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

(April 23 to 26, 1974)

SURVEY OF THE SYSTEMS EXISTING AT THE NATIONAL LEVEL WITH RESPECT TO THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

prepared by the International Bureau

SUMMARY

This document contains an analysis of the replies received from a number of countries to the International Bureau's questionnaire relating to patent procedure with respect to inventions concerning microbiological processes or products thereof.

Introduction

1. The Industrial Property and Copyright Department of the Department of Trade and Industry of the United Kingdom proposed, in a letter dated June 26, 1972, addressed to the Director General of WIPO, that the International Bureau should undertake a study of the question of the protection of inventions relating to microorganisms, with particular reference to the requirements for the deposit of microorganisms for the purpose of patent applications. (The text of this letter is attached as Annex I.) It was suggested that the International Bureau prepare a report, including a survey of the national patent systems, to be submitted to a working group to be convened in 1974.

2. The Executive Committee of the Paris Union, at its eighth ordinary session, held in Geneva in September 1972, decided that the International Bureau should study the proposal made by the Government of the United Kingdom and prepare a report on it, together with a survey of the systems of deposit of microorganisms existing at the national level. (See the report of the Executive Committee, document P/EC/VIII/16, paragraphs 20 to 23.)

3. In compliance with this decision, the International Bureau prepared a questionnaire, which was forwarded to the member countries of the Paris Union. (The questionnaire is reproduced as Annex II to this document.) The purpose of the questionnaire was to collect pertinent information on the applicable provisions existing at the national level relating to patent procedure with respect to inventions concerning microbiological processes or products thereof.

4. By January 18, 1974, 32 replies[1] had reached the International Bureau. The texts of all the replies received are reproduced in Annex III. It should be noted that the answers from Cyprus, Iran, Italy, Luxembourg, Malta and Zambia are not analyzed in this survey, since these countries did not send specific replies to the questionnaire. The essence of the replies of the said six countries is set out in the footnote below.[2]

5. The analysis of the replies of the other 26 countries follows the order of the questions listed in the questionnaire. The survey is therefore divided into three parts. The first part deals with the patentability of inventions involving microorganisms; the second part relates to the requirements for disclosure of microorganisms and their availability to the public; the third part contains additional information regarding the patent procedure with respect to inventions involving the action of microorganisms.

6. In consideration of the fact that a number of countries referred in their replies to Rule 28 of the Implementing Regulations to the Convention on the Grant of European Patents, adopted at the Munich Diplomatic Conference in October 1973, the text of the said Rule is reproduced in Annex IV.

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(1) The following countries replied to the questionnaire: Algeria, Argentina, Australia, Austria, Bulgaria, Canada, Cyprus, Czechoslovakia, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Holy See, Hungary, Iran, Ireland, Italy, Luxembourg, Malta, Netherlands, New Zealand, Norway, Philippines, Poland, Soviet Union, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia, Zambia.

(2) Iran and Zambia reported that no particular patent procedure was applicable to microbiological inventions. Cyprus specified that, for a patent to be registered, all the prerequisites of the United Kingdom Patent Law would have to exist. Italy and Luxembourg indicated that the field of microbiological inventions was not covered by any specific provisions; they added, however, that the question of the patent procedure relating to inventions concerning microorganisms would be studied in the framework of the forthcoming revision of their respective patent laws, taking into account also the relevant provisions contained in the European Patent Convention. Malta pointed out that the existing provisions of its Patent Law were applicable to microbiological inventions.

I. PATENTABILITY OF INVENTIONS INVOLVING MICROORGANISMS

1. Under the law of your country (including court decisions), may a valid patent be obtained for:

(a) a process involving the action of a microorganism not already known and available to the public?

7. Twenty-two countries[3] answered this question in the affirmative. Two of them, New Zealand and Switzerland, qualified their reply by adding that no opinion could be expressed on the question whether a "valid" patent can be obtained for a process involving the action of a new microorganism, since the question of validity is a matter for court decisions. Argentina and Austria replied to this question in the negative, Argentina adding that microbiological processes were protected when they resulted in products capable of industrial application. The Soviet Union reported that, even if the Statute on Discoveries, Inventions and Rationalization Proposals of August 21, 1973, did not regulate the matter covered by this question, there was a recent tendency to protect processes involving the action of microorganisms not already known and available to the public.

1. Under the law of your country (including court decisions), may a valid patent be obtained for:

(b) a product of a process referred to under (a)?

8. Eighteen countries[4] replied that a product resulting from a process involving the action of a new microorganism could be protected by a patent. Six countries (Argentina, Austria, Hungary, Poland, Soviet Union and Switzerland) answered in the negative. Poland added, however, that a patent granted for a process also covered products directly obtained from that process. Switzerland specified that, since products obtained by a microbiological process were chemical substances or alimentary or pharmaceutical products, they were not patentable, as such, according to the Swiss patent law[5].

9. Nine of the countries which answered in the affirmative made additional comments in their replies, which may be summarized as follows. Bulgaria pointed out that such a product could be protected only by an inventor's certificate[6]. Czechoslovakia indicated that, while an inventor's certificate could be granted for any kind of product, with the exception of substances already existing in nature, a patent could be obtained only if the product were not a chemical compound, a medicinal speciality or an alimentary product. Under the laws of Denmark, Finland, Norway and Sweden, patent protection is not granted for medicinal and alimentary products. Finland added that this situation might change in the future, in view of the tendency to admit the patentability of food and medicines. Ireland reported that, according to the practice of its Patent Office, claims for such a product had been allowed. New Zealand specified in its reply that a patent could be obtained.

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(3) Algeria, Australia, Bulgaria, Canada, Czechoslovakia, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Norway, Philippines, Poland, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia.

(4) Algeria, Australia, Bulgaria, Canada, Czechoslovakia, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ireland, Netherlands, New Zealand, Norway, Philippines, Sweden, United Kingdom, United States of America.

(5) See Articles 2(2), 3 and 4 of the Federal Law on Patents for Inventions of June 25, 1954.

(6) See Article 15(a) of the Law on Inventions and Rationalizations of October 8, 1968.

1. Under the law of your country (including court decisions), may a valid patent be obtained for:

(c) a new microorganism existing in nature?

10. Twenty-five countries[7] replied to this question, all in the negative. Seven of them, however, made additional comments in their replies, which may be summarized as follows. Australia indicated that compositions including an organism existing in nature might be acceptable (for example, a new vaccine). Bulgaria pointed out that, indirectly, protection could be obtained for a microorganism through a process for its application. France reported that a court decision issued in 1957[8] had considered the discovery of a so far unknown natural product as patentable on the ground that industrial applications of that product had been indicated. Germany (Federal Republic of) specified that no indications were available on this question; if a new microorganism were to be found in nature, it would be qualified as a discovery of a non-patentable subject matter. The Netherlands stated that no jurisprudence was available on this question. The Soviet Union pointed out that even if the applicable provisions did not contain any restrictions on the protection of microorganisms obtained artificially or discovered in nature, as a rule strains of microorganisms extracted from nature could not be the subject of protection. Yugoslavia specified that a new microorganism existing in nature would be considered a discovery and not an invention.

1. Under the law of your country (including court decisions), may a valid patent be obtained for:

(d) a new strain of an existing microorganism obtained by a process such as mutation?

11. The replies to this question are very diversified and qualified by different comments. A first group of 14 countries[9] replied in the negative; however, three of them added additional clarifications to their answers. Argentina specified that mutation processes were acceptable. Australia and the United States of America indicated that new processes using such organisms might be patentable. Poland stated that it was possible to obtain patent protection for a new process leading to the obtaining of a mutant.

12. The following countries replied in the affirmative, with various qualifications. Bulgaria indicated that a new strain of microorganism, obtained by mutation, could be protected either directly, if its utility was proven, or indirectly, by protecting the process for its production. Canada and Switzerland stated that such a strain would be patentable if the process for obtaining it was reproducible and controllable. Czechoslovakia indicated that it was only an inventor's certificate that could be granted for such a new strain. The German Democratic Republic specified that induced mutants could obtain patent protection if they were involved in a process of application of a microbiological-chemical nature, such as fermentation[10]. According to the replies received from New Zealand and

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(7) Algeria, Argentina, Australia, Austria, Bulgaria, Canada, Czechoslovakia, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Norway, Philippines, Poland, Soviet Union, Sweden, Switzerland, United Kingdom, United States of America, Yugoslavia.

(8) Judgment rendered by the Civil Court of the Seine, on May 9, 1957 (Merk/SIFA), Annales de la propriété industrielle, 1963, pages 329 to 343 (see the reply from France in Annex III).

(9) Argentina, Australia, Austria, Denmark, Finland, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Norway, Philippines, Poland, Sweden, United States of America.

(10) The German Democratic Republic referred to the decision of the Board of Appeals No. III of the Inventions and Patents Office of the German Democratic Republic, dated June 30, 1970, published in Bekanntmachungen des Amtes für Erfindungs- und Patentwesen der DDR, No. 24, December 1970 (Volume 11, p. 539 et seq.). See the reply from the German Democratic Republic in Annex III.

the United Kingdom, such a strain is patentable in those countries unless it has been found in nature. The Soviet Union reported that new strains of microorganisms were considered inventions, but that only inventors' certificates could be granted for the said inventions; moreover, the claims of applications covering strains of microorganisms must contain indications of all features of the strain necessary for that strain to be recognized and for it to be determined that it was a new culture not hitherto described anywhere else. Two countries, France and the Netherlands, expressed doubts on the reply to be given, mainly because of the lack of jurisprudence on this point.

2. Does the law of your country (including court decisions), contain any other provisions relating to the patentability of inventions inventions involving microorganisms?

13. While ten countries[11] replied that no additional information was available, the following thirteen countries added further clarifications to their previous answers. Argentina indicated that mutation processes by physiochemical means were admitted on the condition that they did not include the mutant. Bulgaria stated that a patent application covering an invention involving the action of a microorganism should refer to only one strain. Finland pointed out that all general provisions regarding the novelty of invention and non-ambiguity of description were applicable. It also reported, however, that special regulations had been issued by the Finnish Patent Office on the clearness of the description in microbiological cases. France specified that the invention should be described in such a way that it could be carried out by any person skilled in the art[12]. Hungary added that plant varieties, animal breeds and processes thereof were patentable if they were new, homogeneous and relatively stable. The Netherlands stated that while, at present, patents were granted only for processes involving the action of microorganisms, a prospective change in the patent law would grant protection to new substances as such. Norway specified that for food and medicine protection may be granted only for the process of manufacture. The Philippines and the United States of America referred to the existing applicable regulations developed by the respective Patent Offices[13]. The Soviet Union stated that, as for medical substances, protection for strains of microorganisms would be granted after the necessary approval of the strain itself by the public health services. Switzerland reported that according to the Swiss Patent Law and Swiss jurisprudence only processes for the production of medicines were patentable and that microbiological processes must be considered chemical processes. The United Kingdom pointed out that, although there were no specific provisions in the Patents Act regarding the patentability of inventions involving microorganisms, it could be concluded from a decision[14] that claims relating to microorganisms per se must refer to microorganisms having a practical use.

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(11) Australia, Austria, Canada, Czechoslovakia, Denmark, Germany (Federal Republic of), Ireland, New Zealand, Poland, Sweden.

(12) In this connection, the reply from France referred in particular to the decision of the Court of Paris of June 20, 1969 (see Annex III).

(13) For the texts of the Patent Office regulations of the Philippines and the United States of America, see the replies from the Philippines and the United States of America, in Annex III.

(14) General Electrical Co. Ltd's Application, Reports of Patent, Design and Trade Mark Cases, 1961, page 21.

II. DISCLOSURE AND MAKING AVAILABLE TO THE PUBLIC

1. If a patent application is filed in your country for an invention involving new microorganisms (see I.1 above), is a description of the new microorganism in writing sufficient or is it necessary to make a deposit of the new microorganism in a culture collection and refer to that deposit in the description?

14. The replies to this question contained very detailed information. Fourteen countries[15] indicated that the deposit of a new microorganism was necessary. Four countries[16] stated that such deposit was not necessary but was desirable or recommended. Four countries, Algeria, Canada, Poland and the United Kingdom, specified that a written description was sufficient. Canada added that, in the event that a complete written description of the microorganism was not possible, an indication of the deposit number was acceptable. The United Kingdom reported that, if an adequate taxonomic description of a new microorganism had been given in writing, this was considered sufficient[17].

15. Thirteen out of the 14 countries which consider the deposit of a new microorganism necessary provided the following additional information. Argentina indicated that it was sufficient in that country that the new microorganism be described in writing provided that it was found to be in accordance with international standards; in other words, for this purpose a deposit must be made in an internationally recognized culture collection with the authorization to disclose the microorganism. Bulgaria pointed out that, in the case of an invention involving the action of a new microorganism, a written description alone was not sufficient. The microorganism must be deposited in a culture collection and the number of the deposit and the collection in which the deposit had been made must be indicated in the description, which must also be accompanied by a declaration certifying the deposit. Czechoslovakia specified that it was necessary to make a deposit of a new microorganism in a culture collection and that the description must contain the name and place of the collection together with the deposit number assigned to the microorganism. The German Democratic Republic indicated that in all cases it was necessary, in addition to providing a description of the new microorganism, to make a deposit and to refer clearly to it in the description. Germany (Federal Republic of) pointed out that, even if the deposit of a microorganism was not expressly provided for in its Patent Law, such deposit and a reference to the same in the description were required. Hungary indicated that it was necessary, in the case of both new and known microorganisms, to make a deposit and refer to it in the description; the document proving the deposit must be attached to the patent application; in the case of known strains, the deposit document could be replaced by a copy of the catalogue containing the identification data of the strain. In Ireland, besides a very exhaustive description, the deposit of a sample of a new microorganism is also required. Norway indicated that the description must be very clear so that the invention could be carried out by any person skilled in the art; however, deposit of a new microorganism was required and designation of the deposit should be stated in the specification. The Philippines reported that description and deposit in a culture collection were both requested and that the disclosure should indicate the source and the method of isolation of the strain and the complete description of the characteristics of microorganisms, and should include the description of the process for making the substance or the product using the microorganism; proof of the deposit of the

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(15) Argentina, Austria, Bulgaria, Czechoslovakia, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Norway, Philippines, Soviet Union, Switzerland, United States of America, Yugoslavia.

(16) Australia, Denmark, Finland, Sweden.

