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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

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

(April 23 to 26, 1974)

FIRST SUPPLEMENT TO DOCUMENT DMO/II/2

(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 constitutes a supplement to document DMO/II/2; it contains an analysis of the replies received between February 8 and March 15, 1974, to the International Bureau's questionnaire relating to patent procedure with respect to inventions concerning microbiological processes or products thereof.

Introduction

1. Reference is made to document DMO/II/2, dated February 8, 1974, which contains an analysis of the replies received from a number of countries to the International Bureau's questionnaire[1] relating to patent procedure existing at the national level with respect to inventions concerning microbiological processes or products thereof.

2. This document contains an analysis of the replies from Japan, Monaco, Nigeria, Romania, South Africa and Uganda, which the International Bureau received between February 8 and March 15, 1974.

3. The texts of all the replies received since document DMO/II/2 was issued are reproduced in the Annex to this document. The replies of Monaco and Uganda are not analyzed in detail since these two countries reported that no specific provisions were contained in their respective patent laws as regards microbiological inventions.

Question I.1(a)[2]

4. Japan, Romania and South Africa indicated that a valid patent might be obtained for a process involving the action of a microorganism not already known and available to the public.

Question I.1(b)[2]

5. Japan, referring to Article 32(1), (2) and (3) of the Japanese Patent Law, replied that, as regards products resulting from a process involving the action of a microorganism, an exception from patentability applied with respect to medicinal specialities, food and chemical products. Romania and South Africa stated that all such products were patentable. However, Romania qualified its reply by adding that product patents were granted only to Romanian State enterprises to which an inventor had assigned the rights in his invention.

Question I.1(c)[2]

6. Japan, Romania and South Africa stated that no protection could be granted to a new microorganism existing in nature. However, South Africa qualified its reply by adding that, depending on the particular circumstances of each case, valid protection could be obtained for this type of microorganism when "manufactured," provided that it was possible to produce such organism artificially.

Question I.1(d)[2]

7. Japan specified that, according to Article 29 of the Japanese Patent Law, a microorganism itself was not considered an invention and therefore was not patentable. Romania pointed out that a new strain of an existing microorganism, obtained by any kind of process, was not patentable. South Africa indicated that probably a patent could be obtained for a new strain of any existing microorganism obtained by a process such as mutation.

Question I.2

8. Romania and South Africa reported that no further information was available. Japan specified that, according to Article 27bis of the Patent Law Enforcement Regulations, when an invention involving a microorganism was patentable, the applicant must attach to his application a document certifying that he had deposited the microorganism in an institution designated by the Director General of the Japanese Patent Office, unless the microorganism was easily obtainable by anyone having ordinary knowledge of the field to which the invention related; "easily obtainable" meant that the microorganism was already deposited in a designated institution and could be made available to the public.

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(1) The questionnaire is reproduced in Annex II to document DMO/II/2.

(2) To these questions Nigeria replied that a valid patent might be obtained with respect to microorganisms.

Question II.1

9. Japan and Romania pointed out that besides the written description of the new microorganism, which must contain morphological, taxonomical and fungological characteristics of the organism, it was necessary to deposit the microorganism and refer to such deposit in the description. South Africa specified that, if the new microorganism could be fully identified by the description, that should be sufficient; however, for the purpose of positive identification, it might be necessary to make the deposit and refer to it in the description. Nigeria indicated that a description of a new microorganism in writing was sufficient and no deposit was required.

Question II.2(a)

10. Japan and Romania indicated that the new microorganism must be deposited in a recognized culture collection. Japan further specified that the deposit must be made at the Fermentation Research Institute of Industrial Science and Technology Agency, Ministry of International Trade and Industry. South Africa reported that if a deposit was required it would probably have to be made in a recognized culture collection.

Question II.2(b)

11. Japan stated that, even if the applicant was a foreigner, the microorganism must be deposited in a culture collection designated by the Director General of the Japanese Patent Office. Moreover, in order to enable priority to be claimed, the deposit must be made in an officially recognized culture collection in the foreign country at the time of first filing(3). Romania specified that the deposit of a microorganism could take place abroad. South Africa reported that, even though a definite answer could not be given, in the event that a deposit in a culture collection was required, such deposit might take place abroad.

