patents could be granted for biotechnological inventions, but that there was an area of biotechnological inventions where controversies had arisen with respect to patent protection. The study, therefore, should confirm the generally agreed positions, in particular in the microbiological field, and analyze in detail the situation concerning the cases where controversies had arisen, taking into account not only existing legislative provisions and interpretations of such provisions, but also overall considerations concerning the objectives of any protection, in particular the need to stimulate research and development in the field of biotechnology.

Technological Developments and Biotechnology Relevant to the WIPO Study (Paragraphs 7 to 19 of the Memorandum)

29. With respect to paragraph 7 of the memorandum, it was indicated that the distinction between the traditional method of plant breeding and the new technology of genetic engineering could not be considered as a precise one. Methods which now would have to be qualified as genetic engineering had been in use for quite some time before this expression had started to be used in respect of certain inventions (including plant breeding). In any case, both techniques were complementary and it could be expected that even with the growing importance of genetic engineering methods, plant breeding methods would continue to be used to a large extent. In addition, account should be taken of the fact that the UPOV Convention did not establish a different treatment for new plant varieties created by traditional methods on the one hand and new plant varieties created by methods of genetic engineering on the other. For the purposes of that Convention only the fact that there was a new plant variety had to be considered.

30. With respect to the first sentence of paragraph 10 of the memorandum, it was pointed out that the use of microorganisms in their natural state was not the rule; when using microorganisms for industrial purposes certain factors which were independent of the genetic characteristics came into play, in particular the environment in which they were used.

31. With respect to paragraph 11 of the memorandum, it was pointed out that at present, recently developed genetic engineering methods were not yet used for commercial exploitation in the field of plant breeding but that such exploitation would have to be taken into account in view of possible future developments. In addition to application in industry of genetic engineering methods, application in agriculture should be taken into account in the WIPO study. Moreover, the qualification "scientific" in connection with laboratories should be deleted since other, in particular industrial, laboratories also dealt with research in this field.

32. With respect to paragraph 13 of the memorandum, it was suggested to delete the word "discernible" before "differences" since not only new external features but also internal characteristics, such as resistance against contamination, had to be examined in order to determine the novelty of a living organism or of other biological material.

33. It was pointed out that genetic engineering methods permitted the creation of particularly valuable characteristics of plants and that, if for a new plant variety only the rights established by the special system of plant

variety protection were available, the invention could be freely used in order to develop further varieties without any reward for the efforts made by the inventor. Therefore, the existence of the new technology, wbich normally required important investments, appeared to alter the balance of interests between creators and users whicb had been established under the UPOV Convention and the laws for the protection of plant varieties. The Delegation of Sweden beld tbat this problem could be solved to some extent through appropriate contracts concerning the exploitation of the patent, namely through granting licenses to plant breeders on a royalty basis.

34. With respect to new plant varieties, attention was drawn to the fact that plants normally are self-replicating, not requiring manufacture or use of processes as in the case of inventions in the industrial field. Therefore, under the special system of protection of plant varieties, the exclusive right only related to the propagating material but not to the plant itself. Moreover, one should be aware that a disturbance of the present balanced system of protection in agriculture might lead to an overreaction, with the effect that no protection at all would be afforded to plants.

35. With respect to paragrapb 19 of the memorandum, it was pointed out that, where an invention consisted of the new use of an existing plant, etc., the claims had to specify sucb use. For example, if a new plant which resulted from an invention using genetic engineering bad particular valuable foodstuff properties, the use of such a plant for feeding animals should be accessible to patent protection (such as, e.g., the admixture of vitamins to foodstuff for feeding pigs).

36. Further questions relating to plant varieties, in particular the exclusion of plant varieties from patent protection, are dealt with in paragraphs 46 to 50, below.

Purpose of the WIPO Study (Paragraphs 20 to 23 of the Memorandum)

37. This question is dealt with in paragraphs 102 to 105, below.

Reference to Studies of Other Organizations (Paragraphs 24 to 27 of the Memorandum)

38. It was indicated that the OECD report on patenting of biotechnological inventions, once it has been published, would constitute a valuable source of information, which should be taken into account by the WIPO study.

39. In addition to tbe activities of UPOV referred to in paragraph 27 of the memorandum, reference was again made to the Symposium organized by UPOV on October 17, 1984, concerning "Industrial Patents and Plant Breeders' Rights—Their Proper Fields and Possibilities for Their Demarcation."

40. It was suggested to make reference in the WIPO study to the work of the Commission of the European Communities, which had included the examination of industrial property questions in the priority list of action to be taken in respect of biotechnology.

41. It was agreed that WIPO should be the principal forum for discussing policy questions of international relevance in the field of industrial property protection of biotechnological inventions. The same applied to UPOV as far as plant breeders' rights were concerned. However, this did not mean that the contributions of other bodies currently studying these problems, for example, AIPPI, were not welcome.

Questions Concerning the Legal Protection of Biotechnological Inventions—Protection at the National Level (Paragraphs 29 to 53 of the Memorandum)

42. *Biotechnology and the Concept of Invention (Paragraphs 29 to 31 of the Memorandum).* As regards the borderline between inventions and discoveries, it was pointed out that, whereas a number of laws expressly exclude "discoveries" from patenting, other laws used the term "discovery" in a sense permitting the patenting of both inventions and discoveries, and some laws protected discoveries as such. In this connection, it was explained that no distinction was made between invention and discovery in the UPOV Convention and that discovery was understood there as also comprising mutations. It was agreed to maintain, for the purposes of the WIPO study, the distinction between inventions and discoveries. The decisive criterion for the distinction to be made was rather whether an invention (or discovery) was industrially applicable. As a test for the distinction, it was indicated that the enrichment of knowledge through a discovery was not sufficient to justify protection, but that a teaching of what to do in application of the discovery was the decisive step forward justifying protection. For example, the discovery that a microorganism used for a pharmaceutical product in reality consisted of a mixture of two microorganisms, one of which had the properties required for the pharmaceutical purpose, whereas the other was not required for that purpose, in itself did not justify protection, but the practical application of that discovery in order to use only the pharmaceutically required microorganism was an invention which justified protection.

43. As regards the creation and use of living organisms, it was agreed that the fact that they were living in itself did not constitute an obstacle for considering them as inventions. The decisive question was only whether the general requirements of patentability were fulfilled, namely, that, in addition to novelty of the invention and inventive step, the invention was industrially applicable and disclosed in a way that it could be repeated. These latter two requirements (industrial applicability and repeatability) in themselves might have the effect that

certain biotechnological inventions were not patentable in some countries.

44. In connection with the distinction to be made between various biotechnological inventions, it was pointed out that, in addition to a vertical approach on the basis of categories such as microorganisms, plants and animals, a transversal approach across all species of living organisms was also important when exploring appropriate protection of biotechnology, in view of the very close, often inseparable, relationship between upstream and downstream technologies in biotechnology.

45. In conclusion, it was agreed that the notion of technology did not exclude biology.

46. *Exclusion of Patentability of Certain Sectors of Biotechnology (Paragraphs 32 to 38 of the Memorandum).* With respect to the provision, contained in a number of patent laws, according to which patents may not be granted for plant varieties, it was pointed out that the self-replicating nature of some important plant species was one of the reasons for such an exclusion; this had led to the establishment of a special system of protection; the statement that patent laws excluded plant varieties from patenting only because of the existence of the special system of protection could not be maintained; the reason for the duality of the two protection systems was rather the fact that, if patents were granted for plant varieties, the exclusive right of the patentee would be too extensive, since normally it would cover all plants belonging to the protected variety until the expiration of the patent; in other words, the patentee's authorization would be required for any growing and marketing of plants of the protected variety not only for the first generation but also for further generations. In this context, it was further stated that the main reason for the duality of the two protection systems was the need to open a more appropriate access to protection for plant varieties by establishing a system which was more adapted to the specific requirements of the botanical matter. The UPOV Convention and the national laws providing for a special system of plant breeders' rights established a more limited exclusive right, mainly relating to propagating material, and thus a balance between the interests of plant breeders and the interests of the public. In this connection, it was recalled that, where a UPOV member State provided for patents in respect of new plant varieties, it had to comply with the conditions of the UPOV Convention (including its Article 37), in respect of such patents.

47. On the other hand, it was pointed out that enormous investments were required for modern methods of creation of new plant varieties, in particular including methods of genetic engineering; consequently, the balance established by the UPOV Convention and the special system of protection of plant varieties no longer existed since the invention of a particularly valuable property of a plant (for example, resistance against certain sicknesses) could freely be used for any plant variety which only slightly deviated from the variety for which the invention had been created. Therefore, in addition to plant variety rights, patents should be available for such inventions, or at least the inventor should have an option between a patent and a plant variety right.

48. It was pointed out that the social consequences for breeders and growers of any change in the system of protection should be taken into consideration. In this connection, the view was expressed that, if the extent of protection available under the UPOV Convention was found to be insufficient to encourage the necessary investment in biotechnological research and development in relation to plant varieties, then, rather than seeking to correct the situation by the patent route, consideration should be given to using the opportunities that exist under Article 5(4) of the UPOV Convention to grant "a more extensive right."

49. The Delegation of the United States of America indicated that, apart from the fact that the duality of protection referred to in paragraph 33 of the memorandum existed in its country, the United States Patent and Trademark Office was, in certain circumstances, also granting normal patents for plants produced as a result of human intervention.

50. The Delegation of the Soviet Union indicated that the reference to provisions of the Soviet Union law on "new varieties and hybrids of agricultural crops and other cultivated plants," (paragraph 33 of the memorandum, on top of page 10 of the English version of document BioT/CE/I/2) required a correction. For the said subject matter, which is excluded from patenting, special titles of protection may be granted. The same was true with respect to animal varieties (the relevant provision of the Soviet Union Law is referred to in paragraph 37 of the memorandum).

51. With respect to animal varieties, it was underlined that there was not only the question of exclusion from patenting, as provided for in a number of laws, but also the question of the kind of protection such varieties should enjoy (if the exclusion from patenting was not or no longer justified, patents might be the appropriate form of protection).

52. As regards essentially biological processes for the production of plants or animals (paragraph 38 of the memorandum), it was agreed that the reasoning for the exclusion of such processes from patenting, provided for in a number of laws, should be examined. In this connection, in particular the meaning of the expression "essentially biological" would have to be studied. It would also have to be examined whether there was a connection between the exclusion of the said processes and the exclusion of plant varieties and animal varieties from patenting, and whether, if the study came up with recommendations for or against the exclusion of plant varieties and animal varieties from patent protection,

this would bave an effect on tbe exclusion of essentially biological processes for the production of plants or animals.

53. The Delegation of Japan expressed its interest in a study on the scope of essentially biological processes for the production of plants or animals in the light of Rule 39 of the Regulations under the Patent Cooperation Treaty (PCT) and also indicated that such processes were not excluded from patenting in its national law.

54. It was suggested to distinguish, in connection with the said processes, between reproducible processes and non-reproducible processes. When applying such a distinction, it would turn out that the non-reproducible processes could be considered as essentially biological. Thus, the question of excluding essentially biological processes for the production of plants or animals from patenting could be considered as a question of repeatability of the invention, so that, even if laws did not exclude the said processes from patenting, they would nevertheless not be patentable, because they were not repeatable.