(17) In this connection, the United Kingdom referred in its reply to the case of American Cyanamid Company (Dann's) Patent, Reports of Patent, Design and Trade Mark Cases, 1971, page 425.

microorganism, together with the number of the deposit, must be submitted[18]. The Soviet Union reported that on May 10, 1973, an amendment came into force with respect to item 29 of the Soviet Instructions covering the Methods of Examination of Applications for Inventions; the amendment required that the number of the deposited strain and the location of the culture collection must be included in the claims. Switzerland stated that the description in writing was sufficient in the case of a new strain of an existing microorganism obtained by mutation; in all the other cases the deposit and reference to it were requested. The United States of America stated that, since by definition new microorganisms did not have a known taxonomy, the description must be accompanied by the deposit in an acceptable culture collection and reference to the deposit should be included in the description. Yugoslavia reported that the written description of a microorganism was not sufficient and for that reason a deposit was necessary; the practice of making a deposit had been constantly followed by those filing patent applications involving the action of microorganisms.

16. The four countries which indicated that the deposit of a new microorganism was not necessary but was desirable or recommended qualified their replies with the following comments. Australia indicated that it was not necessary to make the deposit of the microorganism in a culture collection, although such an action was desirable; the Australian reply added that, since the microorganisms might vary widely in their characteristics, it was not possible to set out the minimum criteria necessary to describe each one; however, the recommendation published in the International Bulletin of Bacteriological Nomenclature and Taxonomy[19] could be taken as a reference guide. Denmark specified that the description was sufficient; however, according to the Instructions of the Danish Patent Office on the Processing of Patent Applications concerning microbiological methods[20], a deposit was desirable; new microorganisms must be fully described so that confusion with other microorganisms could be avoided. If the description could not be worked out in such a way that confusion with other microorganisms was excluded, it was appropriate that the organism should be deposited in a scientific institution and the deposit number stated in the description. Finland pointed out that it was not necessary to deposit the new microorganism; however, such an act was considered proper and recommendable. Sweden reported that the description must be sufficiently clear to enable the invention to be carried out by a person skilled in the art; the Swedish Patent Office decided whether a deposit was necessary or not; if it was not possible to draft the description in such a way as to avoid confusion with other microorganisms, or if the microorganism was very rare or not reproducible with certainty, then, according to the Swedish Patent Office Rules[21], it was desirable to make a deposit.

17. Three countries, namely, France, the Netherlands and New Zealand, reported on different practices. France stated that, since no specific requirement was contained in the French Patent Law regarding the deposit of new microorganisms, the applicant must decide whether the indications given in the description were sufficient to identify the microorganisms properly or whether it was advisable to make a deposit in order to refer to it in the description. In the Netherlands, the deposit of a new microorganism is required only if the Patent Office of that country judges that the latter is not available from other sources; in such a case, the microorganism is given to the laboratory for its public collection, on the condition that the patent application is accepted; in the event that the application is not accepted, the strain is destroyed; if it is accepted, it is moved to the public collection; reference to the deposit must be included in the description;

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(18) See the reply from the Philippines in Annex III, which contains the text of the Patent Office Regulations for the filing of patent applications involving microorganisms.

(19) Volume 13, No. 3, of July 15, 1963, at pages 169 and 170.

(20) See the reply from Denmark in Annex III, which contains the text of the Patent Office Instructions.

(21) See the reply from Sweden in Annex III, which contains the text of the Swedish Patent Office Rules.

the President of the Patent Office publishes the names of recognized laboratories in the Official Journal. In New Zealand, sufficient information must be included in the description to identify the microorganism and the source from which a sample can be obtained; this means, according to New Zealand practice, that the deposit of a microorganism in a culture collection is required.

2(a) If a deposit of the new microorganism in a culture collection is required, may the deposit be made in any culture collection or only in a recognized culture collection?

18. The answers to this question can be divided into two groups. A first group of 12 countries[22] indicated that the culture collection must be a recognized collection or must be known at the international level. A second group of three countries[23] specified that for the purpose of the deposit of a new microorganism, even a culture collection which had not been officially recognized was sufficient.

19. The first group of countries qualified their replies by adding the following comments. Australia specified that there were no formal requirements regarding the deposit of a new microorganism; however, when references to a deposit were given in the description, only a deposit in a recognized culture collection was acceptable. Canada pointed out that the deposit of a new microorganism was not required; nevertheless, if made, it should take place in a recognized culture collection. The German Democratic Republic stated that the culture collection must be officially recognized. Hungary pointed out that new strains of microorganisms must be deposited at the National Institute of Public Health, National Collection of Microorganisms, Budapest. Bulgaria, Ireland, New Zealand and the Philippines indicated that the culture collection must be a recognized collection. Denmark, Norway and Sweden specified that the deposit must be made in a scientific institution independent of the applicant, and one that was known at the international level. Yugoslavia pointed out that the culture collection must be an official one or officially recognized.

20. Among the second group of countries, Czechoslovakia stated that any culture collection was acceptable on the condition that it was a public one.

21. In addition to the above-mentioned countries, six other countries qualified their replies with different comments. Austria indicated that no specific standards for recognition of a culture collection had been established. France specified that no provision existed as regards culture collections; it added, however, that, in recent patent cases involving microorganisms, the applicants had made the deposit of a specimen in a culture collection. Germany (Federal Republic of) indicated that the term "officially recognized culture collection" was unknown to the German Patent Law; it specified, however, that the intention was to establish a centralized culture collection in the Federal Republic. In the Netherlands, the culture collection must be recognized by the President of the Patent Office. The Soviet Union specified that there was no requirement that the deposit of a new strain of microorganisms should necessarily be made in a recognized culture collection. The United States of America pointed out that the culture collection must be a public one, i.e., a collection which accords the public complete access to the deposit referred to in a patent.

2(b) May the deposit be made in a culture collection outside the country, in particular if the applicant is a foreigner?

22. Sixteen countries[24] pointed out in their replies that the deposit of new microorganisms could take place outside the country where patent protection was sought. Seven of them, however, added further information. For Bulgaria, a

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(22) Australia, Bulgaria, Canada, Denmark, German Democratic Republic, Hungary, Ireland, New Zealand, Norway, Philippines, Sweden, Yugoslavia.

(23) Czechoslovakia, Finland, Switzerland.

(24) Australia, Bulgaria, Canada, Czechoslovakia, Denmark, Finland, Germany (Federal Republic of), Hungary, Ireland, Netherlands, Norway, Philippines, Sweden, Switzerland, United States of America, Yugoslavia.

foreign culture collection is acceptable on condition that it is a recognized collection. Germany (Federal Republic of) reported that the strain deposited outside the country must be made available to the German public. Hungary stated that the deposit could take place in a collection abroad subject to reciprocity. Ireland specified that the foreign culture collection, in order to be acceptable, must make the samples deposited available to persons in Ireland. The Netherlands indicated that the foreign culture collection, like the domestic one, must be recognized by the President of the Patent Office. The Philippines stated that the foreign culture collection must be a recognized collection. Yugoslavia stated that at present no official culture collection existed in the country; the deposit could therefore take place abroad.

23. Besides the above 16 countries, the following four countries also answered this question, partly qualifying their replies with different comments. New Zealand replied in the negative. Austria stated that foreign culture collections were not excluded. France reported that no provisions were included in the French Patent Law regarding this question; however, on the basis of recent patent cases filed in France and involving microorganisms, there had been signs of a trend towards making deposits of new microorganisms in culture collections abroad[25]. The German Democratic Republic specified that no decision had yet been taken on the question of making deposits in culture collections abroad.

3. If a deposit of the new microorganism in a culture collection is required, when has the deposit to be made:

(a) at the priority date (in case of applications claiming the priority of foreign filings)?

24. Twelve countries[26] replied to this question in the affirmative, and the following eight countries qualified their replies with additional comments. Canada added that the deposit was not required; however, if made, it must be made on the priority date when the priority of a foreign filing was claimed. Denmark stated in its reply that no rule had been established but the affirmative answer given was based on current practice. Finland specified that if no deposit was made at the beginning of patent protection, the microorganism had to be recognized from the description. In France, even if no provisions are contained in the French Patent Law, the deposit should take place, according to the practice of the Patent Office, before the priority date. The German Democratic Republic stated that the deposit must be made on the priority date (or filing date) when it is made in order to compensate defects in the description of the new microorganism. Switzerland specified that it was not necessary to indicate the date of deposit. Sweden pointed out that no special regulations existed concerning this point; however, in accordance with general rules, the deposit ought to be made on the priority date and the microorganisms must be made available 18 months after the priority date. Yugoslavia indicated that, so far, those filing patent applications concerning microorganisms had made the deposit on the priority date; however, a deposit made on the filing date was also acceptable.

3. If a deposit of the new microorganism in a culture collection is required, when has the deposit to be made:

(b) on the filing date?

25. According to the replies of two countries[27], the deposit of a new microorganism must take place on or before the filing date. These countries, however, did not specify whether their reply covered also the case of a filing invoking a foreign priority. If no foreign priority is invoked, the countries referred to in paragraph 24 are also to be listed here as requiring deposit on the filing date.

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(25) A list of culture collections is included in the reply from France in Annex III.

(26) Austria, Bulgaria, Canada, Denmark, Finland, France, German Democratic Republic, Germany (Federal Republic of), Philippines, Sweden, United States of America, Yugoslavia.

(27) Hungary and Ireland.

3. If a deposit of the new microorganism in a culture collection is required, when has the deposit to be made:

(c) on the date of publication of the description?

26. Five countries[28] answered this question in the affirmative. Czechoslovakia qualified its reply by adding that, even if there were no provisions regarding the date of deposit, the latter had to be made before the publication of the description. In the German Democratic Republic, deposit is required also for those new strains which have been clearly characterized in the description of the invention; in these cases, the deposit has to be made prior to the issue of the printed patent document. In the Netherlands, the deposit must be made before the second publication, when the term for opposition begins to run; however, the actual deposit must take place following a specific request by the Patent Office. New Zealand stated that the deposit must take place on or before the date of publication. Norway pointed out that the file number of the deposit should be stated prior to the acceptance of the patent application for laying open to public inspection.

4. If a deposit of the new microorganism is required, has the microorganism to be made available to the public?

27. Fifteen countries[29] answered this question. One of them, Bulgaria, replied in the negative. Germany (Federal Republic of), Hungary, Ireland, the Netherlands, New Zealand, the Philippines, Sweden and the United States of America answered in the affirmative. Australia emphasized that, although it was not required to make the microorganism available, Australian courts would probably follow a decision of the United Kingdom House of Lords concerning this question[30]. Czechoslovakia indicated that the microorganism had to be made available to the Czechoslovak Patent Office for research and identification purposes. Finland specified that no provisions existed on this point. The German Democratic Republic stated that the microorganism must be made available at least to interested specialists in that country. Norway indicated that investigations into the question whether the microorganism was actually available to the public were not carried out. In Switzerland, the only requirement is that the culture collection should be identified in the description and that its accessibility should be mentioned.

4(a) How is the microorganism made available, for instance through an obligation of the laboratory keeping the culture collection to sell a specimen to interested parties?

28. The replies of the 14 countries[31] which answered this question reflect different positions. Austria reported that no specific requirements on how to make the microorganisms available to the public had been elaborated. Czechoslovakia indicated that no provisions existed in the Czechoslovak Patent Law regarding this question; however, the microorganism must be available to the Patent Office for research purposes. The German Democratic Republic stated that no decision had been taken on this point. Germany (Federal Republic of) and Sweden specified that no provisions existed on the question how microorganisms were made available to the public. New Zealand indicated that no answer could be given. Other countries qualified their replies by adding various comments. Bulgaria stated that the microorganism may be published, subject to the consent of the inventor. Canada specified that the deposited microorganism was made available through public access to the laboratory collection. In the case of Hungary, the National Institute of Public

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(28) Czechoslovakia, German Democratic Republic, Netherlands, New Zealand, Norway.

(29) Australia (with the additional comment reproduced above), Bulgaria, Czechoslovakia, Finland, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Norway, Philippines, Sweden, Switzerland, United States of America.

(30) The decision concerned the American Cyanamid Company (Dann's) Patent, (see Reports of Patent, Design and Trade Mark Cases, 1971, page 425).

(31) Austria, Bulgaria, Czechoslovakia, Canada, German Democratic Republic, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Philippines, Switzerland, Sweden, United States of America.

Health must furnish the strains to any person for examination purposes, upon payment of a compensation fee. However, the culture collection must inform the depositor of the fact that the specimens have been furnished. In Ireland, the collection center makes the microorganism available at a reasonable price. The Netherlands reported that the applicant must prove that the laboratory which keeps the deposited microorganism would be willing to give the latter to any person upon request, as from the date of second publication and up to the expiration of the patent; such proof should be given in the form of a receipt from the laboratory indicating that the culture will be made available on request. The Philippines specified that the culture collection must be under the contractual obligation to sell the specimen to any interested party. Switzerland pointed out that the conditions of availability depended on the patentee and the culture collection. The United States of America stated that the contract of deposit must ensure the availability of deposited specimens to the public.

4(b) When has the microorganism to be made available, for instance:

(i) on the filing date?

29. None of the countries which answered the questionnaire indicated the date of filing as being the date when the microorganism must be made available.

4(b) When has the microorganism to be made available, for instance:

(ii) on the date of publication of the description?

30. Nine countries[32] replied to this question. Among them only Czechoslovakia indicated that no provisions were available on this point. For all the other eight countries the microorganism must be available on the date of publication of the description.

4(b) When has the microorganism to be made available, for instance:

(iii) on the date of the grant of the patent?

31. Five countries[33] answered the above question. Apart from Czechoslovakia, which specified that no indications were available regarding this point, the remaining four countries indicated that the microorganism must be available on the date of the grant of the patent. However, the United States of America qualified its reply by adding that, even if it were only required that the deposited microorganism be available at the time of the grant of a patent, an applicant could make his culture publicly available at any time; as a general rule, the culture must remain available throughout the term of the patent and this obligation would terminate after the expiration of the patent.

4(b) When has the microorganism to be made available, for instance:

(iv) on the date of expiration of the patent?

32. Only in the case of Bulgaria must the microorganism be made available on the date of expiration of the patent.

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(32) Austria, Czechoslovakia, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Switzerland, Yugoslavia.

(33) Canada, Czechoslovakia, German Democratic Republic, Philippines, United States of America.

4(c) Are any restrictions imposed on a third party who requests a sample and, if so, what is the nature of those restrictions (e.g. does the third party have to declare that he will not use the sample for commercial purposes and will not hand the sample over to anyone else)?