Question II.3

12. Japan stated that, in the case of a patent application claiming priority, the deposit of a microorganism must have been made on the priority date, while in the case of an application not claiming priority, the deposit should take place on the filing date. Romania pointed out that, in the case of a first filing, the deposit must be made on the priority date. South Africa indicated that, in the absence of any specific provisions, the deposit would probably have to be made on the priority date in the case of a Convention application and on the filing date in the case of a non-Convention application.

Question II.4

13. Japan and Romania stated that the microorganism must be made available to the public. South Africa indicated that, if the deposit of a new microorganism was required, probably the organism would have to be made available to the public.

Question II.4(a)

14. Japan indicated that the request for release of a sample of a deposited microorganism must be fulfilled. In Romania the deposited microorganism is made available to the public through the obligation of the laboratory keeping the culture collection to sell a specimen, on request, to the Romanian State. South Africa indicated that no answer could be given to this question.

Question II.4(b)(i)

15. Only Romania reported that the new microorganism must be made available to the public on the filing date, provided that the filing instrument contained an offer of assignment to a Romanian State enterprise.

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(3) In this connection, Japan referred to Section 3.14(4) of the "Examination Standard of Applied Microbial Industry" (see the reply from Japan annexed to this document).

Question II.4(b)(ii)

16. Japan indicated that the microorganism must be made available after the publication of the examined patent application. South Africa specified that, if the microorganism had to be made available, it would probably have to be made available on the date of publication of the description.

Question II.4(b)(iii)

17. None of the countries covered by this document made any comment on this question.

Question II.4(b)(iv)

18. Only Romania answered this question, reporting that, in the case where the rights in an invention involving the action of a microorganism were not assigned to a Romanian State enterprise, the microorganism must be made available on the date of expiration of the patent.

Question II.4(c)

19. Japan indicated that conditions such as the following might be attached to the document for depositing the microorganism: the sample may be made available within Japan only, the sample may be made available for experimental purposes only, and the person requesting the sample must not sell it to any third party. Romania and South Africa stated that the conditions and relevant restrictions on the availability to third parties of new microorganisms were not regulated by their respective laws.

Question III

20. No further information was communicated under the heading of this question.

/Annex follows/

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ANNEX

JAPAN

A. Q. I

1. (a) Yes. Please refer to Examination Standard for Applied Microbial Industry.

(b) Those pertaining to medicines, food and chemical products are not patentable. See Japanese Patent Law Art. 32, pars. (1), (2) and (3).

(c) and (d) No. Basis: In Japan an organism itself has not been considered as an invention mentioned in Patent Law Art. 29. Therefore, since micro-organism is an organism, it is not patentable.

2. There is no specific provision but as indicated in our answer to Q. 1. (c) and (d) above, an invention involving micro-organism has not been considered patentable in Japan. Even in the case of 1. (a) and (b) above, when an invention concerning micro-organism is patentable, the deposit of the micro-organism concerned must satisfy the stipulation of Patent Law Enforcement Regulations Art. 27 bis. The stipulation of the above is as follows: An applicant wishing to file a patent application for an invention involving a micro-organism, must attach to his application, a document certifying that he has deposited the said micro-organism at an organization designated by Director-General of the Japanese Patent Office, unless the said organism is easily obtainable to anyone having an ordinary knowledge of the field to which the invention belongs.

Japan - continued

Q. II

1. Unless the micro-organism is easily obtainable to those having ordinary knowledge of the field to which the invention belongs, as mentioned in the answer to Q. 1. 2 above, the micro-organism must be deposited and, further, the fungological characteristic of the micro-organism and the deposit number must be mentioned in the specification of the application document.

Note: By easily obtainiable, it means that the micro-organism is already deposited at the designated organization and can be made available to the public. In that case, it is necessary to mention the name of the organization where the micro-organism is deposited and its deposit number must be mentioned in the specification of the application.

2. (a) No, it must be deposited at Fermention Research Institute of Industrial Science and Technology Agency, Ministry of International Trade and Industry. Please refer to Examination Standard of Applied Microbial Industry 3.14 (1).

(b) Even if the applicant is a foreigner, the micro-organism must be deposited in the organization designated by Director General of the Japanese Patent Office. Further, in order to claim priority, the micro-organism must be deposited in an official organ in a foreign country at the time of the first filing. Please refer to Examination Standard of Applied Microbial Industry, 3.14 (4).