55. *The Application of the Conditions of Patentability (Novelty, Inventive Step, Repeatability, Industrial Applicability) to Biotechnological Inventions (Paragraphs 39 to 44 of the Memorandum).* With respect to paragraph 39 of the memorandum, it was suggested to replace the first word ("if") by "as," in order to avoid the impression that biotechnological inventions could be excluded from patenting.

56. In respect of the question, referred to at the end of paragraph 40 of the memorandum, at wbat time a deposited microorganism is to be treated as having been disclosed to the public, the opinion was expressed that, only once the microorganism is available to third parties can it be considered as disclosed. In this connection, it was recalled that deposits made in connection with patent applications had to be kept confidential by depositary authorities until the application was publisbed.

57. Attention was drawn to the fact that it might be difficult for the autborities examining the novelty of an application to prove the identity of two microorganisms which had been deposited by two different people, for example, tbe patentee and a third party.

58. With respect to the question of grace period, referred to in paragraph 41 of the memorandum, it was agreed that the WIPO study sbould not propose to establish a special grace period for biotechnological inventions. The question of the grace period was rather to be solved in a general manner, under the auspices of the WIPO Committee of Experts which had been established for that purpose. Nevertheless, in connection with the study on biotecbnological inventions, a reference should be made to the particular need for a grace period in respect of inventions made by scientists, who have to publish the results of their research. It was noted that, in some of the countries which provided for a grace period for disclosure by the inventor, an important number of the cases in which the grace period was invoked concerned biotechnological inventions.

59. With respect to the condition of repeatability, the opinion was expressed that this condition should be applied in the same way as for all other inventions. It was agreed that the repeatability could concern, depending on the kind of claim or claims, the living organism itself, a process for obtaining the said organism or the use of the said organism. In this connection, attention was drawn to the situation where a microorganism is created through the combination of two other microorganisms. If the said combination is described and the said two microorganisms are deposited with a depositary authority, then the said process would be reproducible.

60. It was indicated that, in the interpretation of the condition of repeatability in some countries, the repeatability was considered to be existent if an expert, after a reasonable number of attempts, was able to repeat the invention.

61. It was recalled that repeatability was not a condition for plant varieties because plants reproduce themselves, and that this was one of the reasons for a special system of protection of plant varieties. However, such considerations could not be applied to patents granted outside that special system of protection, even where they concerned new plants.

62. In respect of microorganisms, attention was drawn to the possibility that such organisms may change their characteristic properties, even after the deposit with a culture collection. The latter possibility was, however, only a remote one because of the progress made with respect to the technology for maintaining deposits. In any case, it was agreed that the change of a deposited microorganism would have the consequence that the decription had become deficient and, therefore, depending on the applicable law, the patent invalid or, at least, unenforceable. In this connection, reference was also made to Article 10(2) of the UPOV Convention, in accordance with which the breeder forfeits his rights when he is no longer in a position to provide the competent authority with reproductive or propagating material capable of producing the new variety with its morphological and physiological characteristics.

63. Reference was also made to the requirement of a viability test under the Budapest Treaty—a matter which had to be studied in connection with the provisions governing deposit, storage and release of microorganisms. As far as repeatability was concerned, the lack of a viability statement certainly led to the conclusion that the invention was no longer repeatable.

64. Attention was also drawn to the fact that the repeatability was different for various categories of invention. In this connection, a distinction had to be made between

isolated naturally occurring microoganisms, artificial mutants, hybridomas or cell fusion technology and recomhinant technology. Whereas the condition of repeatahility usually existed with respect to recomhinant technology, that condition was more difficult to estahlish with respect to the other technologies. It was also suggested that consideration be given to defining "repeatability" (will a functionally equivalent microorganism suffice, or is the same microorganism required?).

65. In respect of the requirement of industrial applicability, the opinion was expressed that this requirement had a special character when applying to hiotechnological inventions, in particular in view of the need that the object of the invention must be capable of being used or produced.

66. As regards the question of the time at which industrial applicability should exist, it was pointed out that, at the time of filing an application, at least one industrial application had to be stated. According to another opinion, statements on industrial application could be added hy the applicant at a later stage.

67. Attention was drawn to the particular problems arising with the requirement of industrial applicability for biotechnological inventions in countries not providing for a grace period. In those countries, inventors were obliged to file as soon as possible, and it could therefore well happen tbat, at the time of filing, they were not yet aware of important industrial applications of the invention.

68. It was agreed that the WIPO study should examine the question of industrial applicability in tbe light of the divergent concepts as to the notion of industrial applicahility as such, and as to the time at which it must be stated by the applicant, and should prepare internationally desirable solutions.

69. *Special Considerations Concerning the Disclosure of a Biotechnological Invention for the Purposes of Patent Procedure (Paragraphs 45 to 52 of the Memorandum).* The wish was expressed that depositors of microorganisms for the purposes of patent procedure and depositary authorities should be given more information on the practical conditions of deposit. Such information could be presented in the form of a "Guide for the Deposit of Microorganisms for the Purposes of Patent Procedure," which the International Bureau of WIPO should prepare.

70. It was pointed out that the purpose of depositing microorganisms was partly to guarantee the existence of the microorganisms and partly to supplement the description, and that a distinction had to he made for patentability purposes hetween the method of ohtaining the microorganism, the microorganism itself and the use made of it.

71. Attention was drawn to the fact that hiotechnology also concerned non-living material that was not capahle of being adequately described and for which, therefore, a deposit was indispensable. However, the Budapest Treaty required international depositary authorities to examine the viability of the deposited microorganism. Therefore, the practice was to deposit non-living material by incorporating it into living organisms. It was suggested that solutions be sought and that, in particular, it be examined whether, by amending tbe Regulations under the Budapest Treaty, it would be possihle to deposit non-living material such as plasmids and cosmids. Instead of a viability test, the Regulations under the Budapest Treaty should provide that such material should be tested for whether it is biologically active.

72. It was indicated that even pure plasmids were already deposited with the American Type Culture Collection (ATCC) and that viahility statements could be made at the depositary institution by incorporating the plasmids into living organisms such as bacteriae. As the Budapest Treaty did not define or limit the viability test, ATCC accepted even pure plasmids as deposits under the Budapest Treaty. This interpretation of the Budapest Treaty was not shared by others.

73. As regards the adequacy of the description, it was suggested that three situations be taken into account. The first was the situation in which disclosure was adequate and enahled the invention to be repeated. In such case, deposit of the microorganism was not normally necessary. The second was the situation where disclosure was insufficient although a deposit had been made, and where, consequently, protection could not be obtained for the microorganism as such since the deposit was not considered sufficient to ensure repetition of tbe invention. The third was the case of a new invention concerning a known microorganism; here the question arose whether it should be required that the known microorganism be deposited to ensure its availability for a period of 30 years. It was pointed out that such a requirement would render the system complicated, cumbersome and expensive. It was also indicated that it was possible to redeposit a microorganism for a further period of 30 years if that was found desirable. This view was not shared by others.

74. Conceming the deposit requirement, the Delegation of Japan explained that a deposit was normally required in its country in those cases where the microorganism could not be readily ohtained hy specialists and that deposit was not required where it could be obtained commercially or wbere an appropriately deposited microorganism was freely available. The directives concerning deposit of microorganisms were presently under review in Japan in order to adapt the procedures to current developments. It was planned, in particular, to no longer require a deposit where the description proved sufficient.

75. With reference to the first sentence of paragraph 45 of the memorandum, it was stated that, in countries

without substantive examination of patent applications, not the grant of a patent but its validity was affected by insufficient disclosure.

76. As regards paragraph 49 of the memorandum, it was stated that deposit of a microorganism should be effected at the latest on the date on which the patent application was filed or, if priority was claimed, on the priority date. Disclosure, and the deposit comprised therein, were aimed not only at permitting the invention to be repeated but also at proving that the depositor possessed the invention at the time of filing or, as appropriate, at the priority date. Furthermore, as regards the duration of the deposit, it was stated that, theoretically, the microorganism should be stored without a time limit, but that, in practice, the 30-year period laid down in the Regulations under the Budapest Treaty represented a reasonable solution. In any event, it would not be compatible with the patent system to envisage a solution under which the deposited microorganism was to be available only until expiry of the patent.

77. The question was raised whether a microbiological invention described in a patent application should be considered as comprised in the state of the art, even if the deposited microorganism involved in the invention was not released by the depositary authority, for example, because the application was withdrawn after publication but before the grant of a patent. It was suggested that, since the conditions for making available the microorganism were complied with at the time of filing the patent application, the invention as described in the published patent application should be considered as comprised in the state of the art.

78. With respect to paragraph 50 of the memorandum, it was indicated that, in order to enable a person skilled in the art to carry out an invention involving a microorganism, it was necessary, besides having access to a sample of the deposited microorganism, to take into account the methods used for obtaining the microorganism and for its storage by the depositary institution and that such methods had to be disclosed in the patent application. Disagreement was expressed with this view.

79. With respect to paragraph 51 of the memorandum, it was pointed out that provisions of national laws varied as regards the release of samples of deposited microorganisms. The said provisions could also vary within a country, depending on the kind of microorganism.

80. In connection with paragraph 52 of the memorandum, it was suggested that samples of deposited microorganisms should be available to any requesting party from the date of publication of the relevant patent application without any restriction. According to that opinion, the solution contained in Rule 28 of the Regulations under the EPC, providing for the release of a sample of a deposited microorganism before the grant of a patent only to an independent expert, was considered a restriction which deviated from the general principle of patent law of free access to all elements of the disclosure.

81. The question was raised whether the so-called "expert solution" provided for under the said Rule 28 was applied in practice. In reply to this question, it was stated that requests for release were rarely filed with international depositary authorities in Europe, but relatively frequently with such authorities in the United States of America, in particular with the American Type Culture Collection (ATCC), and that some of the latter requests were made under Rule 28 of the European Patent Convention. In this connection, it was recalled that third parties requesting the release of a deposited microorganism had a choice as regards the basis for their request, if the depositor had filed patent applications in a number of countries. This opened the possibility for them to avoid recourse to the expert solution procedure. In this context, it was recalled that the expert solution had been thoroughly discussed by the Administrative Council of the European Patent Organisation before being adopted. This solution, applicable during the period between the publication of the patent application and the grant of the relevant patent, was adopted to take into account the fact that, during that period, an exclusive right did not yet exist and that free availability of the deposited microorganism could encourage infringers. The expert solution ensured that the released sample of the deposited microorganism would be used only for experimental purposes and not be transferred to third parties.

82. In that context, the view was also expressed that the expert solution provided for under the said Rule 28 was an appropriate one and that it should be considered in the framework of the WIPO study, in particular since free access to samples of deposited microorganisms made it very easy to produce the patented subject matter in patent-free countries.

83. Attention was drawn to the fact that, under certain patent laws, samples of deposited microorganisms could be released only for research and experimental purposes; however, the released sample could not be transferred by the requesting party to third parties, nor exported outside the country, especially to countries where no patent system was in force.

84. In connection with restrictions concerning the release of samples of deposited microorganisms, it was suggested that the following types of restrictions should be considered: release of samples should be permitted only in connection with an enforceable right; the released sample should be destroyed or returned to the depositor if the relevant patent applied for in respect of the invention involving the released microorganism was not granted; the sample of the microorganism should not be transferred to third parties, nor should it be exported or furnished to residents of countries where

no patent system was in force; restrictions on release of samples should also apply to derived cultures.