33. Twelve countries[34] replied to this question. Five of them, Bulgaria, Canada, Czechoslovakia, New Zealand and the Philippines, specified that no restrictions were imposed on a third party requesting a specimen of a deposited micro-organism. However, New Zealand added that possible restrictions could not be imposed after the publication of the patent specification, while the Philippines pointed out that no restrictions were imposed on a third party requesting a sample; however, the request could be granted only after the patent issue.

34. The other seven countries qualified their answers by reporting the following information. Austria stated that the patentee might impose restrictions on a third party requesting a sample of a deposited microorganism; the nature of those restrictions was not subject to control. Germany (Federal Republic of) pointed out that restrictions appeared necessary for the protection of the patentee and that, in the absence of any guidelines on the subject, it was left to the applicant and the third party to settle the question within the framework of free arrangements. Hungary indicated that a third party requesting a sample of a deposited micro-organism must declare that the strain would be used for examination purposes. Ireland reported that the practice seemed to have been established according to which the issue of a deposited strain should take place only with the consent of the owner. The Netherlands stated that no restrictions were imposed by the Patent Office on third parties requesting samples; however, the depositor might require compliance with certain conditions, for example, the name and address of the third party requesting the sample, a copy of the third party's request, an undertaking from the requesting party not to make the sample available to others[35]. Sweden pointed out that no regulations existed on this point. In the United States of America, no restrictions may be imposed; the specimen may be used for any purpose, including commercialization; the depositor may only require the culture collection to identify the persons receiving the sample.

III. PLEASE GIVE ANY FURTHER INFORMATION RELATING TO THE PATENT PROCEDURE OF YOUR COUNTRY WITH RESPECT TO INVENTIONS CONCERNING MICROBIOLOGICAL PROCESSES OR PRODUCTS THEREOF

35. Eight countries[36] added to the previous replies further detailed information regarding the patent procedure with respect to microbiological inventions. Austria indicated that future developments in the microbiological field would have to take into account the requirements of Rule 28 of the European Patent Convention. Czechoslovakia added that in patent applications relating to organisms of the order Actinomycetales, applicants had to comply with the minimum of requirements specified in the International Bulletin of Bacteriological Nomenclature and Taxonomy[37]. France reported that the question of a modification of the existing regulations on patents was being studied in order to solve the problems arising from inventions involving the action of microorganisms; this study would, of course, take into account the provisions of Rule 28 of the European Patent Convention.

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(34) Austria, Bulgaria, Canada, Czechoslovakia, Germany (Federal Republic of), Hungary, Ireland, Netherlands, New Zealand, Philippines, Sweden, United States of America.

(35) See Rule 28 of the Implementing Regulations to the Convention on the Grant of European Patents, reproduced in Annex IV.

(36) Austria, Czechoslovakia, France, Germany (Federal Republic of), Hungary, Sweden, United Kingdom, United States of America.

(37) Volume 13, No. 3, of July 15, 1963, at pages 169 and 170.

Germany (Federal Republic of) specified that, since no specific legal provisions or guidelines existed regarding patent procedure with respect to microbiological inventions, its replies to the questionnaire should be regarded as giving a non-committal picture of the present legal situation in the Federal Republic. Hungary stated that the scope of patent applications concerning microorganisms had to be defined according to the number of strains deposited. On the other hand, if a patent application covered a process for recovering a substance from a fermentation broth prepared by cultivating a deposited strain, and the description gave sufficient details on the microorganisms, no deposit document was required; moreover, inventions based on a deposited strain could not cover the use of variants of the strain. Sweden specified that the patent procedure in the microbiological field was governed by the Rules of 1967, which corresponded to the Rules of February 1962 (38). The United Kingdom referred to the Report of the Banks Committee, published in July 1970, which recommended that, in the case of a new microorganism not available to the public, the applicant should deposit a sample of the microorganism in a recognized culture collection, withdrawing all restrictions regarding the availability of the same at the early publication date, and should specify in the specification the culture collection in which the sample had been deposited, declaring that all restrictions on the availability of the deposited sample had been withdrawn; the United Kingdom also indicated that, following the Banks Committee recommendation, no legislative change had been made and consideration was being given to the question whether it would be preferable to follow Rule 28 of the European Patent Convention. The United States of America reported that a Bill (39) concerning the revision of the Patent Law was pending in Congress and included provisions regarding the deposit of microorganisms. According to these provisions the deposit must take place in a United States culture collection as a requirement for patenting.

Conclusion

36. The considerable number of replies received to the questionnaire relating to the patent procedure with respect to inventions concerning microbiological processes or products thereof and the detailed information contained in those answers show, firstly, that the competent administrations are well aware of the particular problems connected with the patentability of inventions involving the action of microorganisms. Secondly, the replies received indicate, in most cases, that measures have already been taken at the national level, to face these problems, by establishing specific criteria applicable to patent cases claiming microbiological inventions. Even if the answers which have been analyzed above are very diversified, it seems possible to isolate some of the major trends observed with respect to the most relevant questions posed in the questionnaire.

37. As to the question whether it is required to make a deposit of the microorganism in a culture collection, most of the countries stated that such deposit was required, even if they qualified their statements with differing comments. As to whether the culture collection must be a recognized collection, the majority of the replies received seem to indicate that it should be either a recognized collection or a scientific institution that is known at the international level. With regard to the possibility that the deposit might take place in a culture collection outside the country where the patent protection is sought, it was stated by a number of countries that the deposit of a microorganism could be made in a foreign collection. On the other hand, the replies to significant questions, such as when the deposit of the microorganism has to be made, whether the deposited specimen should be made available to the public and whether any restrictions can be imposed on third parties asking for a sample of a deposited microorganism, showed that there were different and sometimes diverging attitudes among the countries which replied to the questionnaire. The existence, however, of both uniform and divergent positions, depending on the question concerned, appears to be a significant factor. It indicates that the problems relating to microbiological inventions have reached the stage where it seems that the field in question will benefit from harmonization at the international level.

/Annexes follow/

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(38) See the reply from Sweden in Annex III, which contains the text of those Rules.

(39) The text of Sections 112(f) and 119(d) of Bill S.2504 is reproduced, together with the reply from the United States of America, in Annex III.

WIPO

P/EC/VIII/8
ORIGINAL: English
DATE: July 31, 1972

WORLD INTELLECTUAL PROPERTY ORGANIZATION
UNITED INTERNATIONAL BUREAUX FOR THE PROTECTION OF INTELLECTUAL PROPERTY
GENEVA

INTERNATIONAL UNION FOR THE PROTECTION OF INDUSTRIAL PROPERTY (PARIS UNION)

EXECUTIVE COMMITTEE

Eighth Ordinary Session
Geneva, September 25 to 30, 1972

DEPOSIT OF MICRO-ORGANISMS

Report by the Director General

This document concerns a proposal made by the Industrial Property and Copyright Department of the Department of Trade and Industry of the United Kingdom of Great Britain and Northern Ireland, with respect to the protection of inventions relating to micro-organisms and their deposit.

1. The Industrial Property and Copyright Department of the Department of Trade and Industry of the United Kingdom of Great Britain and Northern Ireland, in its letter dated June 26, 1972, addressed to the Director General of WIPO, has suggested including in the program of the International Bureau for 1973 the task of studying the question of requirements for deposit of micro-organisms for the purposes of patent applications. The proposal is reproduced in the Annex to this document.

2. It is proposed that the International Bureau study and prepare a report on the questions raised in the proposal of the United Kingdom. A survey of the systems existing on the national level would be part of such a study. The report should be ready in time for the convocation of a working group in 1974.

3. The Executive Committee is requested to express its views on this matter.

/Annex follows/

P/EC/VIII/8
Annex

PATENT LAW

DEPOSIT OF MICRO-ORGANISMS

The increased activity in recent years in inventions relating to micro-organisms, e.g. in the field of antibiotics, has highlighted the problem of making the micro-organism available to members of the public so that they are able to perform the invention described in the patent. To this end it is now generally thought that an applicant should deposit the micro-organism in a recognised collection. This raises the question of whether it is necessary or desirable that the collection should be located in the country in which application is made.

On the one hand, if deposit in an approved collection in the country in which application is made is required, it follows that applicants will need to deposit the micro-organism in each country adopting this rule and in which application is made. Moreover, if the applicant is resident abroad he may be unable to make his deposit due to import restrictions on the micro-organism in question. On the other hand, if deposit is allowed in a recognised culture collection outside the country in which application is made, there is no assurance that it will be fully available to members of the public in that country since the culture collection might not in practice be prepared or able to release samples for sending abroad, and even if it is released, it might be subject to import restrictions. Neither solution, therefore, appears wholly adequate from an international viewpoint.

It is proposed, therefore, that a study should be undertaken of the question of requirements for deposit of micro-organisms in patent cases with a view to producing, for example, a multi-lateral convention according to which each Contracting State would recognise the culture deposit collections of the other Contracting States, would free from import restrictions cultures deposited in the other States in connection with priority based patent applications and would ensure that cultures deposited in their own collection were released in appropriate cases.

[End of document]

[End of Annex I;
Annex II follows]

WIPO

DMO/I/1
ORIGINAL: English
DATE: August 16, 1973

WORLD INTELLECTUAL PROPERTY ORGANIZATION

UNITED INTERNATIONAL BUREAUX FOR THE PROTECTION OF INTELLECTUAL PROPERTY

GENEVA

QUESTIONNAIRE
RELATING TO PATENT PROCEDURE
WITH RESPECT TO INVENTIONS CONCERNING
MICROBIOLOGICAL PROCESSES OR PRODUCTS THEREOF

I. Patentability of Inventions Involving Micro-organisms

1. Under the law of your country (including court decisions), may a valid patent be obtained for

(a) a process involving the action of a micro-organism not already known and available to the public,

(b) a product of a process referred to under (a),

(c) a new micro-organism existing in nature,

(d) a new strain of an existing micro-organism obtained by a process such as mutation?

2. Does the law of your country (including court decisions) contain any other provisions relating to the patentability of inventions involving micro-organisms?

II. Disclosure and Making Available to the Public

1. If a patent application is filed in your country for an invention involving new micro-organisms (see I.1. above), is a description of the new micro-organism in writing sufficient or is it necessary to make a deposit of the new micro-organism in a culture collection and refer to that deposit in the description?

2. (a) If a deposit of the new micro-organism in a culture collection is required, may the deposit be made in any culture collection or only in a recognized culture collection?

(b) May the deposit be made in a culture collection outside the country, in particular if the applicant is a foreigner?

3. If a deposit of the new micro-organism in a culture collection is required, when has the deposit to be made:

(a) at the priority date (in case of applications claiming the priority of foreign filings)?

(b) on the filing date?

(c) on the date of publication of the description?

4. If a deposit of the new micro-organism is required, has the micro-organism to be made available to the public?

(a) How is the micro-organism made available, for instance through an obligation of the laboratory keeping the culture collection to sell a specimen to interested parties?

(b) When has the micro-organism to be made available, for instance

(i) on the filing date?

(ii) on the date of publication of the description?

(iii) on the date of the grant of the patent?

(iv) on the date of expiration of the patent?

(c) Are any restrictions imposed on a third party who requests a sample and, if so, what is the nature of those restrictions (e.g. does the third party have to declare that he will not use the sample for commercial purposes and will not hand the sample over to anyone else)?

III. Please give any further information relating to the patent procedure of your country with respect to inventions concerning microbiological processes or products thereof.

/End of Annex II;
Annex III follows/

REPLIES TO THE QUESTIONNAIRE CONTAINED IN DOCUMENT DMO/I/1

ALGERIA

I have the honor to inform you that, under Algerian industrial property legislation, a patent may be validly obtained for a microbiological process as well as for products obtained thereby.

Essentially biological processes for the development of vegetable or animal strains are not patentable.

A description of the microorganism in writing is sufficient for the filing of a patent application.

(Translation)

ARGENTINA

With reference to the circular concerning the survey on the deposit of micro-organisms, and in the light of the Argentine Law on Patents, No. 111, we wish to inform you of the following, set out in the same order as in the questionnaire sent us:

I. Patentability of Inventions Involving Micro-organisms

1.(a) No. A microorganism not already known by and available to the public is considered capable of giving rise to an absolute monopoly in the hands of the inventor which would not allow reproduction by a person skilled in the art.

(b) No.

(c) No.

(d) No. The processes by which they are obtained are accepted, however.

2. No. On the other hand, mutation processes by physico-chemical means are allowed, but this does not cover the microorganism resulting from the mutation.

II. Disclosure and Making Available to the Public

1. In the case of processes involving new microorganisms or of products obtained by the action of new microorganisms, it is sufficient that the new microorganism be described in writing provided that it is found to be in accordance with the international standards applicable to the specific case, in other words, to this end, a deposit must be made in an internationally-recognized culture collection, with the authorization to disclose it or to indicate the means of isolating it.

2. 3. 4. These questions do not apply in the case of this country, in view of the fact that the law does not provide for the protection of microorganisms.

III. Microbiological processes are accepted as being protected by the patent law when they result in products capable of industrial application; cultivating processes, pricking out plants, purification of vine stocks, etc., are excluded inasmuch as they are considered to be laboratory techniques: while they may be of a specialized nature, they do not result in an industrial product of the kind indicated in the first part of this paragraph.

(Translation)

AUSTRALIA

I. Patentability of Inventions Involving Micro-organisms

1. (a) Yes.

(b) Yes.

(c) No.

Comment

Whilst a patent for the organism per se could not be obtained, compositions which include such an organism may be acceptable. An example of such a composition would be a new vaccine.

(d) The answer to this may also be "No" but qualified by the following comments.

Processes using such organisms and products of these processes may be patentable.

2. There are no formal provisions covering organisms in the law. The problem of a "full description", as required by the law, is covered under II(1) below.

II. Disclosure and Making Available to the Public

1. Patent applications involving new micro-organisms must include a full description of the organism. Since the organisms may vary widely in their characteristics it is not possible to set out the minimum criteria necessary to describe each one.

As a guide reference may be made to the recommendations published in "International Bulletin of Bacteriological Nomenclature and Taxonomy" Vol. 13, No. 3 of 15th July, 1963, at pages 169 and 170.

It is not necessary to make a deposit of the organism in a recognized culture collection although such an action is desirable.

2. (a) As a deposit of the organism in a culture collection is not required there is no formal requirement in this respect. However, where references are given, only those to recognized culture collections are acceptable.

(b) Further to 2.(a) above, the particular collection may be in a foreign country.

3. (a),(b),(c) and 4.(a),(b),(c)

No comments are necessary here as there is no formal requirement regarding the deposit of the organism in a culture collection.

III. Other Information

(a) Generally speaking, if an organism is well known and there are several references to it in the literature then it can be defined by its name. However, any new one would require a full description (see II(1) above).