Japan - continued

3. For a priority claiming application, (a) and (b) are applied. In this case (a) must be an official organ in a foreign country, and (b) must be the organization designated by Director General of the Japanese Patent Office. For an application not claiming priority, (b) is applied.

4. Yes.

(a) and (b) When the micro-organism is deposited and a third party makes a request for a sample, the request must be fulfilled, at least after the publication (examined) date of the patent application.

(c) On the document for depositing the micro-organism the conditions like the following may be attached:

(1) The samples may be made available within Japan only.

(2) The samples may be made available only for cases where it is evident that they will be used for experimental purposes.

(3) One who obtains the sample must not sell it to a third person.

Q. III

A copy of Examination Standard of Applied Microbial Industry is enclosed. The English version was made by Mr. Kiyoshi Yamashita, a patent attorney, in conjunction with the examiner in charge at the Japanese Patent Office.

Japan - continued

B. Additional Information

EXAMINATION STANDARD
FOR INVENTIONS OF
APPLIED MICROBIAL INDUSTRY

1 Title of Industrial Division

Applied Microbial Industry

2 Scope of the Industrial Division

This examination standard for classified industrial division shall be applied to an invention which is characterized by the use of microorganism.

Accordingly, the invention to which this standard shall be applied principally includes those classified in Class 36(2) and Class 36(5) of Classification Table, though those other than the above may also be subjected to this standard.

The invention which is characterized by the use of microorganism does not praticularly imply an invention in which a new species of microorganism is utilized. Examples of such invention are as in the following.

(1) Process for preparing a new substance utilizing a new strain
(2) Process for preparing a known substance utilizing a new strain
(3) Process for preparing a new substance utilizing a new species

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4) Process for preparing a known substance utilizing a new species

5) Process for preparing a new substance utilizing a known species

6 Process for preparing a known substnace utilizing a known species

7) Process for preparing a new substance utilizing a strain belonging to a known genus

8 Process for preparing a known substance utilizing a strain belonging to a known genus

9) Process for preparing an acidophilus beverage utilizing a new strain

10) An insecticide comprising as an active ingredient a cultured product (living microbe) of a new strain

11) Desulfurization process of petroleum utilizing a new strain

12) Leaching process of minerals utilizing a new strain

13) Process for preparing an acidophilus beverage utilizing a new species

14) An insecticide comprising as an active ingredient a cultured product (ling microbe) of a new species

15) Desulfurization process of petroleum utilizing a new species

16) Leaching prôcess of minerals utilizing a new species

17) Process for preparing an acidophilus beverage utilizing a known species

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18) An insecticide comprising as an active ingredient a cultured product (~~ling~~ living microbe) of a known species

19) Desulfurization process of petroleum utilizing a known species

20) Leaching process of minerals utilizing a known species

21) Process for preparing an acidophilus beverage utilizing a strain belonging to a knwon genus

22) An insecticide comprising as an active ingredient a cultured product (~~ling~~ living microbe) of a strain belonging to a known genus

23) Desulfurization process of petroleum utilizing a strain belonging to a known genus

24) Leaching process of minerals utilizing a strain belonging to a known genus

3 Judgement on Patentability of an Invention in the Industrial Field

3.1 Problems Peculiar to the Industrial Field

3.11 Unpatentable inventons

(1) An invention of microorganisms themselves

The invention of microorganisms themselves is unpatentable, similarly to the case of a living thing, as being not utilizable for industrial use, because the invention shall be deemed as lacking reproducibility.

Japan - continued

(2) An invention of fermentation products themselves

Such substances as may be produced by fermentation as enzymes, organic acids, spirit of wine and other alcohols, antibiotics, vitamins and the like are originally to be prepared by chemical process. Among the substances, there are involved various products falling under the categories of medicines and articles of drink or food, or articles of taste or stimulation, and hence all the substances mentioned above are unpatentable.

3.12 Designation of a Microorganism as a Constitutive Requirement of Invention

The microorganism as a constitutive requirement of invention may be designated by names either of strain, species or genus. In case the production of an objective substance by a microorganism belonging to a certain genus is novel so far as the said genus is concerned, however, the microorganism may be described by the expression such as "substance B-producing strain belonging to genus A", even when only one microorganism belonging to said genus has been exemplified.