85. It was observed in this context that the study should also deal with the problems that restriction on release could be considered as rendering the disclosure less sufficient.

86. Taking into account the foregoing considerations, it was recommended to study the restrictions imposed by national laws on the release of samples of deposited microorganisms and the possibilities of appropriate harmonization, constituting a fair balance between the interests of all parties concerned.

87. Some delegations pointed out that the over-privileging of biotechnological inventions should be avoided. The particular questions raised by those inventions should be examined in the WIPO study, but that study should not come to the conclusion that special treatment should apply to biotechnological inventions.

88. *Rights Conferred by Titles of Protection in Respect of Biotechnological Inventions (Paragraph 53 of the Memorandum).* It was agreed that, in respect of the rights covered by titles of protection, two questions had to be distinguished, the first concerning the subject matter which could be claimed and the second concerning the scope of protection to be granted.

89. As regards claims, it was suggested to take into account the Protocol concerning Article 69 of the European Patent Convention, and to examine in particular the various types of claims, covering also "chains of claims," where the first claim would concern a gene, the second the gene as incorporated in a cell, the third the cell with a gene as incorporated in a plant and the fourth the use of the plant. The study should also cover the problems raised in respect of definition of strains and the use of mutants. It was underlined that, with all kinds of claims, the condition of repeatability was essential. Thus, non-operable elements would be automatically excluded from protection.

90. It was pointed out that mentioning a strain in a patent claim had the consequence that the protection would be much narrower than if a species was mentioned and that additional problems of proof would arise.

91. With respect to the scope of protection, it was suggested to recommend a reversal of the burden of proof where the infringer alleged that he had obtained a known microorganism independently of the patentee. It was also suggested that the study should examine the question of how far the use of mutants could be considered as an infringement.

92. As regards plant varieties, attention was drawn to the problems which might arise if patents were granted for plant varieties. There was, in particular, the problem of defining the scope of protection in the case of inclusion of new living material in an organism of higher order: would any reproduction of the higher organism be an infringement of the patent covering the living material?

93. It was pointed out that the question of scope of protection was within the final competence of the courts, and that the WIPO study should not take a position with respect to specific provisions of national laws, but only deal with the concepts and principles governing protection; the WIPO study should, in that respect, analyze the differences which existed between the various countries and make proposals for harmonization.

Protection at the International Level (Paragraphs 54 to 67 of the Memorandum)

94. In connection with the Paris Convention for the Protection of Industrial Property, attention was drawn to the problem that could result in a situation where the country of the first filing did not require the deposit of a microorganism, whereas the country of the second filing, in which the priority of the first filing was invoked, required such a deposit. The question here was whether a priority could be validly claimed in such a case. It was observed that this question only needed to be examined where the priority claim was relevant, i.e., not in cases where the state of the art in respect of the claimed subject matter had not changed between the priority date and the date of the second filing.

95. With respect to the UPOV Convention, it was suggested that the provision of Article 13 of that Convention, which deals with denomination of new varieties of plants, could be a model for the solution of a similar problem which existed with respect to new microorganisms.

96. In connection with the reference in paragraph 58 of the memorandum to the principle of national treatment (Article 3(1) and (2) of the UPOV Convention), attention was drawn to the exceptions from that principle in other provisions of that Convention, providing for a possibility to apply reciprocity in certain cases (e.g., Articles 3(3) and 5(4) of the UPOV Convention).

97. In addition, attention was drawn to Article 5(3) of the UPOV Convention, in accordance with which authorization by the breeder is not required for the utilization of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such new varieties.

98. As regards the terminology to be used, it was suggested to speak of "special system of plant variety protection" and not of "plant breeders' rights," since the latter could also consist of plant patents.

99. With respect to the Patent Cooperation Treaty, the Secretariat drew attention to the fact that Rule 13*bis* of the Regulations under that Treaty contained provisions concerning the reference to deposits of microorganisms

in international applications. These provisions had to be covered in the WIPO study.

100. With respect to paragraph 60 of the memorandum, concerning the Budapest Treaty, it was recalled that cell lines could be considered as living entities, although they were not organisms, and that the Budapest Treaty should apply to living microorganisms, cell lines, plasmids, etc. The question was raised whether an attempt should be made to include in the Regulations under the Budapest Treaty a definition of microorganism. It was, however, indicated that, at the Budapest Diplomatic Conference, it had been agreed not to adopt a provision defining the term "microorganism," but to leave this question to the depositary authorities, which should be free to accept deposits under the Budapest Treaty of everything they considered a microorganism, provided that the deposits could comply with the conditions established by that Treaty and the Regulations, in particular the conditions as regards storage and viability tests. Thus, a definition of microorganism would not be necessary. In addition, it was observed that, if an attempt to define microorganism was made, at the present stage, taking into account the contents of Article 2 of the Treaty and Rule 1 of the Regulations, it was doubtful whether this could be made by amending the Regulations and whether it was not necessary, for that purpose, to amend the Treaty itself. In any case, possible difficulties in connection with the convocation of a diplomatic conference with a view to revising Article 2 of the Budapest Treaty must be taken into consideration.

101. As regards paragraphs 61 to 67 of the memorandum, it was stated that, in respect of certain questions, in particular the exclusion of plant varieties from patent protection, there existed almost complete harmony in a number of countries. This view was not shared by others who drew attention to the fact that there nevertheless existed some important diversities in that field. The WIPO study should not limit itself to an analysis of the existing situation, concluding, with respect to certain provisions, that there was not an important diversity, but it should apply an independent approach, considering the question of what should be protected on the merits of each case, and making recommendations for adequate protection, in order to stimulate research in biotechnology.

Possibilities for Improvement of Legal Protection of Biotechnological Inventions (Paragraphs 68 to 72 of the Memorandum)

102. With respect to possibilities for improvement of the legal protection of biotechnological inventions at the national or regional level, it was agreed that the WIPO study will have to deal with the question of the improvement of the existing protection from an international perspective. It was therefore not necessary to make a distinction between possibilities for improvement at the national and regional levels and at the international level, as the proposals to be considered would be made from that international perspective. Thus the WIPO study would, in that respect, be directed to the principles governing the protection under existing provisions of national laws or regional treaties and possibilities for their improvement from an international point of view. The conclusions of the WIPO study could be used by national and regional authorities in order to identify the measures which had to be taken at the national and regional levels. Divergent views were expressed as to the question whether the WIPO study should make an attempt to recommend standards on the protection of biotechnological inventions at the national and regional levels and as to the question whether the WIPO study should contain recommendations on the interpretation of existing national laws.

103. With respect to possibilities for improvement of the legal protection of biotechnological inventions at the international level, views were divided on the question whether the adoption of new treaty provisions, either in the form of an amendment of existing treaties, or in the form of an additional treaty, seemed to be required at the present stage. It was, however, agreed that this question should not be excluded from the WIPO study. Consequently, the WIPO study should identify problems, if any, requiring regulation by international treaty provisions. In any case, where it was found that the Regulations under the Budapest Treaty should be amended, suggestions to that effect should be made in the study.

104. It was stated in this context that, to the extent that the result of the study would be the establishment of guidelines (possibly to be adopted as a recommendation of the Paris Union Assembly), such result would be useful as there was a chance in a number of countries that such guidelines would be taken into account for the amendment of national laws and regulations, or when examining questions of interpretation of those texts.

105. In conclusion, it was agreed that none of the possible approaches outlined in the memorandum, in particular in its paragraphs 22 and 68 to 72, should be omitted from consideration in the framework of the WIPO study.

IV. Future Action

106. The Committee of Experts recommended that WIPO prepare the study as outlined in the memorandum and taking into account the observations made during the current session of the Committee of Experts, and that the said study be submitted to a second session, which should be convened in 1986. For that purpose, it noted that the Director General of WIPO would make an interim report to the 1985 session of the Governing Bodies of WIPO on the work so far accomplished on

this matter and suggested that the Director General of WIPO propose for the program and budget of the biennium 1986/1987 the continuation of the work on the study and one or several more sessions of the Committee of Experts, as required.

107. The Committee of Experts noted that the International Bureau of WIPO, in preparing the study, might engage consultants and might seek advice and information from appropriate sources, including information from those circles that actually deal with the making of biotechnological inventions.

108. This report was unanimously adopted by the Committee of Experts at its meeting on November 9, 1984.

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II. INDUSTRIAL PROPERTY PROTECTION OF BIOTECHNOLOGICAL INVENTIONS— MEMORANDUM PREPARED BY THE INTERNATIONAL BUREAU

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I. Introduction

1. At its fourteenth series of meetings (September/October 1983), the Assembly of the International (Paris) Union for the Protection of Industrial Property (hereinafter referred to as "the Assembly of the Paris Union") instructed the International Bureau of WIPO to "study the existing situation concerning the protection, by patents or by other means, of inventions in the field of biotechnology (including 'genetic engineering') and possible means of providing for industrial property protection for such inventions, both at the national and international level" (see document AB/XIV/2, Annex A, item PRG.03(3)). At the same time, it was decided that "the study will be carried out with the help of consultants and a Committee of Experts (meeting once during the biennium [1984/1985])" and that "the conclusions [of the Committee of Experts] will be reported to the 1985 session of the Assembly of the Paris Union for possible further action" *(ibid.)*.

2. The present memorandum constitutes a first step towards the study that the International Bureau has been instructed to prepare. It is intended as a basis for the discussions of the Committee of Experts on Biotechnological Inventions and Industrial Property (hereinafter referred to as "the Committee of Experts"), which will meet from November 5 to 9, 1984. The main purpose of this document is to facilitate the task of the Committee of Experts to give advice on what "inventions in the field of biotechnology" are or, rather, what definition should be given to such inventions for the purpose of their protection by virtue of industrial property laws and treaties. It is on the basis of the comments and advice expected from the Committee of Experts that the study (hereinafter referred to as "the WIPO study") will be completed by the International Bureau.

II. General Considerations

A. Scope of the WIPO Study

(a) General

3. The scope of the WIPO study will depend on the meaning given to the term "biotechnological inventions." The decisive question seems to be the extent to which new technology in the field of biotechnology is to be considered an "invention" for the purposes of the availability of protection by patents or other titles of protection for inventions. The WIPO study will therefore have to consider the area of biotechnology as a whole before a decision is taken on the extent to which new technology developed in that field qualifies as an "invention."

(b) Subject Matter of Biotechnology

4. "Bios" in ancient Greek means life, and "biotechnology" thus seems to comprise any technology that uses living entities, in particular animals, plants or microorganisms, or causes organic changes in them. Despite this simple explanation, however, there is no generally agreed definition of the term. In particular, "biotechnology" does not even seem to be limited to living entities: for example, biological material, such as cell lines (which are not living *entities*, but only parts of them) or enzymes (substances, not living entities but *produced* by living cells and causing certain reactions), may have a function in industrial applications that is similar to that of microorganisms, and thus may be considered subject matter of biotechnology.

5. As a working hypothesis for the WIPO study, it is proposed that biotechnology should be understood to be technology that uses, or causes organic changes in, animals, plants, microorganisms and any biological material that can be assimilated to microorganisms. Such a definition would be based less on scientific criteria than on empirical considerations that would take into account the areas in which inventive work in the field of biotechnology currently is most active and in which the results of that work seem to have great economic importance. The inventive work could concern many sectors, such as the following; agriculture, as regards both animals and plants; fishery; industrial food production; production of pharmaceuticals; production of fertilizers, pesticides and herbicides; protection of the environment; creation and use of energy; extraction of raw materials; cleaning.