(b) Although no deposit in a culture collection is required, the question of availability does arise. The organism should be available on the date of filing the application in Australia (see question II.4.(b)).

(c) It must be emphasized that although it is not a requirement to make the organism available, Australian Courts would probably follow the decision of the House of Lords (U.K.) in American Cyanamid Company (Dann's) Patent (1971 RPC 425). It would seem that a patent which wholly lacks direction as to where an organism is available may fail, in a court action, on the grounds of lack of utility.

AUSTRIA

I.1. (a) No. (Inventions concerning a new micro-organism are patentable; however, the micro-organism must be available prior to the grant of the patent (see reply to II.4. (b)).

(b) to (d) No.

2. No specific provisions.

II.1. No. Deposit of the new micro-organism and reference to that deposit is necessary.

2. (a) No specific standards for recognition of a culture collection are established.

(b) Foreign culture collections are not excluded.

3. Yes. The deposit is to be made at the priority date.

4. (a) No specific requirements how to make the micro-organism available to the public are elaborated.

(b)(ii) The micro-organism is to be made available on the date of publication of the application which date corresponds to the date of publication of the description.

(c) The applicant or patentee may impose restrictions which are part of the arrangement between the applicant or patentee and the third party who requests the sample. The nature of these restrictions is not subject to an examination by an authority.

III. The patent procedure with respect to inventions on micro-organisms is subject to the general provisions concerning patent applications. In particular, no patents may be obtained for inventions of medicaments and substances produced by chemical processes, in so far as the inventions do not relate to a particular technical process for the manufacture of such goods (Section 2 of the Austrian Patent Law 1970). The future development in this area has to take into account the concept of the requirements for European patent applications relating to micro-organisms as laid down in Rule 28 of the European Patent Convention.

(Original)

BULGARIA

I.1. (a) According to industrial property practice in our country, any process by which a biological product of a new microorganism which has not been made available to the public may be the subject of an industrial property title.

(b) The product of a process referred to under (a) above may only be the subject of an inventor's certificate (see Article 14(a) of the Law of October 8, 1968, on Inventions and Rationalizations).

(c) A new microorganism existing in nature is only patentable indirectly, in view of the fact that the inventor has only described an existing microorganism and has not in fact performed an inventive act. However, as we have said, the same microorganism may be protected indirectly on the basis of the process by which it is applied (for instance a process for the obtention of an antibiotic, if the inventor is at the same time the producer of the antibiotic).

(d) According to industrial property practice in our country, a new strain of an existing microorganism, obtained by mutation, may be protected in two ways, both directly and indirectly: on the basis of the strain itself and of the process by which a given product is obtained. In the case of direct protection of the strain, its usefulness must be proved, in other words, it must be shown to have been used to obtain a product which is useful per se.

2. Our industrial property legislation contains express provisions on the contents of the description of a microbiological strain (see the Instruction on the Regularization and Examination of Applications for Inventions, Item 2.20); it also contains the requirement that an application relate to only one microbiological strain (Item 7.3 of the same Instruction).

II.1. When an application is filed in our country in respect of an invention involving a microorganism, the mere submission of a complete description of the organism, that is, a morphological, physiological and biochemical description, is not sufficient: the microorganism has to be deposited in a culture collection; the number of the deposit and the collection in which the deposit has been made must be indicated in the description, which must be accompanied by a declaration certifying the deposit.

2.(a) Industrial property practice in our country requires that the deposit be made in a recognized culture collection.

(b) The deposit may be made in a culture collection outside the country, provided that it is a recognized one.

3. The deposit of the new microorganism in a recognized culture collection must be effected on the priority date.

4. The new microorganism must not be made available to the public.

(a) It may be published, subject to the consent of the inventor.

(b) The new microorganism would become available to the public on the date of expiration of the patent.

(c) The deposited specimen may be requested, before expiration of the patent, by the Patent Office with which the application was filed or by a third party in case of doubt, but it must not be used. The third party must state that he will not make use of the strain.

(Translation)

CANADA

I. Patentability of Inventions Involving Micro-organisms

1. (a) Yes.

(b) Yes.

(c) No.

(d) No, if process not reproducible.
Yes, if process is reproducible and controllable.

2. No.

II. Disclosure and Making Available to the Public

1. The description is sufficient. If no complete description is possible a deposit number would be acceptable.

2. (a) Not required but if made must be in a recognized culture collection.

(b) Could be outside the country.

3. (a) Not required but if made at the priority date if priority of foreign filing is claimed.

(b) Not required, but if made, on filing date.

(c) No.

4. (a), (b), (c). The microorganism has to be made available to the public on the date of the grant of a patent through public access to a laboratory collection. There are no requirements set out in the Patent Act imposing restrictions upon third parties.

(Original)

CYPRUS

The Ministry of Foreign Affairs of the Republic of Cyprus presents its compliments to the Director General of the World Intellectual Property Organization and with reference to the Director's General Note No. 1753-453 of August 16, 1973, regarding the questionnaire on patent procedure with respect to inventions concerning microbiological processes or the products thereof, has the honour to state that for a patent to be registered in Cyprus it must have been first registered in the United Kingdom and therefore all the prerequisites of the United Kingdom Patent Law should exist.

(Original)

CZECHOSLOVAKIA

I. Patentability of Inventions Involving Micro-organisms

1. (a) A valid patent or an inventor's certificate, as to the choice of an applicant, may be obtained for a process involving the action of a micro-organism not already known and available to the public.

(b) A patent only may be obtained for a product of a process referred to under (a) in the case, if the product is not a chemical compound (complex of compounds), medicament or eatables. The patent can be obtained f.e. for a fodder for animals, cosmetic etc.

The inventor's certificate can be obtained for all kinds of products of the process referred to under 1.(a) except of cases when the product is a natural compound (complex of compounds): it means a substance existing already in the nature independently from a human activity. An inventor's certificate can be obtained for new compounds not existing in the nature, which are products of microbiological biotransformation, f.e. semi-synthetic antibiotics, steroids etc.

(c) Neither a patent nor an inventor's certificate can be obtained for a new micro-organism (newly discovered) existing in nature.

(d) A patent cannot be obtained for a new, artificially (f.e. by a mutation) gained strain of already known existing micro-organism, however it is possible to grant an inventor's certificate.

2. The Czechoslovak law does not contain any other provisions relating to the patentability of inventions involving micro-organisms.

II. Disclosure and Making Available to the Public

1. A description of the new micro-organism in writing is not sufficient, it is necessary to make a deposit of the new micro-organism in a culture collection, the description has to contain a title and a place of the collection and deposit number assigned to the micro-organism.

2. (a) The deposit may be made in any culture collection, a recognized culture collection is not prescribed; an official regulation claims only the fact that it has to be public collection.

(b) The deposit may be made in a culture collection either in Czechoslovakia or outside the country--as to a choice of an applicant--(this alternative is especially for foreign applicants).

3. The date of a deposit of the micro-organism is not prescribed. If the applicant did not make the deposit himself spontaneously, he has to do so upon an official appeal and in the time required by the Office. It has to be made before the publication of the description; it's demanded in general to publish the formally and materially complete description. If the invention concerns a new micro-organism, the complete description has to contain a title of a culture collection and the deposit number of the micro-organism.

4. An availability of a deposited micro-organism for public is not required. It follows however logically from the own sense of a regulation that the micro-organism has to be available to the Office for its use especially for a research of invention (mainly in purpose of identification in case of any questions).

(a)(b) It follows from the mentioned above that it is prescribed neither any condition of an availability of the deposited micro-organism to the public or to interested parties nor a date since it is available.

(c) No limitation of an availability of the deposited micro-organism to the third parties is prescribed.

Czechoslavakia - continued

III. The Office asks all applicants to keep in a description of micro-organism relating to Actinomycetales a minimum of demands contained in an international recommendation for offices for patents worked out by International Committee on Bacteriological Nomenclature, subcommittee on Taxonomy of Actinomycetes (published in "International Bulletin of Bacteriological Nomenclature & Taxonomy," 1963, pages 169-170).

(Original)

DENMARK

A. I.1. (a) Yes.

(b) Yes, however not as far as articles of food and of medicines are concerned.

(c) No.

(d) No.

I.2. No.

II.1. Yes, but deposit is desirable, cf. the enclosed Danish Instructions on the Processing of Patent Applications Concerning Microbiological Methods.

I would like to observe that in the process of the applications from the filing date of which priority has been claimed, deposit of almost any new micro-organism has already taken place. Information of place and of number of the deposit, which is usually claimed during the procedure in this country, is forwarded on demand.

II.2. (a) and (b) Deposit in an internationally known, of the inventor (applicant) independent scientific, domestic or foreign institution, is desirable, cf. the above Danish instructions.

II.3. -

II.4. -

III. See the enclosed Danish Instructions.

B. Additional Information

Special Instructions Regarding the Processing of Patent Applications Concerning Microbiological Methods.

As regards applications concerning microbiological methods, it must be observed that in addition to the ordinary provisions on the description and the patent claims the following special demands are fulfilled.

Description

I. Demands on the Description of Micro-organisms.

Micro-organisms must be mentioned in such a way that confusion with other organisms is avoided.

Known organisms are sufficiently characterized through their systematic name, if necessary supplemented with a reference to literature where the method for the systematic determination is described.

New organisms must be so fully described that confusion with other organisms is avoided. To illustrate how detailed an organism must be described, a reference is made to the demands on the description of actinomycetes of the genus Streptomyces, stated in the last section of these instructions. If the description cannot be worked out in such a way that confusion with other organisms is excluded, or if the organism is so rare that it may be assumed to involve difficulties to find it in nature, or if finally its production is not for certain reproducible, it is appropriate and desirable that the organism is deposited in an internationally known, of the inventor (the applicant) independent, scientific, domestic or foreign institution. If so, the deposit number must be stated.

Since the description of the organism cannot be regarded as comprising such mutants, the characteristics of which differ essentially from the characteristics stated, indications such as "the invention is not limited to the application of the organism mentioned, but will also comprise the application of natural as well as artificially produced mutants thereof" cannot be allowed. An indication of the circumstances under which an organism has been found, or of the methods whereby it has been isolated, can usually not be regarded as a satisfactory way to characterize an organism. Fancy names of organisms or names invented by the inventor (the applicant) himself cannot be accepted as a characterization.

Denmark - continued

II. Demands on the Description of Methods.

The methods must be described so clearly and completely that, accordingly, those skilled in the art shall be able to carry them out without other knowledge than that which may normally be expected from such persons.

The method (the actions or the number of actions) by means of which an organism is isolated, cultivated, improved, or brought into use must be described in such a way that it in all essentials can be reproduced with the same result.

In case the organism is new, and the actions for its isolation can be regarded as reproducible, these must be indicated. The growth conditions (culture medium, nutriment, chemical or other means for influence in a wanted direction, if any, pH-value, temperature, irradiation, etc.) must be stated clearly and definitely together with information of limit and optimum values.

III. Demands on the Description of the Product Obtained by Means of the Method.

If the invention consists in the manufacture of a new product (a chemical compound) with valuable properties, first and foremost the properties which determine the utility of the product must be stated. In addition, the product (the compound) must be described in such a way that it can be identified, e.g. by statement of a structural formula or of a gross formula as well as chemical and physical characteristics.

Patent Claims

Known micro-organisms are sufficiently characterized through their systematic name, if necessary with a reference to the literature where the methods for the systematic determination are described.

New micro-organisms must be characterized through a direct or indirect reference to the detailed description of the organism in the specification in connection with the systematic name, if possible. If the organism is deposited in an internationally known, of the inventor (the applicant) independent, scientific, domestic or foreign institution, the deposit number must be stated.

If the product obtained is new, it must be characterized in such a way that it can be identified, e.g. through statement of a structural formula or of a gross formula or through a reference to an IR-spectrum.

Demands on Description of Actinomycetes of the Genus Streptomyces

The description must contain the following information:

1. The name of the organism, its number in a public culture collection, if deposited, as well as date and place of its isolation, if possible.

2. Description of growth in a certain culture medium together with a detailed description of the macroscopic properties and characteristics and the microscopic morphology (including shape and size of the spores, the morphology of the spore formation, the branching tendency of the mycelium, and the hypae width).

3. Growth characteristics (the morphology of the colonies and information of colours and excreted pigment, if any) in at least 10 standard culture media.

4. Physiological characteristics by growth in media containing milk, nitrate, gelatine, starch, tyrosine, and possibly cellulose.

5. The capacity of the organism to form hydrogen sulphide in organic or inorganic medium.

6. The capacity of the organism to use a number of carbon sources.

7. A reference to the nearest related species or number of species which are mentioned in Bergey's Manual of Determinative Bacteriology (1957) together with information of how the organism in question can be distinguished from the known organisms.

Denmark - continued

8. Supplementary information, if any, regarding individual characteristics, such as production of antibiotics.

9. In connection with the description of the physical and chemical characteristics of the antibiotic substance a table covering the quantitative special effects of the product and also a table in which the activity of the antibiotic towards grampositive and gramnegative bacteria, fungi and yeasts, and also towards protozoa, viruses and rickettziae, if such information available, is indicated with + or -.

(Original)

FINLAND

According to the Finnish law new strains of plants or animals are not patentable, only microbiological processes and products of a microbiological process form an exception to the above rule.

However, for the time being the patentability of foodstuffs and medicines is temporarily restricted to methods of producing them only. Therefore the answers to part I.1. in your questionnaire are:

(a) yes

(b) not on food or medicines but yes on other products

(c) and (d) no.

As to part I.2. in the same questionnaire all the normal provisions relating to newness of invention and nonambiguity of the description of the invention are valid. As to what constitutes clearness of the description in microbiological cases, special provisions have been issued by the Finnish Patent Office, acting in co-operation with the other Nordic Patent Offices.

These special provisions also contain most of the answers to part II in your questionnaire. Picking up the pertinent points thereof the answers are as follows:

II.1. It is not absolutely necessary to deposit the new micro-organism in a culture collection. The wording used in the special provisions is "proper and recommendable to deposit the organism in an internationally known scientific organization independent of the inventor and/or applicant either in this country or abroad."

II.2. As can be seen from the wording above any scientific organization suffices and there is no need for any "official" recognition.

II.3. The priority date is the most important item in this respect, that is if no deposition is made at the date of the beginning of the patent protection period the description of the invention must comply with the rules of the special provisions to be acceptable, i.e. the identity of the micro-organisms in question must be recognizable from the description.

II.4. Nothing is specified about this question in the special provisions and we can draw the conclusion that identification of the micro-organism is of prime importance.