However, when a microorganism utilized as a constitutive requirement is expressed by a classification unit broader than genus, at least one microorganism must be exemplified in each classification unit subordinate to the said broader classification unit (e.g. when it is expressed by a name of family, at least one microorganism of every genus belonging to said family must be exemplified.

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3.13 The claimed invention being not complete

(1) In case a microorganism as a constitutive requirement of invention is expressed by a classification unit broader than genus, at least one microorganism must be exemplified in each classification unit subordinate to said broader classification (e.g. when it is expressed by a name of family, at least one microorganism of every genus belonging to said family must be exemplified), otherwise the claimed invention shall be deemed to be incomplete.

(2) When a deposit number of the microorganism utilized is not set forth in the specification as first attached to an application (hereinafter referred to as "specification as first filed), the claimed invention shall be deemed to be incomplete.

(3) When the microorganism is a new species (including the case where said microorganism is expressed as being a strain), and in case the microbiological properties of the utilized microorganism have not been described at all in the specification as first filed or the microorganism to be utilized is not clearly understood because of insufficient description thereof, the claimed invention shall be deemed to be incomplete because the microorganism utilized has not been disclosed.

(NOTE) In case the microorganism utilized is a new species (including the case where the utilized microorganism is expressed as being a strain), the microbiological properties thereof must be described, as stipulated in 3.41(3)A (D), in

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the specification as first filed so that the utilized microorganism may be made substantially clear.

(4) In case a substance to be produced is a novel one, and when the physicochemical properties of three items as stipulated in 4.23 have not been described without clarifying the reasons therefor and the description in substitution for the above is not sufficient, the claimed invention shall be deemed to be incomplete, because the substance cannot be confirmed.

(5) When a substance to be produced is a novel enzyme, and in case the physical properties of three items as stipulated in 4.25 have not been described in the specification as first filed without clarifying the reasons therefor and the description in substitution for the above is not sufficient, the claimed invention shall be deemed to be incomplete, because the enzyme cannot be confirmed.

3.14 Deposition of microorganism utilized

(1) Any person who wants to file a patent application for an invention in which a microorganism has been utilized must deposit the preservation of the microorganism with an organization designated by the Director-General of the Patent Office (hereinafter referred to as "deposition") and must clearly indicate a deposit number of the microorganism in the specification as first filed and attach to the patent application a document verifying the fact if said microorganism is not such as those having average knowledge in the technical field to which the invention pertains can readily obtain.

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Furthermore, the said microorganism must be made available to public after the publication of the patent application.

In the above case, however, when the microorganism utilized has been deposited with Fermentation Research Institute, Agency of Industrial Science & Technology, MITI (hereinafter referred to as "BIKOKEN"), a receipt number given by Bikoken for an application of deposition of the microorganism therewith (hereinafter referred to as "receipt number") may be described in place of a deposition number to be assigned thereto later in the specification as first filed. In this case, the receipt number must be replaced by the deposit number as soon as possible after the filing of a patent application.

(Explanation)

I In an invention characterized by the use of microorganism, a concrete technical means to accomplish an object of the invention lies in the utilization of a specific microorganism. Accordingly, in case the said microorganism is such as may not readily be obtained by those skilled in the art, it cannot be said that the completion of the invention has been objectively supported unless the said microorganism has been deposited with a depository designated by the Director-General of the Patent Office and a deposit number thereof has been described in the specification as first filed. Furthermore, the reproducibility of the invention cannot be recognized unless the microorganism is not available.

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It is therefore necessary that the microorganism utilized is deposited with the designated organization, a deposit number thereof is described in the specification as first filed, and the microorganism is freely distributed as soon as the publication of a patent application is rendered.

In the above case, the distribution of microorganism does not mean a free distribution without limitation. Such restrictions, for example, as (1) distribution of the microorganism is limited in principle to the interior of Japan, (2) distribution of the microorganism is limited to a case where said microorganism is used for experimental research, (3) a receiver of the microorganism is requested not to re-deliver said microorganism to others, and so on, may naturally be provided. These restrictions are clearly and properly provided for, if necessary, at the time of concluding a contract between a depositor and a depository.

II A deposit number of the microorganism utilized should, in principle, be described in the specification as first filed. However, there may be a case where a deposition number cannot be described for unavoidable reasons in the specification by the time of filing a patent application, and hence a receipt number shall be accepted in place of the deposit number.