6. The proposed definition of biotechnology would give a somewhat broad meaning to "technology," including not only physical and chemical, but also biological methods. The basic question that the WIPO study will have to examine is whether, and if so how far, biological methods can, if they are new, be considered inventions for the purposes of industrial property protection.

(c) Technological Developments

7. The WIPO study should present a brief description of the principal features of biotechnology and current developments in the biotechnological field. One of the main areas of inventive work in that field is constituted by the creation of new varieties of plants, animals and microorganisms. For the purposes of this memorandum, a distinction is made between traditional methods and a new technology which is receiving an increasing degree of public attention, namely the artificial modification of the hereditary material of animals, plants and microorganisms by a process known as "genetic engineering,"

(i) The Traditional Methods of Breeding Plants and Animals and Treating Microorganisms

8. Plant breeding has a long tradition. In the beginning there was only the rather primitive art of breeding by selection: the plants that seemed to have the most advantageous qualities were selected for reproduction. Later, additional methods were developed, namely the crossing of different genotypes to create a broader scale of variation for further breeding activities, hybridization (crossing parent plants), which produces varieties that normally cannot transmit their valuable characteristics to the next generation, and mutation (where the breeder effects changes in a genotype by means other than crossing).

9. Similar developments have taken place in animal breeding.

10. In contrast to the breeding of new plant and animal varieties, microorganisms were always used in their natural state. The use of certain microorganisms to initiate fermentation processes—for example, yeast for baking bread, brewing beer or making wine—is one of the oldest technical solutions devised by mankind. More sophisticated methods were developed when microorganisms began to be used for pharmaceutical purposes, and it became very important to obtain pure cultures of certain microorganisms in order to control their action exactly. Consequently, methods of isolating microorganisms were refined, as was the technology for keeping pure cultures alive. And, with the increasing knowledge of the particular properties of each strain of microorganism, new forms of use were developed. So microorganisms are now applied industrially in the production of foodstuffs and pharmaceuticals, and also in other industrial processes, such as the production of energy and the protection of the environment.

(ii) The New Technology: Genetic Engineering

11. In recent years advanced research in scientific laboratories has led to a new method of creating "new" living entities: it has become possible to modify the genes of animals, plants and microorganisms by the introduction of artificially modified hereditary material. This technology has rapidly become applicable to animal and plant breeding and to the creation of new strains of microorganisms, and a number of new enterprises have been established that deal with the industrial application of genetic engineering methods. This technology should be explained further in the WIPO study. Attention is drawn in this context to the Records of a Symposium on Genetic Engineering and Plant Breeding, held on the occasion of the sixteenth ordinary session (October 1982) of the Council of the International Union for the Protection of New Varieties of Plants (UPOV) (UPOV publication No. 340(E); copies may be obtained from WIPO).

(d) Biotechnology Relevant to the WIPO Study

(i) General

12. Whereas genetic engineering is a revolutionary feature in the field of biotechnology, the other areas of biotechnology (i.e., the traditional methods of plant and animal breeding and treating microorganisms)

nevertheless continue to yield new inventions as well; thus there is a broad range of new technology being created in this field. The resulting inventions can be grouped, according to the usual distinction made between product inventions, process inventions and application inventions, as follows (naturally, this distinction does not preclude the combination of several results).

(ii) New Plants, Animals, Microorganisms and Biological Material

13. The first category of biotechnological inventions (product inventions) concerns new "products," namely new plants, new animals, new microorganisms and new biological material. What is meant by new is that there is a discernible difference between the existing plant, animal, microorganism or biological material and the product embodying, or resulting from, the invention.

14. New plants and animals may be produced either by the classical methods of plant and animal breeding (see above, paragraphs 8 and 9) or by genetic engineering. The invention to be considered here may be either the plant or animal *per se* or the plant or animal as produced by a particular process. This distinction may be important for the securing of industrial property protection, since one of the conditions for granting protection for an invention is that it be capable of repeated use on the basis of the description, and since inventions resulting in new plants or animals *per se* do not always lend themselves to repeated use without knowledge of the process for obtaining them.

15. Not only new plants, new animals, new microorganisms and new biological material as such fall into the product category, but also new products produced by new or known plants, etc. For example, if a new detergent were developed using a particular kind of (new or known) enzyme, the subject of protection would not be the enzyme as such (which, however, if it were new, might in itself constitute a patentable invention) but the new product developed using the enzyme (see paragraph 14).

16. As regards microorganisms, a distinction has to be made between the identification and isolation of a microorganism strain that exists in nature, and the creation of a new microorganism, in particular by genetic engineering. If a microorganism is only isolated and not newly created, there arises the fundamental question—to be considered later (see below, paragraph 30)—whether the newly isolated microorganism is an invention or a discovery. In any case, with biotechnological inventions, the same distinction has to be made as with plants and animals, namely between the microorganism *per se* and the microorganism as produced (or isolated) by means of a particular process (see paragraph 14).

17. With respect to biological material, such as cell lines, enzymes, etc., various processes for their production may exist, but considerations similar to those concerning microorganisms apply regarding the distinction between products *per se* and products produced by a particular process.

(iii) New Biotechnological Processes for the Creation of Plants, Animals, Microorganisms or Biological Material

18. The second category of biotechnological inventions (process inventions) concerns new biotechnological processes for the creation of new plants, animals or microorganisms, for the isolation of microorganisms or for the production of biological material. It should be noted that, whereas the product (plant, animal, microorganism, biological material) may or may not be new, the process used to obtain the product must be new and biotechnological in nature.

(iv) New Uses of Plants, Animals, Microorganisms or Biological Material

19. The third category of biotechnological inventions (application inventions) consists in new uses of a plant, an animal, a microorganism or biological material. Here the plant, etc., is not necessarily new, but the use made of it must be new. Examples would be the new industrial use of an existing microorganism or the new pharmaceutical application of a microorganism or of a compound containing a microorganism or biological material.

B. Purpose of the WIPO Study

(a) General

20. As already stated in paragraph 1, above, the WIPO study will have to deal with possible means of providing industrial property protection for inventions in the field of biotechnology (including genetic engineering), at both the national and international levels. The WIPO study will have not only to analyze the present situation, but also, where appropriate, to consider possibilities for improving it.

(b) Possible Results of the WIPO Study

21. If it is found that the existing protection granted to biotechnological inventions at the national and international levels is satisfactory in every respect, the result of the WIPO study would be a statement to that effect.

22. If, however, it is found that the present situation with respect to the protection of biotechnological inventions is not satisfactory, the WIPO study could make suggestions for improving it. Those suggestions could relate to:

(i) the establishment of treaty provisions, providing, for example, that each country must grant at least a certain level (the minimum level) of protection to biotechnological inventions or providing that certain features of the national laws and procedures

of the contracting States must be the same or essentially the same (harmonization);

(ii) the establishment of model provisions for national laws and regulations;

(iii) recommendations for the interpretation of existing legislative provisions;

(iv) the preparation of a manual or guide on the treatment of biotechnological inventions, the purpose of which would be to provide guidance for all those who wish to familiarize themselves with the problems relating to the legal protection of biotechnological inventions.

23. It seems premature to choose among the above courses of action before the WIPO study is completed, in particular before an opinion bas been formed on the question whether the existing protection at the national and international levels is entirely satisfactory.

C. Reference to Studies of Other Organizations

24. Whereas WIPO will, with the proposed study, be dealing for the first time with biotechnological inventions, aspects of the subject have already been examined by other intergovemmental organizations.

25. Within the framework of the United Nations, the United Nations Industrial Development Organization (UNIDO) is promoting the setting up of an international center for genetic engineering and biotechnology. The statutes of that center cover some aspects of the legal protection of research results obtained in the center, in particular, biotechnological inventions.

26. As regards the countries grouped in the Organisation for Economic Co-operation and Development (OECD), the Committee for Scientific and Technological Policy of the OECD has requested the OECD Secretariat to prepare a report on patent protection in biotechnology, and a draft of that report will be considered by the Committee at its session on October 23 and 24, 1984.

27. Of particular interest are the activities of tbe International Union for the Protection of New Varietics of Plants (UPOV), whose Administrative and Legal Committee considered, in April 1984, a study, prepared by the Office of the Union, entitled "Biotechnology and Plant Variety Protection" (document CAJ/XIII/3).* That study deals with the question of the patentability of plant varieties—whether obtained by breeding or by genetic engineering methods—a question which will be relevant also to the WIPO study. Copies of the UPOV study, and of the report of the April 1984 session of UPOV's Administrative and Legal Committee (document CAJ/XIII/8)* which reflects that Committee's discussions on the study, may be obtained from WIPO. Reference is also made to UPOV's 1982 Symposium referred to in paragraph 11, above.

* These documents are superseded by the Records of UPOV's 1984 Symposium ("Industrial Patents and Plant Breeders' Rights—Their Proper Fields and Possibilities for Their Demarcation") held on October 17, 1984. The Records, which incorporate a background paper based on document CAJ/XIII/3, are being produced in the English, French, German and Spanish languages. They may be ordered from WIPO and are free of charge.

III. Questions Concerning the Legal Protection of Biotechnological Inventions

A. General

28. Having defined the possible scope of the WIPO study, this memorandum will now suggest some questions to be examined in connection with the legal protection of biotechnological inventions. The list of questions should not be considered exhaustive, and the selection of the questions in this memorandum should not be understood as an expression of an opinion on the replies to be given to them. Both matters are reserved for the future WIPO study, which will have to analyze the existing situation in order to determine whether there are any shortcomings in the protection of biotechnological inventions and, if so, how that situation could be improved.

B. Protection at the National Level

(a) Biotechnology and the Concept of Invention

29. One of the most important problems raised in respect of biotechnological inventions is that of the extent to which the traditional concept of invention, as currently applied for the purposes of industrial property protection, covers those inventions. In this connection a distinction will have to be made between the various biotechnological inventions, as outlined in Chapter II A(d) (see paragraphs 12 to 19, above), namely between:

- new plants, animals, microorganisms and biological material,
- new biotechnological processes for the creation, production or isolation of plants, animals, microorganisms or biological material, and
- new biotechnological uses of plants, animals, microorganisms or biological material.

The question is particularly relevant to the first category, namely new plants, animals, microorganisms and biological material.

(i) Borderline Between Inventions and Discoveries

30. When defining what an invention is for the purposes of industrial property protection, it is usual to distinguish between an invention and a discovery. Subject to further elaboration in the WIPO study, the decisive test seems to be whether the subject matter already exists in nature (and therefore has only been discovered) or whether it has been created by the human mind (and therefore has been invented). This distinction is easier to state than to apply, in particular where new results of scientific research are used directly

for technological purposes. It has been suggested that the concept of invention was defined at a time when it seemed possible to make a clearer distinction between science and technology, and that modern development, in which scientific results may immediately be used for technological purposes, requires a new definition of invention, encompassing more than it is formally understood to encompass at the present time. The WIPO study will have to deal with this question, in particular since the possibility of creating a new kind of living entity (for example, a new strain of microorganism) through genetic engineering might be considered a scientific discovery, and a thorough analysis is required—as shown in the decision of the Supreme Court of the United States of America in *Diamond v. Chakrabarty*, 206 USPQ 193 (1980)—before it can be concluded that such a result of scientific research is to be considered an invention.