III. As already stated earlier in this letter no patents on food or medicines even if microbiologically produced may be granted at the present time but only on methods of producing the same. This may, however, be changed when sufficient time has passed for the public to become accustomed to the idea of also medicines being patentable.

(Original)

FRANCE

I Patentability of Inventions Involving Micro-organisms

1. The Law of January 2, 1968, on patents and the texts for its implementation contain no specific provisions concerning the conditions of patentability of inventions involving microorganisms. Consequently common law is applied as regards the patentability of such inventions (requirements of industrial character, novelty and inventive step).

If, moreover, account is taken of Article 2(b) of the 1963 Strasbourg Convention, signed but as yet not ratified by France, which provides expressly that patents may be granted in respect of microbiological processes and the products thereof, there seems to be nothing to prevent a patent from being validly granted in respect of:

(a) a process involving the action of a microorganism;

(b) a product of such a process.

Although decisions on this subject have been few and have been rendered under the old Patent Law of 1844, the following may be mentioned to illustrate the patentability of microbiological processes and the products thereof:

- A judgment rendered by the Civil Court of the Seine on May 9, 1957 (MERCK/SIFA)--(Annales de la propriété industrielle, 1963, pages 329 to 343), which declared patentable on one hand a new application of a known microorganism, namely Streptomyces Griseus, for the manufacture of a new product, namely Vitamin B 12, and on the other hand the product obtained by the said process, for the industrial uses described in the patent.

- A judgment rendered by the Court of Appeal of the Seine on March 29, 1965 (PFIZER/TORAUDE and PIERREL), which recognized the patentablility of a process for the preparation of antibiotics, the essential characteristic of which was the use of the properties of the species of microorganisms called "Streptomyces Rimosus".

- The judgments and decisions rendered between 1967 and 1971 (MERCK/VEGETADROG and PIERREL), also concerning the patentability of Vitamin B 12 with respect to its industrial applications and the process of its manufacture by the action of a class of microorganisms (Annales de la propriété industrielle, 1971, pages 85 to 106).

(c) As for the discovery of a new microorganism existing in nature, like any discovery of a natural product or phenomenon, it is not patentable as such. The 1968 Law (Article 7(1) took over the principle of the 1844 Law (Article 30)), according to which purely scientific discoveries for which no industrial applications have been indicated are not patentable. A patent for a mushroom was declared null on the grounds that "a natural product, however interesting its discovery might be and whatever its usefulness in industry, cannot be the subject of a patent independently of all industrial methods for the application of new industrial processes" (Civil Court of the Seine, July 16, 1921, and Paris Court of Appeal, June 22, 1922--AMYLO/BOULARD--Annales de propriété industrielle, 1922, pages 3 4 6 et seq.). In the case of Vitamin B 12, on the other hand, the above-mentioned decision of May 9, 1957, held that the discovery of an unknown natural product for which industrial applications were indicated could be patentable.

(d) The question of the patentability of a new strain of microorganism obtained by a process such as mutation could give rise to difficulties, not only with regard to the nature of the process (mutation and selection operations which may require the action of natural phenomena) or its novelty, but also with regard to whether protection may be claimed solely for the species obtained by the process or also for intermediate mutations.

2. As mentioned earlier, common law is applied with respect to the patentability of inventions involving the action of microorganisms; the same is true as regards the validity of patents in respect of such inventions: the description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, failing which the patent is declared null

France - continued

and void (Article 49 of the 1968 Law). While these provisions (or those of Article 30(6) of the old 1844 Law) have not as yet given rise to any jurisprudence which could be applied directly to this particular subject, we could nevertheless quote, for information, a decision rendered by the Court of Paris on June 20, 1969 in a case involving the firms MERCK on one hand and VEGETADROG and PIERREL on the other: "...the description of the process meets the requirements of the law when it allows a person skilled in the art to carry out without recourse to anything other than his professional knowledge; ... it is sufficient, therefore, in order to determine the microorganisms whose fermentation produces Vitamin B 12 if a laboratory man can select, on the basis of the information in the patent and the usual technical knowledge, the species and the appropriate strain of bacteria without having to invent anything himself".

II. Disclosure and Making Available to the Public

1. In the absence of specific provisions in the law, the applicant has to decide, if he considers that the information given in the patent application is insufficient to meet the relevant legal requirements, whether he should make a deposit of the new microorganism in a culture collection, in order that he may refer to that deposit in the description. It is up to the courts, however, to determine whether such a deposit compensated for the insufficiencies in the written description as specified in Article 49 of the 1968 Law. For while the regulations (Decree of December 5, 1968, Article 3(c)) give the applicant the possibility of referring in the description to "samples," the purpose of those samples is not stated, and it is not provided anywhere that they may at least complement a description of the invention, if not actually be substituted for it.

2. Practice has shown that the description accompanying patent applications of foreign origin, filed in France and claiming priority for inventions involving microorganisms, often refer to a deposit of the microorganism in a culture collection. The depository of this culture collection may be located either in the country of origin of the prior application or in another country. Thus, the names of the following institutions have been mentioned in descriptions:

NRRL (Fermentation Division of the Northern Regional Research Laboratory) = Northern Utilization, Research & Development Division of the U.S. Department of Agriculture, Peoria, Illinois (United States of America)

ATCC (American Type Culture Collection)
2112 M. Street NW, Washington 7 D.C. or
12301 Park Lawn Drive, Rocksalle, Maryland 20852
(United States of America)

Department of Microbiology, Type Culture Collection, Rutgers University, New Brunswick, State University of New Jersey (United States of America)

Commonwealth Mycological Institute, Kew, Surrey (United Kingdom)

National Collection of Industrial Bacteria, Aberdeen (United Kingdom)

National Chemical Laboratory, Teddington (United Kingdom)

Centraal Bureau voor Schimmelcultures, Baarn (Netherlands)

National Institute of Public Hygiene (Hungary)

Fermentation Research Institute, Agency of Industrial Science & Technology, 8-1, 5-Chome, Inage-Higashi, Chiba Prefecture (Japan)

France - continued

Up to the present time, in the absence of legal provisions on the subject, no French depository of culture collections has considered itself competent to receive deposits of microorganisms in connection with patent applications. For this reason French nationals filing patent applications in respect of microorganisms who have wished to adopt this procedure have made a deposit of a strain of the microorganism with one of the aforementioned foreign institutions, with an indication, in the descriptions and the claims, of the institution with which the strain has been deposited and of the identification number assigned to it. It should be noted that, occasionally, the French application claims the priority of a first filing in the country in which the institution having received the strain of the microorganism mentioned in the application is located.

Recently, however, the Natural History Museum of Paris (Cryptogam Department) did accept a deposit of microorganisms in connection with a patent application in France.

3. In the examples indicated under 2 above, the deposits were made before or on the priority date or on the date of the deposit in France, depending on the circumstances of the case.

4. No information is available on the questions raised in this paragraph.

III. An amendment of the French patent system is currently being studied, with a view to providing for inventions involving microorganisms. This study will naturally take into account the provisions adopted on the subject under the European Patent Convention of October 5, 1973.

(Translation)

GERMAN DEMOCRATIC REPUBLIC

I. 1.(a) Yes.

(b) According to art. 1 par. 3 of the Patent Act of the GDR of September 6, 1950, patents are granted for certain manufacturing processes only. However, if a patent is granted for a process, the effect of the patent also extends to the products directly resulting from the process (art. 1 par. 4 of the Patent Act of the GDR of September 6, 1950). These provisions also apply to biochemical inventions.

(c) No.

(d) No.

2. Processes for producing of defined mutant strains with application of techniques of induced mutation already known, are not yet reproducible up to now and are, therefore, not accessible to protection by patents.

However, induced mutants are admitted to be protected by patents if they are involved in a process of application of a microbiological-chemical nature (process of fermentation).

(Cf. decision of the board of appeals No. III of the Inventions and Patents Office of the GDR dated from June 30, 1970, published in "Bekanntmachungen des Amtes für Erfindungs- und Patentwesen der DDR", number 24, December 1970 (volume 11), p. 539 and following pages).

II. 1. Besides a description of the new micro-organism, it is necessary in all cases to make a deposit and to refer clearly to that deposit in the description.

2.(a) The deposit must be made in an officially recognized culture collection.

(b) It has not yet been decided in the last resort if deposits made in official culture collections outside the country are recognized.

3.(a)-(c) So far as the deposit shall not only give evidence of the effects produced by the invention or shall compensate defects in the identifiably clear description of the new micro-organism offered by the invention, the deposit has to be made already at the filing or priority date (requirement of priority).

According to present day jurisdiction, the deposit is also required for those new strains which have been clearly characterized in the description of the invention deposited on filing. In these cases, the deposit must have been made prior to the grant of the patent at the latest, i.e., prior to the issue of the printed patent specification at the latest.

4. The new micro-organisms of the invention must be available in the culture collection, at least to interested specialists of the GDR, without difficulties.

(a) This question has not yet been decided in the last resort.

(b) The free accessibility according to item No. 4 is not yet required at the priority date, but only when the patent takes effect. According to art. 9, par. 1 of the Patent Act of the GDR of September 6, 1950, a patent will take effect with the issuance of the patent specification.

(c) -

III. See:

Guiding principles and reasons of the decision of the board of appeals No. III of the Inventions and Patents Office of the GDR, dated from June 30, 1970, in the case Reg. No. 248/68, published in "Bekanntmachungen des Amtes für Erfindungs- und Patentwesen der DDR", number 24, December 1970 (volume 11), p. 539-542.

(Original)

GERMANY (FEDERAL REPUBLIC OF)

I.1. (a) Yes, if the other requirements for patentability are met and provided that the micro-organism was deposited in an appropriate culture collection not later than the date of filing of the application and the filing documents, the place of deposit and the deposit specification were declared. The strain must be made available to the public not later than the date of the first publication of the patent application.

(b) Yes, if the requirements mentioned under (a) are met.

(c) This question has not yet been cleared up by court decisions. If the new micro-organism is to be found in nature, this will be qualified as discovery of a non patentable substance.

(d) No, as according to the opinion of the experts, a mutation can never be repeated at will.

2. The German patent law does not contain any specific provisions relating to the patentability of micro-organisms; so far, there is no established case law either.

II.1. Description only is not sufficient for disclosure; in addition, deposit of the micro-organism in an appropriate culture collection, which is not expressly provided for in the Patent Law, and a reference to the said deposit in the description are required.

2. (a) So far, the German Patent Law does not know the term "officially recognized culture collection", but there is the intention to establish a centralized culture collection for the Federal Republic. An appropriate culture collection, however, has to meet the following requirements:

In the first place, the culture collection must, with respect to the technical facilities and the staff available, be in a position to secure maintenance of the collection for an unlimited period. Furthermore, it must be recognized by the experts as to proper keeping. Finally, the culture collection must meet the legal and administrative requirements for observing the deposit modalities and securing regular execution of the transmission to third persons.

(b) Yes, provided that the making available to the German public of strains deposited outside the country is secured. This is not secured, for instance, in the event that the provisions of the state concerned prohibit or obstruct transmission of the strain to foreigners.

3. (a) Yes, as the preliminary deposit which gives rise to a priority right already has to include sufficient disclosure.

(b) Only in the event of a first application not containing any priority claim.

(c) -

4. Yes.

(a) As to the question of how micro-organisms are made available to the public, legal provisions, guidelines, contractual arrangements or court decisions do not exist so far; there are only some doctrinal ideas.

(b) This question remains controversial. However, according to the opinion which presently prevails an invention relating to a micro-organism is sufficiently disclosed only if the strain of the micro-organism itself is made available to the public. The conclusion often to be drawn is that the strain of the micro-organism must be available to the public at the date of the publication of the patent application.

(c) Such restrictions appear necessary for the protection of the applicant. Guidelines on the subject do not yet exist, so far it was left to the applicant and the third person to settle the question within the framework of free arrangements.

III. When answering the present questionnaire, only a rough and non-committal picture of the present legal situation in the Federal Republic of Germany may be drawn as for the time being no specific legal provisions or guidelines and no established case law exist according to which similar patent applications have to be dealt with.

HUNGARY

I. 1. (a) A valid patent may be obtained for processes of this type;

(b)-(d) The invention is not patentable, a relative valid patent can not be obtained.

2. The enacting clause of the Act contains concrete regulations relating to patent applications for inventions based on the use of either new or known microorganism strains. According to these, the deposition document of the microorganism should be attached to the patent application concerning an invention based on the use of microorganism strains. The deposition should precede the filing of the patent application. If the strain was deposited after the filing date of the patent application, the date of the regular deposition should be considered as filing date. In case of known strains, the deposition document may be substituted with a proper copy of the catalogue of the depository containing the identification data of the strain.

According to Article 6(2) of the Patent Law plant varieties and animal breeds and the processes for obtaining them shall be patentable if the variety or breed is new, homogenous and relatively stable. Articles 67-71 of the Patent Law contains special rules on plant varieties and animal breeds.

As microorganisms can be considered as plants, they would be patentable in sense of the Law but patentability of microorganism strains has not been confirmed by jurisprudence.

II. 1. It is necessary to make a deposit and to refer to it in the specification in case of either new or known microorganisms.

2. (a) The microorganism strain has to be deposited at the National Institute for Public Health, at the National Collection of Microorganisms/Budapest.

(b) The deposit may be made at a culture collection outside the country. The deposition made at a foreign body, can be taken into consideration however, only in case of mutuality. In the question of mutuality, the position taken by the President of the National Office of Inventions is competent.

3. (b) The latest on the filing date.

4. The microorganism - either new or known - has to be made available to the public.

(a) The National Institute for Public Health has to treat the data relating to the deposited strain in secret until the publication of the patent application; afterwards the Institute has to give the strain to anybody for examination purposes upon payment of compensation and to inform the depositor of the delivery.

(b)(ii) On the date of the publication of the application.

(c) It follows from the regulation of the Law, that a third party has to declare that the strain will be used for examination purposes.

III. Since the entering into force of the new Patent Law, position has been taken to the undermentioned questions on the basis of the patent practice of the last three years:

(a) In the field of microbiology, the scope of the patent application has to be defined in accordance with the number of the deposited strains. The deposition number given by the culture collection has to figure in the claims.

(b) No deposition document is required if the application concerns a process for recovering a substance from a fermentation broth prepared by cultivating a deposited strain, supposing that the specification gives detailed informations on the microorganism and the cultivation process.

(c) In case of an invention based on the use of a deposited strain, the scope can not cover the use of the mutantes or variantes of the strain.