Furthermore, even when said receipt number cannot be set forth owing to unavoidable circumstances in the specification as first filed, the following procedure may

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be taken in place of the receipt number. That is, the procedure may be accepted when the fact that the said microorganism has been mailed to be deposited with Bikoken by the filing date of application (i.e. a registered mail number) is described in the specification and an evidence capable of confirming the above fact (i.e. an official receipt of registered mail order) is attached to the patent application, and then a receipt number can be supplemented later.

III A document for verifying the effect that a microorganism relevant to a patent application was deposited with a depository designated by the Director-General of the Patent Office, which is to be attached to the Patent application, means a copy of a written notice of receipt number of the microorganism or a card of receipt number of an application for deposition of the microorganism by Bikoken. Further, in case of the above II, where the fact that the said microorganism has been mailed to be deposited with Bikoken by the filing date of application is described in the specification and an evidence capable of confirming the above fact, i.e. an official receipt of registered mail order, is attached to the patent application, and then a receipt number is supplemented later, a copy of a card of receipt number of an application for deposition of the microorganism by Bikoken, in which the united relation between the contents of said registered mail and the reciept number has been clarified, must be submitted to the Patent Office.

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(2) Scope of microorganisms required to be deposited

In invention where microorganisms have been utilized, when the microorganism utilized is recognized to be an indispensable constitutive requirement of invention, deposition of said microorganism is required to be made.

Examples of the case are as follows:

(1) A process for preparing substance B, characertized by culturing in a medium a B susbtance-producing strain belonging to genus A to accumulate the substance B therein and recovering the accumulated substance B.

(2) A process for preparing substance B by fermentation, characterized by culturing in a medium containing additive X a strain belonging to genus A, thereby to produce and accumulate the substance B in the medium and recovering the accumulated substance B.

(3) A method for improving food A in flavor and taste in the processing of said food A which comprises inoculating microorganism B and cultivating same therein.

(4) An insecticide comprising as an active ingredient a cultivation product (living microbe) which contains microorganism A.

(5) A process of removing compound B present in petroleum, characterized by contacting microorganism A with the petroleum to remove the compound B therefrom.

(6) A process for leaching metal compound B present in

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a mineral ore, characterized by contacting microorganism A with the ore and leaching the compound B therefrom.

(3) Microorganisms exempted from deposition

1 Microorganisms which cannot be preserved for technical reasons by a deposition organization (for example, pathogenic microbes for vaccine, virus, bacteriophage, fungi the fruit body of which is utilized, mixed microbes for waste water treatment, algae, etc.).

2 Microorganisms which are readily available to those skilled in the art.

(a) Commercially available microorganisms such as baker's yeast, koji (Aspergillus oryzae), Bacillus natto, etc.

(b) A microorganism which has been preserved in a reliable depository and is freely distributed (including a standard preserved strain).

In the case of an invention in which the above mentioned preserved strain itself is utilized, no deposition is required. In the case of an invention newly invented by use of a variant of the above-mentioned preserved strain, however, the variant is required to be deposited.

In the cases of the foregoing 1 and 2, when necessary, an applicant must submit a written statement explaining the reasons for exemption of the deposition.

(4) In the case of a convention application directed to an invention involving the utilization of a microorganism which cannot readily be available to those having orginary

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knowledge in the technical field to which the invention pertains, if the deposition of said microorganism has been made in accordance with the provisions of 3.14(1) and the specification filed in the first country, on which the Convention priority claimed is based, describes that the same microorganism has been deposited with a public depository, the deposition made in Japan in accordance with the provisions of said 3.14(1) shall be regarded as having been done on the priority date.

3.2 Judgement of Identity

When objective substance of the two inventions are identical with each other, the identity of the inventions shall be determined depending on the differences between the microorganisms utilized in said two inventions.

3.21 Strain vs.Strain

It is recognized that the invention of an earlier-filed application utilizing a strain and that of a later-filed application utilizing a strain which has the same microbiological properties as the first said strain are identical with each other.

The strain referred to above does not mean an isolated strain but a specific strain having a definite microbiological property.