(ii) Biotechnology as a Technical Field in Which Inventions Can Be Made

31. Whereas the borderline between inventions and discoveries concerns all fields of technology, the question whether—and if so to what extent—hitherto unknown discoveries made in the field of biotechnology could be considered inventions, despite the fact that most of them concern living entities, is a special question in this particular field, and the answer to it again depends on the concept of invention. Here an examination will have to be made, in particular, of the argument that biological methods do not belong to the field of technology, so that such discoveries could not be covered by the concept of invention.

(b) Exclusion from Patentability of Certain Sectors of Biotechnology

32. Even if all new discoveries in the field of biotechnology are to be considered inventions, there may be reasons for excluding some kinds of biotechnological inventions from patent protection, and in fact there are laws which do so. In this connection, the following categories of biotechnological inventions in particular will have to be considered.

(i) Plant Varieties

33. In a number of countries, plant varieties are protected by special legislation which establishes a particular system of protection, typically excluding any other form of protection. In those countries, therefore, the laws for the protection of inventions exclude plant varieties from patentability. This is true, for example, of the European Patent Convention and of the national laws that follow the same approach as the European Patent Convention. The Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents of 1963, which at present binds nine countries,[1] permits its contracting States in Article 2 not to grant patents for "plant or animal varieties or essentially biological processes for the production of plants or animals"; the European Patent Convention of 1973, which at present groups 11 countries,[2] made use of that permission and excluded the foregoing from patenting in Article 53(b), and a number of countries party to the European Patent Convention follow the same approach.[3] The WIPO Model Law for Developing Countries on Inventions (1979) contains the same provision, in Section 112(3)(ii), as the European Patent Convention. The Statute on Discoveries, Inventions and Rationalization Proposals of the Soviet Union, as last amended on December 28, 1978,[4] also contains a special provision, in Section 22, for "new varieties and hybrids of agricultural crops and other cultivated plants," excluding them from patenting, but providing for the grant of inventors' certificates. Under the Patent Act of the United States of America, special "plant patents" are granted for asexually reproduced varieties (i.e., for varieties reproduced by means other than by seed, for example, by grafting, budding, cuttings, layering, division and the like), whereas special titles of protection are available under the Plant Variety Protection Act for sexually reproduced varieties (i.e., for varieties reproduced by seed).

34. The special systems for the protection of plant varieties have some features in common with the patent system. But there are also essential differences, which typically relate to the following: the breeder of a new plant variety does not have the right to prevent use or importation but only the right to prevent other persons from producing propagating material and from marketing such material; the new variety must not only be clearly distinguishable from other existing varieties but must also be sufficiently homogeneous and stable in its essential characteristics; novelty of the variety is determined on the basis not of disclosure to the public but of offering for sale or marketing (with a special grace period system).

35. The essential features of the national laws on the protection of plant varieties are reflected in the International Convention for the Protection of New Varieties of Plants (UPOV Convention), which was concluded in 1961 and revised in 1972 and 1978 and which at present binds 17 States.[5] As far as is relevant to this memorandum, the UPOV Convention contains, in particular, provisions on the conditions for grant and

[1] France, Germany (Federal Republic of), Ireland, Italy, Liechtenstein, Luxembourg, Sweden, Switzerland, United Kingdom.

[2] Austria, Belgium, France, Germany (Federal Republic of), Italy, Liechtenstein, Luxembourg, Netherlands, Sweden, Switzerland, United Kingdom.

[3] Those countries include, in particular, France, Germany (Federal Republic of) and the United Kingdom.

[4] English translation published in *Industrial Property Laws and Treaties*, SOVIET UNION — Text 2-003.

[5] Belgium, Denmark, France, Germany (Federal Republic of), Hungary, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States of America.

invalidation, on the minimum scope and minimum duration of protection, on national treatment and on a right of priority, and in Article 2(1) it obliges its contracting States to provide only one form of protection (patent protection or *sui generis* protection) for the same botanical genus or species. Most UPOV contracting States have established a special *sui generis* system of protection for plant varieties but some protect plant varieties by a kind of patent specially adapted for that purpose.

36. The WIPO study will have to examine the aforementioned situation in greater detail, particularly as regards new plant varieties obtained not by traditional breeding methods but by genetic engineering. For the time being, reference is made to UPOV document CAJ/XIII/3 (see paragraph 27).

(ii) Animal Varieties

37. The situation regarding animal varieties differs from that regarding plant varieties in that there does not seem to be any special system of legislation for the protection of animal varieties. Animal varieties are expressly excluded from patenting under a number of laws. However, whereas the law on inventions of the Soviet Union excludes certain animal varieties from patenting, it does allow the grant of inventors' certificates for such varieties. The WIPO study will have to examine the considerations applying to animal varieties, whether obtained by breeding methods or by genetic engineering.

(iii) Essentially Biological Processes for the Production of Plants or Animals

38. As already stated (see paragraph 33 above), some laws exclude from patenting "essentially biological processes for the production of plants or animals." It is proposed that the WIPO study cover the rationale, limits and consequences of this exclusion.

(c) The Application of the Conditions of Patentability (Novelty, Inventive Step, Repeatability, Industrial Applicability) to Biotechnological Inventions

(i) General

39. If biotechnological inventions are not excluded from patenting, they may be the subject of applications for the grant of patents (or, where applicable, inventors' certificates). Usually, patent laws require an invention to be new, to represent an inventive step and to be industrially applicable in order to be patentable. In addition—and this is a condition which is generally implied—inventions must be repeatable, because their disclosure through the patent system must enable others to repeat the technical solution described in the patent. With respect to the conditions of patentability, the question arises whether any specific considerations apply on account of the special nature of biotechnological inventions.

(ii) Novelty

40. As regards the condition of novelty, national patent laws usually contain a provision according to which an invention is not new if it has been disclosed to the public, either in writing or orally, by use or otherwise, before the filing date or the priority date. In this connection, it will have to be examined whether, and if so under what conditions, deposits of microorganisms with culture collections can be considered elements of disclosure to the public. The deposit of microorganisms for the purposes of patent procedure is examined in the following chapter (see paragraphs 45 to 52, below). With regard to the determination of the state of the art that forms the background to a new invention, the deposit of a microorganism is not a written or an oral disclosure, neither is it a disclosure by use, but it may be considered a disclosure by other means, provided that samples of the deposited microorganism are available to the public. One question in particular that will have to be examined in this respect is at what time is a deposited microorganism to be treated as having been disclosed to the public.

41. A further question in connection with the condition of novelty is the extent to which the specific conditions of biotechnological inventions require the introduction of provisions concerning non-prejudicial disclosures. In view of the fact that most biotechnological inventions are made by scientists, and that scientists like to publish the results of their research as soon as possible, there appears to be a particular need for a grace period for disclosures made by inventors of biotechnological inventions before a patent application is filed. In this regard, attention is drawn to the fact that the question of a grace period is the subject of a WIPO activity that started in February 1984, the purpose of which is to achieve international agreement on a general grace period (see WIPO documents GP/CE/I/2 Rev. and 3). Within the parameters of the study on biotechnological inventions, which is limited to specific aspects of biotechnology, the question arises whether any special rules concerning non-prejudicial disclosures are required for biotechnological inventions; this question might become redundant, however, if the solution adopted in the framework of the other WIPO project also satisfies the specific requirements concerning biotechnological inventions.

(iii) Inventive Step

42. The WIPO study will also have to deal with the question whether any particular requirements apply to the condition of involving an inventive step, which in most patent laws is a condition of patentability of an invention.

(iv) Repeatability

43. The condition of repeatability is of particular importance to biotechnological inventions because living entities—in contrast to machines, etc.—have the

capacity to adapt to their environment, and because the solution found by an inventor may not be easily repeatable by another expert in the field. Wbether the condition of repeatability will require special interpretation or adaptation to the special situation prevailing in biotechnology, or whether it will only need to be applied in the normal way, but with a special bias towards biotechnological inventions, is a question to which the WIPO study will have to pay particular attention.

(v) Industrial Applicability

44. As regards the requirement of industrial applicability, the WIPO study should, in particular, examine tbe point in time at which a biotechnological invention must be industrially applicable. It bappens tbat biotechnological inventions are not immediately considered with a view to industrial application. If a patent application is filed early in the life of a biotechnological invention, the question of industrial applicability may thus arise. Since the industrial applicability of a biotechnological invention may not become known until after the filing of a patent application, the question of whether the "subsequent" industrial applicability of a biotechnological invention would be sufficient for the purpose of patent protection should be studied.

(d) Special Considerations Concerning the Disclosure of a Biotechnological Invention for the Purposes of Patent Procedure

(i) General

45. Industrial property laws make the granting of a patent or other title of protection conditional on full disclosure of the invention. Disclosure takes place by means of a written description whicb, of all the technical documents contained in the patent application file, is the essential one, since it enables the invention to be evaluated and is intended to permit a person skilled in the art to carry it out. It is usually required (see, for example, Article 5 of the Patent Cooperation Treaty, and Section 123(3) of the WIPO Model Law for Developing Countries on Inventions) that the description disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. A "person skilled in the art" is generally taken to mean a person having average technical competence and the usual knowledge in the field of the invention. As regards tbe concept of "sufficiency of the description," the invention must be disclosed completely enough to highlight its actual teaching and also to give all necessary information to enable the person with average skill in the art to "reproduce" it. Where the description does not enable the proposed solution to be understood, and is so insufficient that it is impossible for a person skilled in the art to carry out the invention, the grant of a patent is refused or any patent already granted is invalidated.

(ii) Description of Biotechnological Inventions and Requirement of Deposit

46. Achieving sufficient disclosure in a written description (accompanied, where necessary, by drawings) in the case of inventions concerning plants and animals is often rather difficult, but achieving sufficient disclosure in the case of inventions in the field of microbiology (for example: processes to isolate living organisms that are to be found in nature; the organisms themselves; processes in which a microorganism is an agent; and microorganisms obtained by means of microbiological processes or by genetic modifications) is even more problematical, in particular, because of the enormous difficulties encountered with respect to sufficiently describing the characteristic features of microorganisms. Although in some cases inventions belonging to the field of microbiology (for example, some processes for the identification and/or isolation of existing microorganisms) can in fact be described adequately according to the usual rules of patent law, there are inventions concerning a microorganism or the use of a microorganism to which tbe public does not have access (for example, because the microorganism has not been conserved or because it has been kept by a private person or undertaking). In the latter case, a description giving the taxonomy (family, genus, species, etc.) of the microorganism frequently does not enable a person skilled in tbe art to "reproduce" the invention. In particular, where the invention concerns an industrial process involving the use of a microorganism as an agent to initiate the process (such as processes for the culture, fermentation or preparation of chemical substances by microbiological means), the description of the process and of the microorganism to be used as the raw material is generally inadequate. If the microorganism described is not contained in the prior art, and if the person skilled in the art is not able to produce it solely on the basis of the description, the essential means of carrying out the process and obtaining the final product are absent, and consequently the description does not meet the requirements laid down by patent law. In this connection, it is to be noted that, if the invention claimed concerns not the process for obtaining a microorganism but the microorganism as such, for instance a new strain or a new microorganism obtained by genetic engineering, protection of the products themselves may be available only where the process—the technical method enabling the products to be obtained—is described in an adequate manner, ensuring repeatability to the extent that a person skilled in the art can repeat the invention for an unlimited number of times by following the description set out in the patent.