(Original)

IRAN

We inform you that there is no special regulation for patent registration concerning microbiological process or products thereof or its application. But according to item 1. and 2. of Article 27 of the Iranian Patent Registration Code, its translation is as follows:

"Those may apply for registration who pretend to:

1. have invented new industrial products

2. have invented new means or have made a new application to known means for the obtaining of results either of an industrial product or an agricultural product" the above mentioned inventions are patentable.

(Original)

IRELAND

I. 1. Patents have been granted in Ireland for processes involving the action of micro-organisms not already known and available to the public. Claims have been allowed for a product when produced by the process of such an invention. No claims are allowed for the micro-organism itself whether existing in nature or as an induced mutant.

2. There is no specific provision in Irish Patent Law relating to micro-organisms and no court decisions have been given on such cases. The comments above relate to office practice.

II. 1. and 2. Under the Patents Act 1964 the specification as filed is opened to public inspection eighteen months after the earliest priority date claimed. Every applicant is required to particularly describe his invention, the method by:

(a) which it is to be performed and disclose the best method of performing it in the complete specification. It follows that in the case of an invention for a process involving the use of a new micro-organism the applicant must describe the process, give a full taxonomic description of the micro-organism and deposit a sample of it in a recognized culture collection centre which will make it available to the public at a reasonable fee.

(b) There are no such centres in Ireland so foreign centres are acceptable provided they make samples available to persons in the State. This means that the applicant must withdraw irrevocably at the OPI date all restriction on the availability of his culture to the Irish public.

3. The sample should be deposited at the culture collection centre on the application date. In microbiological inventions the use of a particular micro-organism in a process is the essence of the invention. The applicant must show he was in possession of the invention on the application dates by giving a taxonomic description of the micro-organism, its deposition number at a recognized culture collection centre and a description of a process utilizing it.

There is no rule in the Irish Act defining the date when the micro-organism should be available to the public. The date need not be earlier than the OPI date. Interpreting the OPI requirement as disclosing the invention in full to the public would mean that micro-organism samples should be available on this date. It would seem reasonable that samples should be made available for the purpose of testing in the event of opposition proceedings.

4. Release on the date of publication after acceptance would therefore seem late if time for testing and preparation of opposition proceedings is to be reasonable. Safeguards against misuse in the period from OPI to grant should also be provided as a third party is not entitled to practice an invention before the expiry date of the patent. The Patents Act 1964 has no provisions covering such safeguards and no court decisions have been given.

It seems to have been a practice that the issue of samples from Culture Collection Centres is only with the consent of the owner. This is understandable but not satisfactory. It has been suggested that the owner's consent be mandatory on a request from the Controller who would attach conditions safeguarding the patentee's rights e.g. no commercial use be made of the micro-organism and that samples should not be handed over to other parties.

III. There is nothing further to add regarding the patent procedure in Ireland with respect to inventions concerning microbiological processes or products thereof.

(Original)

ITALY

With reference to your Circular dated August 16, 1973, we wish to inform you that the legislation of our country contains no specific provisions on the patentability of inventions relating to microorganisms; patentability is governed by the general provisions of the law on the grant of patents.

It may nevertheless be expected that, in the course of a forthcoming revision of the national patent law, specific provisions will be introduced on this subject, due account being taken of the result of the work performed by your Organization and of the corresponding provisions which already exist in the European Patent Convention.

(Translation)

LUXEMBOURG

I refer to your Circular No. 1753 - 453, dated August 16, 1973, with which you submitted a questionnaire to me relating to patent procedure with respect to inventions concerning microbiological processes or products thereof. I have the honor to submit to you herewith the reply of the Luxembourg authorities:

Luxembourg legislation does not contain any specific provisions governing microbiological inventions, and so far no concrete case has yet been referred to the Industrial Property Service in this connection.

The fact remains, however, that the question is one of growing importance at the present time, and that it is being studied not only within WIPO but also by a certain number of national Offices and international non-governmental organizations. It is worth mentioning that the European Patent Convention, signed at Munich on October 5, 1973, contains express provisions on the patentability of such inventions. The filing of the said inventions, however, poses a certain number of fairly complex problems, especially with regard to the deposit of micro-organism strains. A solution to these problems will have to be found by the date of entry into force of the European Patent Convention at the latest. The Luxembourg authorities will therefore follow closely the studies currently being undertaken, and hope to be able to benefit from them in the course of the forthcoming revision of the Luxembourg Patent Law.

(Translation)

MALTA

Re: part 1 of the questionnaire--Patentability of Inventions involving Micro-organisms--Section 3 of the Industrial Property (Protection) Ordinance states that the following are patentable.

a. The invention of a new industrial process or result.

b. The invention of new methods, or the new application of known methods, for obtaining an industrial result or process.

While Section 4 lists what is not patentable namely:-

a. Inventions or discoveries relating to trades which are contrary to law, morals or public safety;

b. Inventions or discoveries the subject whereof is not the production of corporal substances;

c. Inventions or discoveries which are purely theoretical; and

d. Schemes and combinations relating to credit or finance.

Part II--Disclosure and making available to the public

According to our law an application in writing is sufficient, provided it complies fully with Sections 8, 9, and 10 of the Industrial Property (Protection) Ordinance which states:-

Section 8 - "Any such application shall be filed by the inventor or his special attorney, and must contain:

a. the name, surname, nationality, and place of residence of the applicant and of his attorney, if any;

b. a declaration to the effect that the person making the application or in whose name the application is made, or, in the case of a joint application, that one or more of the applicants is or are in possession of an invention or discovery, whereof he or they claims or claim to be the true and first inventor or inventors, and for which he or they desires or desire to obtain a patent.

Section 9 - Where the application for a patent is made by two or more persons jointly, a patent may be granted to them jointly.

Section 10 - The said application shall be accompanied by:-

a. two copies of a specification, which may be either a provisional or a complete specification;

b. the fee payable under this Ordinance on the filing of an application for a patent;

c. the original title, or an office copy thereof, showing the grant of the foreign patent whenever the patent is claimed under section 5;

d. if there be an attorney, the power, in public or private form, provided that, in the latter case, the signature of the principal be attested by the diplomatic or consular representative of the Government of Malta in that country or by a person serving in a diplomatic, consular or other foreign service of any country which, by arrangement with the Government of Malta, has undertaken to represent that Government's interests in that country, or by a person authorised in that behalf by the Governor-General, or, in the absence of such persons, by the competent Government or Municipal Officer of the district in which the principal resides;

e. a list of the papers and articles produced."

Malta - continued

Consequently it is felt that there is no need to answer paragraph 2, 3 and 4 of Part II of the questionnaire.

There is no further information relating to patent procedure in Malta with respect to inventions concerning micro-biological processes or products thereof.

(Original)

NETHERLANDS

I. Patentability of Inventions Involving Micro-organisms

1. (a) Yes.

(b) Yes.

(c) Uncertain. There is no jurisprudence.

(d) Doubtful. There is little jurisprudence. In 1956 a patent was not granted because of non-reproducibility and the method being obvious (Bijblad bij De Industriële Eigendom 1956. p.75).

2. In Statute Law there are no separate provisions regarding patentability of inventions involving micro-organisms. As is apparent from jurisprudence (Patent Office and Courts) patents are granted for processes involving micro-organisms. A prospective change in the law will provide for the protection of novel substances as such independent of their method of preparation.

II. Disclosure and Making Available to the Public

1. A deposit of the new micro-organism and a reference to it in the description is required but only if the Patent Office judges that the micro-organism is not readily available from other sources. No such requirement is made if e.g. the micro-organism according to the opinion of the Patent Office can easily be isolated from its natural habitat or if it is already available from public collections.

2. (a) Only in a collection recognized by the President of the Patent Office.

(b) Yes, subject to 2(a).

3. (a)
(b) } No.
(c)

The deposit takes place at the request of the Patent Office. This request is not made before applicant has filed a petition for a decision on the grant of a patent (Art. 22 J Patent Act). At any rate the deposit has to be effected before the second publication, i.e. after examination when the term appointed for opposition purposes begins to run. (Cf. Art. 25 Netherlands Patents Act).

4. Yes.

(a) The applicant has to furnish proof of the fact that the laboratory keeping the culture has been instructed to deliver cultures of the deposited strains, - and of their being prepared to do so,- to any person upon request from the date of the second publication until expiration of the patent. The above mentioned proof should be in the form of a receipt given by the laboratory keeping the culture to the effect that the culture is in their care, shall be kept alive and shall be made available on request as from the date mentioned under 4(b).

(b) On the date of the second publication, i.e. after examination when the term for opposition purposes begins to run. (Netherlands Patents Act, Article 25)

(c) No restrictions are imposed by the Patent Office on third parties requesting a sample from a patent-culture, but the applicant may make some specified conditions if he wishes to do so.

The applicant must not attach any other conditions to the cultures being delivered but the following:

1. the person making the request shall give his name and address;

2. a copy of his request shall be forwarded to the applicant or proprietor;

3. the person making the request shall undertake vis-à-vis the applicant or proprietor not to make the culture(s) available to any other person. (Cf. Rule 28 of the European System for the Grant of Patents as approved in Munich, September 1973).

Netherlands - continued

A laboratory keeping a culture collection can charge normal cost for the delivery and forwarding of the cultures.

III. The President of the Netherlands Patent Office publishes in the official Journal of the Patent Office the "Bijblad bij De Industriële Eigendom" the names of the laboratories keeping culture collections recognized as depositories for micro-organisms with a view to their preservation and availability.

Until October 1973 the only recognized depositories were domestic collections: "C.B.S." at Baarn for fungi (and Actinomycetales) and "Het Laboratorium voor Microbiologie" of the Technical University at Delft for bacteria.

The Patent Office had concluded agreements with these collections. In the course of time the actual procedure has evolved thus: when the examiner thinks a micro-organism is indispensable in order to enable a person skilled in the art to carry out the invention and where this micro-organism is not to be had in any other way, he tells the applicant a deposit is required.

To this end a set of papers has been devised: forms A, B_1 and B_2. The request for a deposit is made on A, the applicant is then to fill up B_1 or B_2 and send it together with his strain(s) to the depository.

Applicant cedes his cultures to the laboratory for its public collection on the condition that his application will be accepted. In the case of acceptance a second publication of the application follows and the term for opposition purposes begins to run. This cession cannot be undone. The Netherlands Patent Office requires a receipt from the laboratory keeping the culture as a voucher.

Lastly the Patent Office informs the laboratory keeping the culture of the decision concerning the acceptance of the application (form C). The strains are moved to the public collection (in case of acceptance) or destroyed (if the application is not accepted).

(Original)

NEW ZEALAND

I. Patentability of Inventions Involving Micro-organisms

1. The question of validity is a matter for Court determination, and in the absence of any decisions no opinion can be given.

(a) A patent could be obtained for such a process.

(b) A patent could be obtained for such a product.

(c) No patent could be obtained for a micro-organism discovered in nature.

(d) It is likely that such a process would be patentable, and that the product of that process, other than when present or discovered in nature, would be patentable.

2. No.

II. Disclosure and Making Available to the Public

1. The complete specification must give sufficient information to identify the micro-organism to those skilled in the art, and must identify a source from which a sample can be obtained, as of right, at the date of publication of the specification. It is considered that this would mean an unconditional deposit in a recognized New Zealand culture collection by the date of publication of the specification.

2. (a) It is considered that only a recognized culture collection would suffice in view of the necessity of free availability at the date of publication of the specification and the necessity of continuous availability.

(b) No.

3. On or before the date of publication of the specification.

4. The micro-organism must be made available to the public.

(a) No answer can be given.

(b) On or before the date of publication of the specification.

(c) There can be no absolute restriction after publication of the specification.

III. No further information is available.

(Original)

NORWAY

I. 1. (a) Yes.

(b) Yes.

(c) No.

(d) No.

2. With regard to inventions concerning food or medicines a patent may not be granted for the product itself, but only for the process of manufacture until otherwise decreed by the Government (Patents Act, section 72,1).

II. 1. According to the Patents Act, section 9, 2nd paragraph, the description must be so clear that any person skilled in the art can work the invention on the basis thereof. In addition to a description of the new micro-organism it is therefore required that a deposit of the new micro-organism is made at an internationally known, scientific, domestic or foreign institution independent of the inventor (the applicant). The designation of the deposit should be stated in the specification.

2. See II. 1 (above).

3. The file number of the deposit should be stated prior to the acceptance of the application for laying open to public inspection.

4. Hitherto we have only handled applications which have not been charged with reservations regarding to availability of the micro-organism. Investigations whether the micro-organism is really available to the public are not carried out.

(Original)

PHILIPPINES

A. I.1. (a) Yes.

(b) Yes.

(c) No.

(d) No.

2. Yes, Section 14(a) of the Philippines Patent Law, Republic Act No. 165, as amended, and supplemented by Patent Office Memorandum-Circular TSE-73-1. of January 8, 1973.

II. Disclosure and Making Available to the Public

1. A description of the new-microorganism must be set forth in the disclosure of the patent application. The deposit of the new microorganism in a culture collection is also a requirement; please see attached copy of Memorandum Circular TSE73/1.

2. (a) The culture collection agency must be recognized.

(b) The culture collection may be outside of the Philippines, provided it is recognized.

3. (a) Yes, the deposit must be made at the priority date.

(b) On the filing date if not under the Convention.

(c) No, it must be under conditions (a) and (b), above.

4. (a) Yes, deposit of new microorganism is required and the same must be available to the public (please see Memorandum-Circular TSE/73-1), and this may be, for instance, an obligation on the part of patentee or of the depository keeping the culture to sell the specimen to any interested party.

(b) The microorganism has to be made available on the date of the patent grant.

(c) No restrictions are imposed on the third party who requests the sample. The request anyway can be granted only after the patent grant.

III. We feel that the attached copy of Memorandum-Circular sets forth all the information relating to the patent procedure in the Philippines with respect to inventions concerning microbiological processes or products thereof.

B. Additional Information

Republic of the Philippines
Department of Trade and Tourism
PHILIPPINES PATENT OFFICE

MEMORANDUM CIRCULAR TSE/73-1

To: All concerned
From: The Director of Patents

Subject: Patent Specification Requirements for Subject Matters Involving Use of Microorganisms in Process for Preparing Substances Having Therapeutic Properties and Other Useful Substances

It has been observed that certain patent applications for inventions concerning processes involving use of culture of microorganisms contain disclosures which are inadequate for purposes of meeting the requirements of Section 14-(d) of the Patent Law or that certain formal requirements have invariably been overlooked during prosecution.