3.22 Species vs. Species

In case a species utilized in the invention of an earlier-filed application is identical with a species utilized in the invention of a later-filed application in

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the microbiological properties for reference of a group of microorganism to which said two species are belonging, it is recognized that the said two inventions are identical with each other, regarding said two species as identical.

Classification of microorganisms is based on species. However, a scientific and absolute standard has not been provided, because it is biologically quite difficult to discriminate the species, and so the identification or discrimination of species may be said to be a task of most difficulty.

Reagardless of a theory, therefore, the discrimination of species is made depending on the microbiological properties for reference as specified in a reference manual commonly used (for example "Bergey's Manual of Determinative Bacteriology" in respect of bacteria).

3.23 Strain vs. Species

It is recognized that the invention of the earlier-filed application utilizing a species and the invention of a later-filed application utilizing of strain which is belonging to the species are identical with each other.

However, the invention of a later-filed application having a superior effect over the invention of an earlier-filed application shall be recognized as being different, even when a strain utilized in the invention of the later-filed application is belonging to the species utilized in the invention of the earlier-filed application.

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Independent on whether the invention of an ealier-filed application utilizes a species or a strain, comparison between the microorganisms utilized should be made not on the basis of all the mycological properties specifically described in the specifications but within the such range of microbiological properties as used for species grouping in determination of a group of microorganisms in which the utilized microorganisms are included.

This practice has been provided for the fear that as a strain per se is liable to vary, the narrow interpretation of microbiological properties of strain shall lead to the double patenting within the extent of the normal variation thereof.

3.24 Species vs. Genus

It is recognized that the invention of an earlier-filed application, in the claim of which a microorganism utilized is referred to as being "a substance B-producing strain belonging to the genus A", and the invention of a later-filed application utilizing a known species belonging to the said genus are identical with each other.

It is recognized, however, that the invention of an earlier-filed application, in the claim of which a micro-organism utilized is referred to as being "a substance B-producing strain belonging to the genus A'" and the invention of a later-filed application utilizng a new species belonging to the genus A which is different from said microorganism

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exemplified in the specification of said earlier-filed application are different with each other.

3.3 Judgement of Progressiveness

3.31 When a microorganism utilized in an invention is a known species and belongs to the same genus as another microorganism which has been known to produce a substance as aimed at by the former, no progress can be found in the said invention so far as the effect attained by utilizing the former microorganism is considered to be outstanding compared with the effect attained by utilizing the latter microorganism.

(Explanation)

It is very difficult to presume a substance productivity and the effect attained thereby between two different species. However, between at least the known species belonging to the same genus, it is considered easily practicable to deduce a substance productivity and effect attained thereby cultivating each microorganism.

To the contrary, when microorganisms utilized belong to respectively different genera, it cannot be easily considered that confirmation of a substance productivity and effect attained thereby is easily practicable.

3.23 When a microorganism utilized in an invention is determined to be a new species (including the case where designation is made in the term of strain), the said invention will be deemed as having progress, even when the objective

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substance is the same as that of another invention.

(Explanation)

Even when an objective substance is the same and a microorganism utilized is one beloging to the same genus, progress can be observed in that a new species is found and a novel method which is industrially utilizable is provided by using the above new species.

3.4 Others

3.41 Description of the Specification

(1) Expression of microorganism

Microorganisms shall be expressed in principle by scientific names in accordance with the zoological, botanical and microbial nomenclatures.

(2) Description of the claim

A Microorganism utilized

(A) A new strain, variant or known strain shall be expressed by a name of strain.

Example

(1) Process for preparing an antibiotics A9828, characterized by culturing a strain A9828 belonging to Streptomices griseus and then recovering the antibiotics A9828 from the cultured product.

(2) Process for preparing streptomycin, characterized by culturing a strain 43797 belonging to Streptomyces genus and then recovering the streptomycin from the cultured product.

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(3) Process for preparing glucoamylase, characterized by culturing Arumplaster C14, a varient of Aspergillus niger.

(B) A microorganism of a new species, variant or known species shall be expressed by a name of species.

Example

(1) Process for preparing streptomycin, characterized by culturing Streptomyces griseus and then recovering the streptomycin from the cultured product.

(2) Process for preparing chlortetracycline, characterized by culturing Streptomyces aureofaciens.