47. Insufficiencies in the description of a microorganism, whether a microorganism resulting from an invention or a microorganism used as an agent to stimulate a process that is the subject of the invention, may be due, in many cases, to the difficulty or even

impossibility of classifying a new type of microorganism according to its species because of the great diversity of species, the frequently minute differences between strains and the differences of opinion among scientific experts as to whether, by reason of its characteristics, a new microorganism belongs to a new species or to an already known one. Despite the existence of a number of scientific works on taxonomy, and the searches that have been made for solutions offering greater security in the classification of microorganisms, it does not appear to have been possible to set up a system that is at the same time generally accepted, reliable and capable of satisfactorily resolving the innumerable and often nearly insurmountable difficulties raised by such classification.

48. To make up for the insufficiency of the description of an invention concerning a microbiological process or the product of such a process, where the invention involves the use or production of a microorganism to which the public does not have access, the patent procedure of an increasing number of countries requires not only the filing of a written description but also the deposit of a sample microorganism with an authorized depositary authority which maintains a culture collection. The task of the authority is to accept and store deposited microorganism cultures in order that samples may be released to third parties, subject to certain conditions. For obvious reasons industrial property offices are not equipped to handle microorganisms; their storage and the furnishing of samples requires special expertise and equipment to keep them viable, to protect them from contamination and, for health reasons, to protect the environment from contamination. The procedure of the countries that have introduced the possibility of deposit includes the obligation to deposit the microorganism where it proves impossible adequately to describe the invention involving the microorganism. The deposit supplements the description of the microorganism, so that a person skilled in the art is able, on the basis of the description that refers to the deposit, to identify the type of microorganism involved, to procure a specimen of the microorganism and to carry out the invention. In such a case the description consists of information on the microorganism and on the manner of dealing with it, the necessary information on the deposited culture and also on the deposit as such, which thus becomes an integral part of the description. Naturally, the applicant is free to make or not to make such a deposit, depending on whether he feels that the description, without a deposit, is adequate or not. If there is any doubt, he is well advised to make a deposit in order to avoid possible subsequent refusal of the patent application, or possible cancellation of the patent itself, if the description of the invention is considered insufficient. On the other hand, if he considers that the microorganism is well known and available without any particular difficulty, it is sufficient for him to state the scientific name of the microorganism in the description.

49. Where deposit is required, the time at which it has to be made with the depositary authority and the required duration of storage need to be regulated. Those questions will have to be examined further by the WIPO study.

(iii) Conditions for the Release of Samples

50. The purpose of the deposit of microorganisms in connection with patent procedure is to enable a person skilled in the art to carry out the invention. This requires that the deposited microorganism—or rather a sample thereof—be made available to anyone interested in obtaining one. The questions that arise here have to do with when samples are to be made available, and also whether any conditions may be imposed on the requesting party who obtains one.

51. The answers to these questions differ from country to country. In some countries, samples of the deposited microorganism must be made available upon first publication of the patent application; in others, the availability of samples starts only after the beginning of protection (or at least after the beginning of provisional protection). As regards the conditions for release, some countries specify that the sample may be used only for certain purposes, or may not be exported, or may be released only to certain specially authorized persons.

52. The WIPO study will have to analyze the existing solutions for the release of microorganisms, and examine whether any problems arise from the diversity of those solutions.

(e) Rights Conferred by Titles of Protection in Respect of Biotechnological Inventions

53. As regards the rights conferred by titles of protection (patents, inventors' certificates) in respect of biotechnological inventions, the WIPO study will, in particular, have to deal with the manner in which the scope of protection of biotechnological inventions, as compared with inventions in other fields of technology, is to be defined, and with the question whether any special considerations should be applied (for example, the extent to which technical features that closely resemble the features of the protected invention must be included). In this connection, attention is also drawn to the problems relating to proof of infringement.

C. Protection at the International Level

(a) General

54. As regards the international protection of biotechnological inventions, two subjects would seem to require examination. The first concerns the protection that biotechnological inventions enjoy under the existing international treaties. The second concerns the possibilities left open under the existing international

treaties: it will become clear that the existing international treaties, with the exception of the International Convention for the Protection of New Varieties of Plants, allow national laws and administrative practice considerable latitude, and that the resulting diversity of legislation may cause a number of problems for the international protection of biotecbnological inventions.

(b) The Protection Enjoyed by Biotechnological Inventions under the Existing International Multilateral Treaties

(i) General

55. For the purposes of the WIPO study, the consideration of international treaties that have a bearing on the protection of biotechnological inventions sbould be limited to multilateral treaties of worldwide scope. Regional treaties, such as the European Patent Convention or the Agreement Relating to the Creation of an African Intellectual Property Organization, will not require consideration, since any action to be taken in relation to those treaties would be outside WIPO's competence, and since, by reason of their contents, they should rather be treated, for the purposes of the WIPO study, in the same way as national laws, in respect of which certain recommendations could be made.

56. There are four worldwide treaties that have to be taken into account: tbe Paris Convention for the Protection of Industrial Property, the International Convention for the Protection of New Varieties of Plants, tbe Patent Cooperation Treaty and the Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. When considering the relevant provisions of those four treaties, it will have to be borne in mind that any suggestions that might be made regarding amendment of those treaties will not of themselves acquire the status of recommendations for amendment unless the competent organs established by each of the four treaties take the appropriate steps. Those competent organs are the Assembly of the Paris Union for the Protection of Industrial Property, the Council of the International Union for the Protection of New Varieties of Plants, the Assembly of the International Patent Cooperation Union and the Assembly of the Budapest Union for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

(ii) The Paris Convention for the Protection of Industrial Property

57. Tbe Paris Convention, the basic treaty in the field of industrial property, wbich was concluded in 1883 and now comprises 94 contracting States, establishes basic principles for the international protection of inventions. However, it does not regulate in detail the protection that each contracting State has to grant to inventions, or the question what is to be considered an invention. The basic principles are the national treatment principle in Article 2 (according to which each contracting State has to treat nationals and residents of other contracting States in the same way as its own nationals) and the right of priority under Article 4 (by virtue of whicb the applicant for a patent, or under certain conditions for an inventor's certificate, enjoys the right, in all other contracting States of the Paris Union, to invoke the date of the first application in procedures relating to subsequent applications filed in any of the 93 other contracting States of the Paris Union, provided that those subsequent applications are filed within 12 months of the first application). The Paris Convention also contains two provisions establishing a certain minimum protection of inventions: under Article 4*bis*, patents granted in one country of the Union are independent of patents granted for the same invention in other countries of the Union; under Article 5A, certain conditions must be fulfilled before a patent is revoked or a compulsory license granted (particularly in the case of non-working or insufficient working of the patented invention). Apart from some other provisions of relatively minor importance, the Paris Convention leaves the contracting States free to regulate tbe protection of inventions. Thus, as already mentioned, each contracting State is free to establish its own definition of an invention, to regulate the contents and duration of the rights conferred by titles of protection and to establish tbe conditions of protection, in particular novelty, inventive step, repeatability, industrial applicability and the requirement of complete disclosure.

(iii) The International Convention for the Protection of New Varieties of Plants

58. In contrast to the Paris Convention for the Protection of Industrial Property, the International Convention for the Protection of New Varieties of Plants, which was adopted in 1961 and revised in 1978 and which now comprises 17 contracting States, contains a more detailed regulation of the protection which the contracting States have to grant to new varieties of plants. Those conditions concern, in particular, the rights to be granted, the duration of those rights and the conditions of protection. According to Article 2(1) of the Convention, contracting States may protect new varieties of plants either by patents or by a special system of plant breeders' rights, provided that one and the same species or genus may be protected only under tbe patent system or only under the special system. In addition, the Convention also contains the principle of national treatment and establishes a right of priority.

(iv) The Patent Cooperation Treaty

59. Wbereas the aforementioned two Conventions deal with substantive aspects of protection, the Patent Cooperation Treaty, which was concluded in 1970 and now comprises 37 contracting States, deals with patent procedures. It offers the possibility of filing international applications with effect, at the option of the

applicant, in all or some of its contracting States. For each internatiooal application, a novelty search is made by an International Searching Authority and, under certain conditions, an examination report is prepared by an International Preliminary Examining Authority. The Patent Cooperation Treaty does not define the concept of invention. Under Rules 39.1(ii) and 67.1(ii), however, it allows any International Searching or Preliminary Examining Authority not to carry out an international search or preliminary examination of an international application if, and insofar as, that application has as its subject matter plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes. These seem to be the only provisions of the Patent Cooperation Treaty and its Regulations that have a certain relevance to biotechnological inventions.

(v) The Budapest Treaty for the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

60. This Treaty establishes a system of International Depositary Authorities which accept deposits of microorganisms for the purposes of patent procedure. Such deposits are recognized by all of the contracting States, so that applicants are oot obliged to make several deposits if they file patent applications in all or some of them. International Depositary Authorities have to release samples of deposited microorganisms at the request of the industrial property offices of countries in which applications have been filed with reference to the deposit and, after the publication of the description, at the request of any third party, provided that the third party proves, by means of a certificate to be issued by an industrial property office with which an application concerning the deposited microorganism has been filed, that he is eotitled to receive samples of the microorganism. The Budapest Treaty does not define what a microorganism is. It therefore appears to be applicable not only to living entities but also to such biological material as can be stored in the same way as microorganisms, for example cell lines. As regards the question of patenting microorganisms, the requirement of deposit and the requirement of release of samples, the Budapest Treaty does not establish rules of its own; instead, it refers to the applicable national law.

(c) The Diversity of Treatment of Biotechnological Inventions Under National Laws and the Resulting Problems

(i) General

61. One of the main problems to be dealt with in the WIPO study would be the extent to which the diversity of treatment of biotechnological inventions under national laws creates problems for the protection of those inventions. In this connection, national laws and regional agreements such as the European Patent Convention, which have the same functions as national laws, are to be considered in the same way.

62. There are various aspects of the protection of biotechnological inventions in which differences exist between national laws. It is proposed that the WIPO study should deal in particular with the following.

(ii) Diversity as Regards the Concept of Invention

63. Because of the diversity of the concept of invention in various countries, it may happen that, for example, a new living entity obtained by genetic engineering is considered an invention in one country and not in another. This raises the problem of a patent being obtainable for that invention in the first country, provided that other factors do not exclude it from patenting, and no patent protection whatsoever being available in the other.

(iii) Diversity as Regards Exclusion from Patentability

64. Some countries exclude certain biotechnological inventions from patenting, whereas others do not provide for such an exclusion. For example, plant varieties and essentially biological processes for the production of plants are excluded from patenting under the European Patent Convention and the national laws following the same approach as that Convention, whereas other countries do not exclude them. It is obvious that this diversity will create a number of problems which the WIPO study should examine.

(iv) Diversity as Regards the Conditions of Patentability and the Interpretation of Those Conditions

65. The conditions of patentability (in particular the standard of novelty and possible exceptions in favor of non-prejudicial disclosures) vary from country to country. This obviously creates diversity in the protection that biotechnological inventions cnjoy in various countries. It should be examined whether and to what extent the WIPO study should consider that diversity, since the differences may be of a general nature, applicable to all kinds of inventions, and therefore beyond thc scope of a study on biotechnological inventions.