Philippines - continued

In order to establish an examination procedure which shall be uniform and standard for all cases involving use of microorganisms, hereunder outlined are guidelines which shall henceforth be followed:

1. Whenever a claimed process for making a useful substance or product specifies the use of any novel strain of microorganism, the disclosure should set forth the source and method of isolation of the strain, and a complete description of the microbiological characteristics of the microorganism. This is necessary to properly identify the microorganism and to enable the Examiner to compare the taxonomic description with those of known strains so as to confirm that the strain is really new, if newness of strain is in issue.

The disclosure must also include a detailed description of the process for making the useful substance or product using the microorganism.

2. That requirement set forth in the preceding item should also be complied with if the claim is also directed to the useful substance or product.

3. However, if at the time of filing of a patent application the requirement in the first paragraph of Item 1 of the Guidelines is not satisfied but the applicant or applicants have deposited in a recognized public depository before or at the time of the filing of the patent application the culture of the strain of microorganism, the application may be amended to include the taxonomic description of the said microorganism, provided a sworn statement is filed to the effect that the said taxonomic description sought to be entered in the application corresponds to the microorganism as deposited and properly identified, and provided further that evidence of deposit of the microorganism and the identification number as assigned to it by the depository is submitted to this office.

4. On the other hand, if at the time of filing of a patent application no deposit of the culture of microorganism has yet been made in a recognized public depository but taxonomic description of the microorganism, its source and method of isolation have been set forth in the patent application as filed, the patent examiner shall require such deposit to be made and shall require submission of proof of such deposit together with the deposit or identification number assigned to it by the depository.

5. In all cases, a patent application shall be allowed only when all the following conditions are met:

(a) that a deposit was made in a public depository of recognized standing;

(b) proof of such deposit together with the proper identification or deposit number assigned by the depository is submitted; and

(c) that the depository should be under the contractual obligation to place the culture in permanent collection, and to provide access to persons who shall have interest therein in regard to matters relating to the patent as soon as it issues.

This Memorandum-Circular shall take effect immediately.

January 8, 1973

(Original)

POLAND

I. Patentability of Inventions Involving Micro-organisms

1. (a) Under the law of our country a valid patent for a process involving the action of a new micro-organism may be obtained, under the condition, that in the specification of invention there will be exact characteristic of morphological features of such micro-organism.

(b) A product of a process referred to under a) is not patentable, but a patent granted for a process shall also cover products directly obtained from that process. In the case of litigation, such product shall be presumed to have in fact been produced by that process.

(c) A new micro-organism existing in nature is not patentable.

(d) A new strain of an existing micro-organism obtained by mutation is not patentable, but there is a possibility to grant protection for a new process concerning the obtaining of mutant.

2. The law of our country does not contain other special provisions relating to the patentability of inventions involving micro-organisms.

II. Disclosure and Making Available to the Public

1. If a patent application for an invention involving new micro-organism is filed in our country, a description of the new micro-organism in writing is sufficient.

III. The patent procedure of our country with respect to inventions concerning microbiological processes is the same as relating to all the other processes.

(Original)

SOVIET UNION

I. Patentability of Inventions Involving Micro-organisms

In accordance with the Statute on Discoveries, Inventions and Rationalization Proposals enacted by Decree of the Council of Ministers of the USSR of August 21, 1973, No 584, Section 21, new strains of micro-organisms shall be recognized as inventions.

The Statute also determines that only inventors' certificates shall be granted for strains of microorganisms. When filing applications for strains it is required that the claims of the invention contain an indication of the whole totality of features of the strain sufficient to recognize the strain and sufficient to determine the fact that the strain indeed is a new culture and such culture had not been described earlier anywhere.

The claims in any case must indicate what kind of a useful substance is produced by the said strain (or for what purposes the strain is applied if it does not produce any useful substance). Thus, in fact, only the strains having useful application shall be the subject of protection.

The Statute does not regulate the matters indicated in items (a), (b) and (c).

In the Soviet Union there is no protection of a product obtained by a microbiological process. The normative statements which are now in force regulating the examination of the applications for inventions (Instructions Concerning the Methods of Examination of Applications for Inventions - EZ-2-67, item 2.18) do not contain any restrictions as to the protection of the strains of microorganisms which depend on whether the strains were obtained artificially or whether they were discovered as existing in nature; as a rule the strains of micro-organisms extracted from nature shall not be the subject of protection (as is the case with useful minerals). However, recently in the USSR, instead of the protection of a strain itself the practice has developed of protecting processes involving the action of a micro-organism not already known and not available to the public.

2. The procedure for the protection of strains of microorganisms, e.g. producers of substances, in particular medical substances, was put on the same footing as the procedure applied for the protection of the methods for treatment of diseases, namely, that the inventors' certificate for the strains shall be granted after the appropriate approbation of the strains by the public health services.

II. Disclosure and Making Available to the Public

Until very recently there was no requirement to make a preliminary deposit of the new micro-organism in a culture collection or to refer to that deposit in the descriptions when filing an application for a new strain of micro-organism. However from May 10, 1973 an amendment came into force to item 29 of the Instructions Concerning Drafting of an Application for Invention which are applied in the USSR. The amendment requires, in particular, that an indication be made in the claims of the registration number of the strain in the collection of micro-organism as well as an indication of the location of the collection. There is no requirement to make a deposit of the new strain of micro-organism only in a recognized culture collection.

As to items 3 and 4 of Part II we are not able to give replies at the present time since these questions need further study and research.

(Original)

SWEDEN

A. I. Patentability of Inventions Involving Micro-organisms

1. (a) According to the Patent Law, Section 1, a patent may be granted for a microbiological process.

(b) A patent for a product of a microbiological process may at present be granted provided that the product does not concern food or medicine (cf. Entry into Force and Transitional Provisions of the Patent Law, point 1).

(c) No.

(d) No. According to the Patent Law, Section 1, a patent shall not be granted for plant or animal varieties or essentially biological processes for the production of plants or animals.

2. No.

II. Disclosure and Making Available to the Public

1. According to the Patent Law, Section 9, the application shall contain an explicit statement of what is sought to be protected by the patent and the description must be sufficiently clear to enable the invention to be worked by a person skilled in the art. In the light of this regulation The Patent Office decides, whether a deposit is necessary or not. In the Rules issued by the Swedish Patent Office the following is stated as regards the description of microorganisms: "If it is not possible to draft a description such as to exclude confusion with other organisms, or if due to the organism being very rare there is reason to assume that it will be difficult to find it in free nature, or if, finally, its production is not reproducible with certainty, then it is suitable and desirable that the organism be deposited at a scientific internationally known Swedish or foreign Institution which is independent of the inventor (applicant). In that case the name (depository designation) attributed to the organism at the Institution should be stated." At present there is no requirement of compulsory deposition.

2. (a) If a deposit is required by The Patent Office it may only be made at a scientific internationally known institution which is independent of the inventor.

(b) Yes.

3. No special regulations exist concerning this point. In view of general regulations such a deposit ought to be made at the priority date.

4. Yes--according to general regulations.

(a) No regulations exist concerning this point.

(b) The microorganism has to be made available 18 months after the priority date.

(c) No regulations exist concerning this point.

III. The patent procedure in the microbiological field is regulated by rules of 1967. These rules in fact correspond to the rules of February 1962, of which a copy is enclosed.

Sweden - continued

B. Additional Information

Information supplied by the Society of Swedish Patent Agents

Rules Issued by the Swedish Patent Office in February 1962 for Patent Applications Relating to Microbiological Processes.

Specification:

According to Sect. 4 Subsect. 1 of the Patent Law the specification has to be sufficiently clear and complete to enable anyone skilled in the art to carry out the invention.

To ensure that this prescription is fulfilled also in case of applications relating to microbiological processes the following special conditions have to be fulfilled:

I. As regards the description of microorganisms:

Microorganisms should be described in a manner such as to avoid the possibility of confusing them with other organisms.

Known organisms are characterized sufficiently by their scientific names or other scientific designations, if necessary accompanied by a reference to some publication describing the technique employed for their systematic determination. Organisms that have been hitherto unknown must be described so fully and elaborately that confusion with other organisms is avoided. As an example of the elaborate description required, reference is made to the enclosed List of Requirements showing how Actinomycetes of the genus Streptomyces should be described. If it is not possible to draft a description such as to exclude confusion with other organisms, or if due to the organism being very rare there is reason to assume that it will be difficult to find it in free nature, or if, finally, its production is not reproducible with certainty, then it is suitable and desirable that the organism be deposited at a scientific internationally known Swedish or foreign Institution which is dependent of the inventor (applicant). In that case the name (depository designation) attributed to the organism at the Institution should be stated. Since the description of the organism is not considered to comprise mutants differing in their properties substantially from these set forth in said description any such statements as "the invention is not limited to the use of the said organism but comprises also the use of both natural and artificially produced mutants thereof" cannot be allowed. Statements about the conditions or circumstances under which an organism was found, or about the methods by which it was isolated, cannot as a rule be accepted as defining the organism in a satisfactory manner. Fancy names and designations invented by the inventor (applicant) himself cannot be accepted as characterizations of the organism.

II. As regards the description of processes:

Processes should be described so clearly and completely as to enable anyone skilled in the art to carry out these processes, without any further knowledge than that which such a person skilled in the art can be normally expected to have.

The process (= the measures or steps taken or series of such measures or steps) by which an organism is isolated, cultivated, improved or put to use has to be described in such a manner that it can be reproduced with in all essential respects the same result. In cases where an organism is novel and the steps taken for isolating it may be considered to be reproducible, these steps have to be described. The cultivating conditions (substrates, nutrients, any chemical or other agent used for stimulation and influencing the development in a desired direction, pH, temperature, irradiation etc.) have to be described in clear and definite terms, with a statement also about the limit values and optimum values.

III. As regards the description of the product obtained by the process:

If the invention consists in the preparation of a novel substance having valuable properties a description should be given of in the first place these properties which are responsible for the usefulness of the substance. Moreover the substance has to be described in a manner such as to permit its identification, for instance by statements about its structural formula, empirical formula and chemical and physical properties.

Sweden - continued

Claims:

According to Sect. 4 Subsect. 1 of the Patent Law the conclusion following after the specification has to consist of one or more claims in which the features forming the characteristics of the invention and desired to be covered by patent protection are set forth in definite terms.

In case of applications relating to microbiological processes the following special conditions should be fulfilled:

Known microorganisms are sufficiently characterized by their systematic names, if necessary accompanied by a reference to some publication describing the technique employed for their systematic determination.

Hitherto unknown microorganisms should be characterized by a direct or indirect reference to the detailed description of the organism in the specification, if possible in combination with its systematic designation. If the organism is deposited in a scientific, internationally known, Swedish or foreign Institution which is independent of the inventor (applicant) the depository designation should be stated.

If the product produced is hitherto unknown it has to be characterized in such a manner that it can be identified, e.g. by setting forth its structural formula, empirical formula or reference to IR spectrum.

List of Requirements as Regards Description of Microorganisms Exemplified by Actinomycetes of the Genus Streptomyces. (Appendix to the Rules Issued by the Swedish Patent Office in February 1962 for Patent Applications Relating to Microbiological Processes).

Statements Required:

1. Name of organism, or possibly its reference number in a public cultivation deposit and where possible (desirable) date and place of isolation.

2. Description of growth on or in a specific substrate, with a detailed description of the macroscopic properties and characteristics and of the microscopic morphology (including shape and size of spores, morphology of sporulation, branching characteristics of mycelium, and width of hyphae).

3. Growth properties (morphology of colonies, statement about colors and also about secreted pigments if any) with respect to at least 10 standard substrates.

4. Physiological properties of the organism when grown in substrates containing milk, nitrate, gelatine, starch, tyrosine and if desirable cellulose.

5. Capacity of the organism to produce hydrogen sulfide on inorganic and organic substrates.

6. Statement about its ability to utilize a number of carbon sources.

7. Reference should be made to the most closely related strain or strains mentioned in Bergeys Manual of Determinative Bacteriology (1957) accompanied by a statement as to how the organism may be distinguished from these known organisms.

8. Supplemental statements, where possible or desirable, as regards individual properties such as for instance production of antibiotics.

9. The description of the physical and chemical properties of the antibiotic should be accompanied by a Table setting forth the quantitative special effects of the substance. Furthermore, there should be a Table indicating by merely plus (+) and minus (-) signs whether or not the substance is active against Gram-positive and Gram-negative bacteria, fungi and yeasts, and possibly moreover against protozoans, virus and Rickettsiae if this is known to applicant.

May 1962.

(Original)

SWITZERLAND

Preliminary remarks

The Swiss Patent Law* contains no specific provision concerning the protection of microorganisms. Therefore, when inventions or patent applications involve microorganisms, the general provisions of the Law must be applied interpretatively. It may be deduced from the Law that, in this respect, the ultimate decision in the event of dispute lies with the courts. The question of the protection of microorganisms seems to have been referred to a Swiss court only once (cf. the decision published in the Swiss Industrial Property and Copyright Review, 1970, pages 71 et seq.).

This reply is based for the most part on the current practice of the Federal Bureau of Intellectual Property with respect to the examination of patent applications relating to the microbiological field. It should be mentioned in this connection that these applications are not subject to preliminary examination, that is, examination for novelty, inventiveness and technological progress reflected in the invention. It follows from the foregoing paragraph that the accuracy of the solutions presented in our replies under I and II would have to be determined by the court in relation to the circumstances of each case; the court is not legally bound by the current practice of the Federal Bureau in the event of a dispute on the validity of a patent involving microorganisms.

With regard to the future, there is reason to suppose that Swiss legislation, which has been revised with a view to the ratification of the European Patent Convention, signed at Munich on October 5, 1973, will not depart in this respect from the provisions of Rule 28 of the Regulations under that Convention.

I. Patentability of Inventions Involving Microorganisms

1. (a) The Bureau does not grant patents for processes involving the action of a microorganism which, according to its description, is not already known, unless it is made available to the public by means of its description and deposit in a culture collection (see II.1 below).

(b) Products of microbiological processes are chemical substances, foodstuffs or pharmaceutical products, and as such are unpatentable according to Article 2(2), (3) and (4) of the Patent Law.

(c) The Bureau considers that a new microorganism existing in nature and claimed as such is a discovery and not an invention; such claims are therefore rejected.

(d) If on the basis of the description it is established that the process for obtaining a new strain of a microorganism may be reproduced, the Bureau accepts a claim in respect of that process and/or the microorganism which it produces.

2. According to Article 2(2) of the Patent Law, only chemical processes for the manufacture of curative products are patentable. According to jurisprudence (Swiss Industrial Property and Copyright Review, 1(c)), microbiological processes are to be treated as chemical processes.

II. Disclosure and Making Available to the Public

1. In the case referred to under I.1(d) above, a description of the process is sufficient; in all other cases the Bureau requires that the description identify a culture collection in which the new microorganism is deposited.

2. (a) and

(b) Subject to accessibility (see under 4 below), the deposit may be made in any collection, whether in Switzerland or abroad.

3. It is not necessary to indicate the date on which the deposit in the culture collection was made, but other data identifying the deposit must appear in the description or be added before the patent is granted.

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* Federal Law on Patents for Invention, of June 25, 1954, hereinafter referred to as "the Patent Law."

Switzerland - continued

4. (a) and

(c) The Bureau merely requires that the description identify the deposit and mention that it is "accessible." The conditions of access are, therefore, determined by the collection and the owner.

(b) Normally the question of accessibility does not arise until after publication of the patent. This could, however, come under "knowledge of the contents of the patent application" referred to in Article 73(3) of the Patent Law, which provides that action for damages may only be brought once the patent has been granted, but that the defendant may then be obliged to make compensation for damages occasioned from the time when he had knowledge of the contents of the patent application.

III. No further information.

(Translation)

UNITED KINGDOM

I. 1(a) Yes. This has been established UK practice for many years, for example, in the field of antibiotic production and brewing.

(b) Yes.

(c) A patent may cover a new micro-organism strain; but such a patent will not be construed as extending to that strain when found in nature. Such a construction of a patent claim to a new micro-organism is in accordance with Section 4(7) of the United Kingdom Patents Act 1949 which reads as follows:

"Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature".

(d) A patent may cover such a mutant strain, but again following Section 4(7) of the United Kingdom Patents Act, the claim will not be construed as extending to such mutant strains when found or produced naturally.

2. There are no specific provisions in the United Kingdom Patents Acts relating to the patentability of inventions involving micro-organisms; but there is an authority, General Electrical Co. Ltd's Application 1961 Reports of Patent, Design and Trade Mark Cases at page 21, which suggests that claims to micro-organisms per se (cf. answers to (c) and (d) in question I, above) must be for micro-organisms having a practical use, e.g. bakers' yeasts.

II. 1. If an adequate taxonomic description of a new micro-organism is given in writing this is considered sufficient. Under United Kingdom law, as it stands at present, deposit in a culture collection cannot be insisted upon. Our leading case on this subject is American Cyanamid Company (Dann's) Patent, 1971 Reports of Patents, Designs and Trade Mark Cases at page 425.

2-4. Since we do not require deposit there is no relevant United Kingdom law on these topics.

III. The Report of the Banks Committee, published in July 1970, makes the following recommendation:

> Where an invention involves the use of a micro-organism of a type which is not readily available to the United Kingdom public, the applicant for a patent should (a) deposit a sample of the micro-organism in a recognised culture collection at or before the filing date of the complete specification, and withdraw irrevocably all restrictions on the availability of the sample to the United Kingdom public at the early publication date of the specification, and (b) in the complete specification at its filing date, describe the micro-organism, specify the culture collection in which a sample of the micro-organism has been deposited, and declare that all restrictions on the availability of the sample to the United Kingdom public will be withdrawn irrevocably at the early publication date of the specification.

As yet no legislative changes have been made consequent upon this recommendation, and consideration is being given as to whether it would be preferable to follow Rule 28 of the European Patent Convention.

The following is a list of United Kingdom patents which have claims to micro-organisms and may therefore be of interest:

1,331,472
1,298,668
1,152,286
1,138,740
1,090,754
868,633
813,992

UNITED STATES OF AMERICA

A. I. 1. (a) Yes. Microbiological processes are patentable on the same basis as other processes.

(b) Yes. Products of microbiological processes are also patentable on the same basis as other products.

(c) No. A microorganism which exists in nature is regarded under United States law as a "product of nature," and is unpatentable as such.

(d) No. An already existing microorganism is not patentable, regardless of the process by which it is obtained. A novel process for obtaining an existing microorganism may be patentable, however. It is also settled that microorganisms cannot be patented under the plant patent provisions of United States law, even though a scientific argument might be made that microorganisms are plant-like in nature.

I. 2. The Patent Office and the courts of the United States have developed a body of law concerning the patentability of microorganisms and processes involving them. This body of law primarily concerns the adequacy of the description of the microorganism required in United States patents. For new microorganisms, having no known taxonomy, the description must be complemented by an acceptable deposit of the microorganism. The Patent Office regulations concerning the deposit of microorganisms are attached.

II. 1. A new microorganism, by definition, can have no known taxonomy. Therefore, a written description of the microorganism cannot suffice to satisfy the disclosure requirements of our patent laws. Deposit of the microorganism in an acceptable culture collection, and reference to that deposit in the patent application, are necessary.

2. (a) This question cannot be answered with a yes or no answer. An acceptable deposit must be made in a public culture collection , i.e. a collection which accords the public complete access to the deposit referred to in a patent. A deposit in a private culture collection will not suffice, because no guarantee can be offered that public accessibility will continue after the issuance of a patent involved. The Patent Office has ruled that accessibility to deposits in private collections is a private contractual matter between the depositor and depository, and any contract might later be amended, voided or unenforceable. "Recognized" culture collections may be private collections. If so, they would be unacceptable.

(b) Yes, whether or not the applicant was a foreigner, if the depository is a public depository. The Patent Office has no statutory authority to refuse a patent because the culture was deposited outside of the United States in a public depository meeting the requirements specified for depositories. Even if the microorganism cannot be imported into the United States, the Patent Office recognizes the acceptability of a foreign deposit at this time.

3. (a) Yes. The deposit must be made by the priority date.

(b) Yes. U.S. applicants must make their deposits by the filing date.

(c) Not applicable to U.S. patent practice.

4. The microorganism must be available to the public at the time the patent issues. Patent Office regulations so specify.

4. (a) A microorganism is ordinarily kept available by the depository. The contract of deposit must include provisions assuring continuing availability of specimens to the public. A depositor is usually required to pay a nominal fee for maintenance of the deposit, usually up to the date of patenting. Members of the public may be required to pay a nominal fee for a specimen. However, public depositories as a public service often afford accessibility, after patenting.

United States of America - continued

(b) The Patent Laws only require that the culture be available at the time of grant of a patent. However, an applicant may make his culture publicly available at any time. The culture must remain available throughout the term of the patent. Patent Office regulations impose no requirements for availability after expiration of the patent.

There are limited situations under United States patent law when the deposit must be made available to only another party during the pendency of an application. These situations are provided for in Patent Office regulations.

(c) Under United States law, no restrictions may be imposed on (third) parties requesting a specimen. The specimen may be used for any purpose, including commercialization. The only exclusionary rights available to the depositor are those accorded by the patent. However, it would be proper for the depositor to include a contractual provision requiring the depository to identify persons receiving specimens. Such provisions do not impinge on free availability.

III. S. 2504, now pending in our Congress, a bill for revision of the United States patent laws, includes provisions concerning the deposit of microorganisms in section 112(f).

Provisions are also made for deposits insofar as the right of priority is concerned under section 119(d). A copy of these provisions is attached. These provisions generally codify United States decisional law, as explained above. I would point out, however, that S. 2504 will require deposit in a United States depository as a requirement for patenting in our country.

B. Additional Information

Deposit of Microorganisms

Some inventions which are the subject of patent applications depend on the use of microorganisms which must be described in the specification in accordance with 35 U.S.C. 112. No problem exists when the microorganisms used are known and readily available to the public. When the invention depends on the use of a microorganism which is not so known and readily available applicants must take additional steps to comply with the requirements of Section 112.

In re Argoudelis et al., 168 USPQ 99 (CCPA, 1970), accepted a procedure for meeting the requirements of 35 U.S.C. 112. Accordingly, the Patent Office will accept the following as complying with the requirements of Section 112 for an adequate disclosure of the microorganism required to carry out the invention:

(1) The applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under Rule 14 of the Rules of Practice in Patent Cases and 35 U.S.C. 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;

(2) Such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository and the taxonomic description to the extent available is included in the specification; and

(3) The applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.

A copy of the applicant's contract with the depository may be required by the Examiner to be made of record as evidence of making the culture available under the conditions stated above.

April 29, 1971

United States of America - continued

S2504 Section 112 (f)

"(f) When the subject matter sought to be patented relates to a process involving the action of a microorganism not already known and available to the public or to a product of such a process, the written description required by subsection (a) of this section shall be sufficient as to said microorganism, if -

(1) not later than the date that the United States application is filed, an approved deposit of a culture of the microorganism is made by or on behalf of the applicant or his predecessor in title, and

(2) the written description includes the name of the depository and its designation of the approved deposit and, taken as a whole, is in such descriptive terms as to comply with subsections (a) and (b) of this section.

(g) for the purpose of subsection (f)(1) of this section, an approved deposit shall be a deposit which -

(1) is made in any public depository in the United States which shall have been designated for such deposits by the Commissioner of Patents by publication, and

(2) is available, except as otherwise prohibited by law, in accordance with such regulations as the Commissioner may prescribe -

(A) to the public upon issuance of a United States patent to the applicant or his predecessor or successor in title which refers to such deposit, or

(B) prior to issuance of said patent, as specified in sections 122 and 132 (c) of this title."

S2504 Section 119 (d)

"(d) When the application claiming priority under this section disables an invention relating to a process involving the action of a microorganism not already known and available to the public or to a product of such a process and an approved deposit is made under section 112(f) of this chapter, the approved deposit shall be considered to have been made on the earliest date that an application in a foreign country, the priority of which is being claimed, contains a reference identifying a deposit of the same microorganism made in a public depository."

(Original)

YUGOSLAVIA

In reply to your Circular No. 1795-453 concerning the patentability of inventions involving microorganisms, we have the honor to inform you of the following:

The Law on Patents and Technical Improvements of October 31, 1960 (La Propriété industrielle, No. 9, September 1961), currently in force in Yugoslavia, does not contain any special provisions relating to inventions concerning microbiological processes or products thereof.

Under Article 11 of the Law, an invention may only be patented if it constitutes a new solution to a specific technical problem which may be used in industry. Under Article 13, on the other hand, a patent may not be granted in respect of medicaments or substances obtained by chemical processes, although the new processes by which the substances are manufactured are themselves patentable. It is these two Articles which have to be applied to microorganisms and on which the practice of the Federal Patent Office must be based.

A new microorganism existing in nature is not patentable in view of the fact that it involves a discovery and not an invention. A process involving the action of a microorganism, however, may be patented on condition that the hitherto unknown microorganism is clearly defined in the description of the invention.

The Federal Patent Office does not consider a written description of the microorganism sufficient for its identification or for the application of the invention (Article 47 of the Law). A deposit of the microorganism would therefore be necessary. To date, all patent applications for inventions involving microorganisms have indicated that a deposit of the respective microorganisms has been made.

In view of the fact that, for the moment, there are no official culture collections in Yugoslavia, deposits may be made outside the country. It is preferable that such collections be official or officially recognized. WIPO might perhaps study this problem and propose a solution.

In all the cases which have occurred to date, the applicants have made the deposit of their microorganisms on the priority date. However, the deposit of the microorganisms on the date of the deposit of the application would also be acceptable. As for the time at which the microorganisms has to be made available to the public, this would, under Yugoslav law, be the date of publication of the application.

(Translation)

ZAMBIA

I refer to your circular letter of August 16, 1973, and the questionnaire concerning Patent Procedures with respect to Inventions Concerning Microbiological Processes. I hope that the following general explanation adequately answers the various questions you have raised:

1. There are no Court decisions in Zambia specifically affecting these questions, so far as I am aware.

2. Under Section 2(1) of the Patents Act "Invention" means any new and useful art (whether producing a physical effect or not), process, machine, manufacture or composition of matter which is not obvious, or any new and useful improvement thereof which is not obvious, capable of being used or applied in trade or industry and includes an alleged invention.

On the face of which I would have thought that this definition might well be wide enough to include at least some of the things you mention in sub-paragraphs (a) to (d) of paragraph 1 of your questionnaire.

3. Every Patent application in Zambia has to be either (in the case of a Convention application) accompanied by or, in the case of other applications, accompanied or followed by a complete specification. A complete specification must among other things:

(a) fully describe the invention and the manner in which it is to be performed;

(b) disclose the best method of performing the invention known to the applicant at the time when the specification is lodged at the Patent Office; and

(c) end with a claim or claims defining the subject-matter for which protection is claimed.

Thus, if these criteria can be met without the deposit of a microbiological organism in a culture collection there would be no need for such a deposit.

To sum up, we have no patent procedures expressly relating to microbiological organisms and if confronted with an application of that kind, we would interpret the general provisions of the Patents Act on the lines indicated above.

(Original)

IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANT OF EUROPEAN PATENTS

Rule 28

Requirements of European patent applications relating to micro-organisms

(1) If an invention concerns a microbiological process or the product thereof and involves the use of a micro-organism which is not available to the public, the European patent application and the resulting European patent shall only be regarded as disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art if:

(a) a culture of the micro-organism has been deposited in a culture collection not later than the date of filing of the application;

(b) the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism;

(c) the culture collection, the date when the culture was deposited and the file number of the deposit are given in the application.

(2) The information referred to in paragraph 1(c) may be submitted within a period of two months after the filing of the application. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the culture deposited being made available to the public in accordance with this Rule.

(3) The culture deposited shall be available to any person upon request from the date of publication of the application. The request shall be addressed to the culture collection and shall be deemed to have been made only if it contains:

(a) the name and address of the person making the request;

(b) an undertaking *vis-à-vis* the applicant or proprietor not to make the culture available to any other person;

(c) where the request is made before the date of publication of the mention of the grant of the patent, an undertaking *vis-à-vis* the applicant to use the culture for experimental purposes only.

(4) A copy of the request shall be communicated to the applicant or proprietor.

(5) The undertaking provided for in paragraph 3(b) shall cease if the application is refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, on the expiry of the patent in the designated State in which it last expires.

(6) The undertaking provided for in paragraph 3(c) shall cease if the application is refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, on the date of publication of the mention of the grant of the patent.

(7) The undertaking under paragraph 3(c) is not applicable in so far as the person making the request is using the culture under a compulsory licence. The term "compulsory licence" shall be construed as including *ex officio* licences and the right to use patented inventions in the public interest.

(8) The President of the European Patent Office shall publish in the Official Journal of the European Patent Office the culture collections which will be recognised for the purpose of this Rule and shall conclude agreements with them, in particular in respect of the deposit, storage and availability of cultures.

/End of document/