(v) Diversity as Regards the Requirement of Deposit of Microorganisms and the Conditions for the Release of Samples

66. Whereas a number of countries require the deposit of microorganisms in order to supplement an otherwise insufficient description, other countrics have not (yet) introduced such a requirement. Moreover, therc are differences as regards the time at which thc deposit must be effcctcd, the time at which samples of the deposited microorganisms must be available for release and thc conditions of release. It is obvious that such diversity creates problems for the protection of biotechnological inventions which the WIPO study should examine.

(vi) Diversity as Regards the Rights Conferred by Titles of Protection in Respect of Biotechnological Inventions

67. The differences existing with respect to the rights conferred by titles of protection may create problems for the protection of biotechnological inventions. It is proposed that the WIPO study examine those differences.

D. Possibilities for Improvement of the Legal Protection of Biotechnological Inventions

(a) At the National and Regional Levels

(i) Changes in Laws, Regulations and Office Procedures

68. One possible approach towards solving the problems resulting from the diversity of protection of biotechnological inventions would be to change the national laws and regional agreements that appear to be unsatisfactory—or not fully satisfactory—as regards the protection of biotechnological inventions. For that purpose, a certain recommended standard would have to be established, and the WIPO study should make an attempt to establish such a standard, which would apply not only to laws, but also to regulations and office procedures.

(ii) Changes in the Interpretation of Existing Provisions

69. A less ambitious approach would be for the WIPO study not to establish a standard for questions to be regulated in laws, regulations and office procedures, but only to make recommendations concerning the interpretation of existing laws and regulations. One of the important areas which could be covered by such recommendations would be the interpretation of the concept of invention. It would already be an important achievement if a uniform approach could be adopted with respect to the borderline between inventions and discoveries.

(b) At the International Level

(i) Adoption of Additional Treaty Provisions

70. The WIPO study could go one step further than is indicated in the preceding chapter and examine the possibility of new treaty provisions concerning the protection of biotechnological inventions, with the aim of harmonizing national laws in this field.

(ii) Recommendations by the Paris Union Assembly

71. If it appears that—under the present circumstances—the prospects of new treaty provisions being adopted are not sufficient to justify work in that direction, it could nevertheless be envisaged that the WIPO study would deal with the preparation of an instrument that could be adopted by a competent body, such as the Paris Union Assembly, and would contain recommendations to the contracting States of the Paris Union with respect to the treatment of biotechnological inventions.

(iii) Other Measures

72. In addition to the measures considered in paragraphs 68 to 70 above—or as an alternative to them—the WIPO study could deal with the possibilities for preparing guidelines or a manual which, in addition to the purposes of disseminating information on the protection of biotechnological inventions, could nevertheless aim at achieving some harmonization of existing systems of protection.

IV. Advice Requested of the Committee of Experts

73. The Committee of Experts is requested to make comments and give advice on the questions raised in this memorandum.

WIPO Meetings

WIPO/Government of Portugal

Seminar on Industrial Property for Portuguese-Speaking African Countries

(Lisbon, September 3 to 7, 1984)

NOTE*

A Seminar on Industrial Property for Portuguese-Speaking African Countries, organized and financed jointly by the Government of Portugal and WIPO, was held in Lisbon from September 3 to 7, 1984.

Industrial property officials from Angola, Guinea-Bissau, Mozambique and Sao Tome and Principe, as well as Government officials and patent attorneys from Portugal, participated in the Seminar. This was the first meeting on industrial property organized for those countries of Africa wbose official language is Portuguese. Tbe list of participants follows this Note.

The Seminar was opened by the Director General of WIPO, by representatives of the Ministers for Foreign Affairs and for Industry and Energy of Portugal, and by the Director General of tbe National Institute of Industrial Property (INPI) of Portugal, who also presided over the Seminar. The purpose of the Seminar was to inform participants on industrial property activities in general and, in particular, within the framework of WIPO and the National Institute of Industrial Property of Portugal.

Lectures, followed by discussions, were given by officials of WIPO and INPI and by Portuguese patent agents. The participants gave accounts of the industrial property situation in their countries.

The Seminar concluded with the adoption of recommendations concerning tbe future development of the industrial property system in the participating countries, in cooperation with the Portuguese Government and WIPO.

LIST OF PARTICIPANTS**

I. States

Angola: D.O.F. Balombo; A.A. Dos Santos. **Guinea-Bissau:** C. Nhate; H. Paquete. **Mozambique:** J.F. Mabuie; D. Martins da Silva; P. S. Nhancala. **Sao Tome and Principe:** N.C. Alegre.

II. Observers

M.O.S.O. Barros Henriques; M.S.Vieira Peireira Ferreira; J. Cruz; M.A. Albranches de Soveral; M.E. Barroso Gonçalves.

III. WIPO/Government of Portugal

WIPO: A. Bogsch *(Director General)*; I. Thiam *(Director, Development Cooperation and External Relations Bureau for Africa and Western Asia)*; N. Scherrer *(Head, PCT Publications, Fees and Statistics Section)*.

INPI: J. Mota Maia *(Director General)*; R. Serrão *(Director, Trademark Service)*; A. Sampaio *(Head of Division)*; J. Alvim *(Head of Division)*; M. Rio Abreu *(Head of Division)*.

* Prepared by the International bureau.

** A list containing the titles and functions of the participants may be obtained from the International Bureau.

WIPO Permanent Committee on Patent Information (PCPI)

I. Working Group on Patent Information for Developing Countries

Fifth Session
(Geneva, September 17 and 19, 1984)

NOTE*

The Working Group on Patent Information for Developing Countries (hereinafter referred to as "the Working Group") of the WIPO Permanent Committee on Patent Information held its fifth session in Geneva on September 17 and 19, 1984.

Eighteen members of the Working Group were represented at the session: Algeria, Austria, Canada, Cuba, Finland, France, Germany (Federal Republic of), Japan, Philippines, Senegal, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America, Viet Nam, European Patent Office (EPO). The International Federation for Documentation (FID) and the International Patent Documentation Center (INPADOC) were represented by observers. The list of participants follows this Note.

The Working Group assessed the situation under the WIPO State-of-the-Art Search Program and noted that,

* Prepared by the International Bureau.

from September 1975 to August 31, 1984, a total of 2,157 search requests had been received and 1,955 search reports had been furnished. Of this latter total, 1,076 search reports had been provided by Austria, 220 by the Federal Republic of Germany, 214 by Sweden, 134 by the German Democratic Republic, and 115 by other industrial property offices. In 196 cases, the International Bureau had been able to provide search reports itself.

The Working Group noted with appreciation the contributions made by the various industrial property offices and, in particular, new contributions announced by Japan and Finland and an additional contribution announced by the Soviet Union.

The Working Group stressed the necessities of keeping response times to search requests within reasonable limits and of a flexible approach to search requests that were not formulated with sufficient clarity. In the latter case, at least cross-sectional searches should be attempted in order to assist the user in better identifying his needs. In particular, the results of on-line searches might serve this purpose. The Working Group endorsed recommendations made by the PCPI Working Group on Special Questions concerning steps to be undertaken by the International Bureau in order to facilitate the access by users from developing countries to patent information data bases.

The Working Group also discussed an analytical summary, prepared by the International Bureau, of evaluation questionnaires returned by the users and noted that the direct transfer of technological knowledge and the stimulation of indigenous research and development activities have obviously remained the main reasons for requesting the services.

The Working Group noted with appreciation a detailed study prepared by the Council of Scientific and Industrial Research (CSIR), India, on the technological and economic impact of the free-of-charge search reports and invited all industrial property offices contributing to the WIPO State-of-the-Art Search Program to comment on the conclusions drawn by CSIR with regard to possible improvements of the services rendered.

The Working Group noted a flow chart for establishing technical monographs based on patent documents, and it concluded that this flow chart needed to be studied in more depth.

The Working Group underlined the potential importance of monographs based on patent documents for facilitating access to technological information not only for users in developing countries, but also, for instance, for users in small and medium-sized enterprises in industrialized countries. The International Bureau was requested to compile a bibliographic survey on the monographs based on patent documents published so far by various industrial property offices and organizations and to explore suitable ways and means for facilitating access to those monographs for users in developing countries.

Finally, the Working Group recommended that the "Guidelines for the Planning and Organization of a Patent Documentation and Information Center in a Developing Country" (document PCPI/GEN/1) should be revised and updated, and that the maintenance and regular updating of a price list of patent documents should be a continuing task.

The Working Group also had an exchange of views on the WIPO *Journal of Patent Associated Literature* (JOPAL) and recommended that the "experimental" character of JOPAL should, from 1985 onwards, be changed to a continuing item among the PCPI activities.

LIST OF PARTICIPANTS*

I. Member States

Algeria: M. Sadou. **Austria:** J. Fichte. **Canada:** P. Trépanier. **Cuba:** M. Jiménez Aday. **Finland:** R.K. Laukkarinen. **France:** A. de Pastors. **Germany (Federal Republic of):** M. Voegtel. **Japan:** T. Hashimoto. **Philippines:** A.L. Calubig. **Senegal:** M.M. Ndiaye. **Soviet Union:** Y. Gyrdymov. **Spain:** C. Garcia Gallo; R. Vazquez de Parga y Pardo. **Sweden:** K. Bergström. **Switzerland:** M. Leuthold; E. Caussignac. **United Kingdom:** V.S. Dodd. **United States of America:** W.S. Lawson; T.F. Lomont. **Viet Nam:** Vu Huy Tan.

II. Member Organization

European Patent Office (EPO): G. Giroud.

III. Observer Organizations

International Federation for Documentation (FID): F.J. Leloux. **International Patent Documentation Center (INPADOC):** G. Quarda.

IV. Officers

Chairman: W.S. Lawson (United States of America). *Vice-Chairmen:* J. Fichte (Austria); Y. Gyrdymov (Soviet Union). *Secretary:* R. Blumstengel (WIPO).

V. International Bureau of WIPO

L.E. Kostikov *(Deputy Director General)*; P. Claus *(Director, Patent Information and Classification Division)*; R. Blumstengel *(Head, Developing Countries Section (Patent Information))*; R. Andary *(Senior Program Officer, Developing Countries Section (Patent Information))*; Y. Hashimoto *(Program Officer, Developing Countries Section (Patent Information))*.

* A list containing the titles and functions of the participants may be obtained from the International Bureau.

II. Working Group on Planning

Fourteenth Session
(Geneva, November 19 to 23, 1984)

NOTE*

The Working Group on Planning (bereinafter referred to as "tbe Planning Group") of the WIPO Permanent Committee on Patent Information (hereinafter referred to as "the Permanent Committee") held its fourteenth session in Geneva from November 19 to 23, 1984.[1]

Fourteen members of the Planning Group were represented at the session (Australia, Austria, Brazil, Denmark, France, Germany (Federal Republic of), Japan, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America and the European Patent Office (EPO)). The list of participants follows this Note.

The Planning Group discussed a proposal by tbe Soviet Union for obligatory printing of IPC indexing codes on those published patent documents that form part of the PCT minimum documentation and invited the members of the Planning Group to submit further comments. It noted the possibility and desirability of achieving the main purpose of the proposal without attempting to make it compulsory for the members of the IPC Union to print indexing codes on their publisbed patent documents.

The Planning Group reviewed, in a first reading, a revised "Long-Term Program of the PCPI" and offered a certain number of preliminary observations and comments. Among tbose comments was tbe suggestion that the International Bureau look into the overall structure of the Program, with a view to reducing overlap of subject matter between the so-called "broad beadings." It was felt, bowever, that the subdivisions under the "broad headings," namely, "objective," "present status," "current work" and "possible future work areas," should be retained. In order to enable it to prepare a final recommendation on this question at its next session, the Planning Group asked all members of the Permanent Committee to submit comments on and make proposals for the revised "Long-Term Program of the PCPI," particularly as regards the following aspects:

(a) proposals for new possible future work areas;

(b) comments, if any, on the "broad beadings";

(c) with regard to the presently included "possible future work areas" that had been included in the Long-Term Program for two or more years since its adoption by the Permanent Committee and which were thus likely to be deleted from tbe Program by the Permanent Committee at its next session in September 1985, each proponent Office should either submit a detailed proposal or declare why the said "possible future work areas" should be kept on the Long-Term Program;

(d) any further observations of a general nature wbich would enable the Permanent Committee to achieve its goals and objectives as laid down in its Organizational Rules.

The Planning Group emphasized tbat in any comments or proposals made tbe interests and concerns of developing countries in all questions concerning patent information and documentation should be closely kept in mind.

The Planning Group noted with interest the progress report prepared by the International Bureau concerning the work of tbe EPO DATIMTEX Working Party on tbe filing of patent applications in machine-readable form, underlined tbe importance of this task and agreed that the legal implications and feasibility as well as several basic questions of standardization posed by the filing of patent applications in machine-readable form were matters requiring detailed study by the PCPI and other relevant bodies of WIPO. Accordingly, the Planning Group requested tbe International Bureau to draft a detailed proposal concerning the presentation of patent applications typed in Optical Character Recognition (OCR) format.

LIST OF PARTICIPANTS*

I. Member States

Australia: H. Preston. **Austria:** F. Sohs. **Brazil:** S.M. Da Silva; A.R. Cavalcanti. **Denmark:** H.I. Rasmussen. **France:** A. de Pastors. **Germany (Federal Republic of):** M. Voegtel. **Japan:** S. Kodera; S. Ono. **Soviet Union:** V. Blinnikov; B. Rozov. **Spain:** A. Gomez Garcia. **Sweden:** L.G. Björklund; K. Bergström. **Switzerland:** E. Caussignac. **United Kingdom:** V.S. Dodd; G.K. Lindsey. **United States of America:** W.S. Lawson; T.F. Lomont.

II Member Organization

European Patent Office (EPO): A.Vandecasteele; R. Baré.

III. Officers

Chairman: W.S. Lawson (United States of America). *Vice-Chairmen:* F. Sohs (Austria); A. de Pastors (France). *Secretary:* P. Claus (WIPO).

IV. International Bureau of WIPO

L. Kostikov *(Deputy Director General);* P. Claus *(Director, Patent Information and Classification Division);* B. Hansson *(Head, Patent Classification Section, Patent Information and Classification Division);* P. Higham *(Head, Patent Information Section, Patent Information and Classification Division);* G. Negouliaev *(Senior Patent Information Officer, Patent Information Section).*

* Prepared by the International Bureau.

[1] For a note on the thirteenth session, see *Industrial Property*, 1984, p. 275.

* A list containing the titles and functions of the participants may be obtained from the International Bureau.

III. Working Group on Special Questions

Sixth Session
(Geneva, November 19 to 23, 1984)

NOTE*

The Working Group on Special Questions (hereinafter referred to as "the Working Group") of the WIPO Permanent Committee on Patent Information (hereinafter referred to as "the Permanent Committee") held its sixth session in Geneva from November 19 to 23, 1984.[1]

Fourteen members of the Working Group were represented at the session (Australia, Austria, Brazil, Denmark, France, Germany (Federal Republic of), Japan, Soviet Union, Spain, Sweden, Switzerland, United Kingdom, United States of America and the European Patent Office (EPO)). The International Patent Documentation Center was represented by an observer.

The Working Group, following tbe mandate given to it by the Permanent Committee, adopted a revised version of the Standardized Recording of International Patent Classification (IPC) Symbols on Machine-Readable Records (WIPO Standard ST.8).

The Working Group discussed further action to be undertaken in respect of summary reports and conclusions prepared by the International Bureau concerning a detailed study of the consistency in the application of symbols of the International Patent Classification to patent documents.

The Working Group approved material prepared by the International Bureau so as to complete the inventory of computerized search systems that are devoted wholly, or to a substantive degree, to patent information. It also approved a general outline, also prepared by the International Bureau, of a handbook on telex interrogation of on-line patent data bases.

The Working Group approved a proposal by the International Bureau to publish, generally once a year, in the *PCT Gazette*, corrections to the list of periodicals established according to PCT Rule 34.1(b)(iii) and approved a procedure to enable such corrections to be so published. The Working Group also approved a revised distribution of work in connection witb the selection of articles from the said list of periodicals whose bibliographic details are publisbed in the WIPO *Journal of Patent Associated Literature* (JOPAL) following the coming into force on January 1, 1985, of a revised list of such periodicals.

Finally, the Working Group discussed the topic of mass storage media for patent documents. It agreed to ask members of the Permanent Committee to identify those aspects of the topic that should receive detailed consideration and at the same time to give information whicb would enable the International Bureau to prepare a survey of the present and planned future use of such media within Offices.

LIST OF PARTICIPANTS*

I. Member States

Australia: H. Preston. **Austria:** F. Sohs. **Brazil:** S.M. Da Silva; A.R. Cavalcanti. **Denmark:** H.I. Rasmussen. **France:** A. de Pastors. **Germany (Federal Republic of):** M. Voegtel. **Japan:** S. Kodera; S. Ono. **Soviet Union:** V. Blinnikov; B. Rozov. **Spain:** A. Gomez Garcia. **Sweden:** L.G. Björklund; K. Bergström. **Switzerland:** E. Caussignac. **United Kingdom:** V.S. Dodd; G.K. Lindsey. **United States of America:** W.S. Lawson; T.F. Lomont.

II Member Organization

European Patent Office (EPO): A.Vandecasteele; R. Baré.

III. Observer Organization

International Patent Documentation Center (INPADOC): G. Quarda.

IV. Officers

Chairman: W.S. Lawson (United States of America). *Vice-Chairmen:* F. Sohs (Austria); A. de Pastors (France). *Secretary:* P. Higham (WIPO).

V. International Bureau of WIPO

L. Kostikov *(Deputy Director General);* P. Claus *(Director, Patent Information and Classification Division);* B. Hansson *(Head, Patent Classification Section, Patent Information and Classification Division);* P. Higham *(Head, Patent Information Section, Patent Information and Classification Division);* G. Negouliaev *(Senior Patent Information Officer, Patent Information Section).*

* Prepared by the International Bureau.

[1] For a note on the fifth session, see *Industrial Property*, 1984, p. 275.

* A list containing the titles and functions of the participants may be obtained from the International Bureau.

General Studies

The Encouragement, Rewards for and Protection of Inventions and Creations in China

WU HENG*

Calendar of Meetings

WIPO Meetings

(Not all WIPO meetings are listed. Dates are subject to possible change.)

1985

February 25 to March 1 (Geneva) — Group of Experts on Copyright Protection of Computer Software (convened jointly with Unesco)

March 11 to 15 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on General Information

March 18 to 22 (Paris) — Group of Experts on Copyright Problems in the Field of Direct Broadcasting Satellites (convened jointly with Unesco)

April 22 to 26 (Paris) — Joint Unesco-WIPO Consultative Committee on the Access by Developing Countries to Works Protected by Copyright (convened jointly with Unesco)

May 6 to 17 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on Search Information

June 3 to 7 (Geneva) — Nice Union: Committee of Experts

June 6 to 14 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Groups on Planning and on Special Questions

June 17 to 25 (Paris) — Berne Union: Executive Committee (Extraordinary Session) (sitting together, for the discussion of certain items, with the Intergovernmental Committee of the Universal Copyright Convention)

June 26 to 28 (Paris) — Rome Convention: Intergovernmental Committee (Ordinary Session)(convened jointly with ILO and Unesco)

September 11 to 13 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on Patent Information for Developing Countries

September 16 to 20 (Geneva) — Permanent Committee on Patent Information (PCPI) and PCT Committee for Technical Cooperation (PCT/CTC)

September 23 to October 1 (Geneva) — Governing Bodies (WIPO General Assembly, Conference and Coordination Committee; Assemblies of the Paris, Madrid, Hague, Nice, Lisbon, Locarno, IPC, PCT, Budapest, TRT and Berne Unions; Conferences of Representatives of the Paris, Hague, Nice and Berne Unions; Executive Committees of the Paris and Berne Unions; Committee of Directors of the Madrid Union; Council of the Lisbon Union)

October 7 to 11 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on General Information

November 18 to 22 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Groups on Special Questions and on Planning

November 25 to December 6 (Geneva) — Permanent Committee on Patent Information (PCPI): Working Group on Search Information

UPOV Meetings

1985

March 27 and 28 (Geneva) – Administrative and Legal Committee

March 29 (Geneva) – Consultative Committee

May 8 to 10 (Wageningen) – Technical Working Party on Automation and Computer Programs

June 4 to 7 (Hanover) – Technical Working Party for Agricultural Crops, and Subgroup

June 18 to 21 (Aarslev) – Technical Working Party for Fruit Crops, and Subgroup

June 24 to 27 (Aars and Aarslev) – Technical Working Party for Ornamental Plants and Forest Trees, and Subgroups

July 8 to 12 (Cambridge) – Technical Working Party for Vegetables, and Subgroup

October 14 (Geneva) – Consultative Committee

October 15 and 16 (Geneva) – Meeting with International Organizations

October 17 and 18 (Geneva) – Council

November 12 and 13 (Geneva) – Technical Committee

November 14 and 15 (Geneva) – Administrative and Legal Committee

Other Meetings Concerned with Industrial Property

1985

March 1 (Hamptoo Court Palace, Nr. London) — Pharmaceutical Trade Marks Group: 30th Conference on "Computer Law as Applied to Industrial Property"

April 18 and 19 (Tokyo) — Japanese Government: Celebration and Symposium Commemorating the Centenary of the Japanese Industrial Property System

May 13 to 19 (Rio de Janeiro) — International Association for the Protection of Industrial Property: Executive Committee

June 3 to 7 (Augsburg) — Internatinnal Federation of Industrial Property Attorneys: World Congress

June 10 to 14 (Munich) — European Patent Organisation: Administrative Council

September 2 tn 6 (Budapest) — Hungarian Group of the International Associatinn for the Protection nf Industrial Property and the Hungarian Association fnr the Protectinn nf Industrial Property: Sixth International Conference nn "New Technical Tendencies and Industrial Property Protection"

September 16 to 18 (Geneva) — International Association for the Advancement of Teaching and Research in Intellectual Property: Assembly and Annual Meeting

December 4 to 7 (Munich) — European Patent Organisation: Administrative Council

1986

June 8 to 13 (London) — International Association for the Protection of Industrial Property: XXXIII Congress