(C) When a microorganism in relation to the purpose of use thereof is novel as a genus to which the microorganism belongs, the microorganism may be expressed, for example, by such expression "B substance-producing microorganism belonging to genus A", even if only one microorganism of those belonging to the genus is exemplified.

This practice was provided to avoid vagueness of the borderline of patent right in the relevant microorganism due to its variability and quite difficulty in descriminating from analogous strains.

Such being the case, even if only one microorganism of new species is exemplified, the recovery step thereof must be described in the specification because said microorganism is treated merely as being an exemplification.

Example

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Process for preparing substance B, characterized by culturing a B substance-producing strain belonging to genus A and then recovering the substance B from the cultured broth.

B Recovery step

In case a microorganism utilized, which is described in the claim, is a known one or those inlcuding known ones, it is necessary that the recovery of an objective substance from the resulting fermentation product be described as being an indispensable matter for construction of the invention concerned.

In case there exists any fact that a known microorganism has been cultured to obtain a known substance therefrom, a process for preparing a substance by use of a microorganism is not recognized as being novel until a new substance has been found out in the known cultured product and recovered therefrom.

(3) Description of Detailed Explanation of the Invention

A Microorganism utilized

(A) Even when a microorganism utilized, which has been described in the claim, is expressed by any of classification units, it is necessary that a concrete example of the utilized strain (e.g. Aspergillus niger BIKOKENKINKI No. A) be set forth.

When a microorganism utilized is such as may not easily be available to those skilled in the art, a deposit

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number of said microorganism deposited in accordance with 3.14(1) must be described in the specification as first filed. When a microorganism utilized is readily available to those skilled in the art, a source of supply of said microorganism (e.g. a supply source, trade name or registered trade name in the case of commercially available strain, and an organization in which a microorganism is being preserved and a preservation number of said strain in the case of preserved strain).

Furthermore, all the microorganisms disclosed in working examples must bear the respective deposit numbers or supply sources thereof.

(B) In case a microorganism utilized is a strain, it is necessary to clearly describe characteristics of the strain and differences (microbiological properties and effects) existing between said strain and known strains of the same species.

(C) When a microorganism utilized is a known species or a variant, it is necessary to describe the scientific name thereof with reference to a literature that discloses said known species and the reasons why the microorganism utilized is identified to the known species or variant.

When a microorganism has the same microbiological properties as a known species has, it is necessary to indicate a literature disclosing the said known species. Further, when a microorganism is identical with a variant,

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it is necessary to describe the name of a known species to which the said variant is belonging, with reference to a literature disclosing the said known species.

(D) When a microorganism utilized is a new species (including the case where it is expressed as being a strain), it is necessary to fully describe the taxonomical properties of said microorganism and clarify the reasons why the microorganism utilized is recognized as a new species, if necessary, with showing its microscopic photograph or electron microscopic photograph. That is, it is necessary to describe clearly the difference between said new species and the conventional similar species and the name of literature on which the recognition of the microorganism as a new species has been based. Furthermore, the new species is desirably named in accordance with the Agreement of International Nomenclature.

For convenience's sake, microorganisms are roughly divided into yeasts, molds, fungi, bacteria and actionmyces, and the matters to be described in connection therewith are indicated below. In describing these matters, it is necessary that an experimental observation be conducted on a strain under favorable conditions for its growth, and conditions such as the kind of culture medium (or composition of a medium), cultivation temperature, cultivation time, method of recovering living cells and so on, be described. With respect to an isolation

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source, it is desirable to clearly describe the date (month and year) when a strain has been isolated, an isolation source (in case of animals and plants, they are expressed by scientific names as much as possible), and an origin of isolation.

a. In case a new species is such as belonging to yeasts, the following matters are to be described.

(a) Growth condition thereof in Various media

Slide culture in ① Malt extract or MY liquid medium, ② Malt extract-agar or MY-agar medium, and ③ Potato or corn extract-agar medium.

With respect to the growth condition in these media, there should be described the size and shape of vegetative cell, and the mode of propagation (budding, distination of fission, and existence of mycelia and pseudo ~~hypha~~ mycelia). In addition thereto, there should be described as fully as possible a medium or media in which the characteristics of said microbe are markedly displayed.

(b) Formation of ascospore

Existence of the formation of ascospore is to be examined using Golodkova medium, gypsum-sodium acetate medium, malt extract-agar medium, vegetable extract-agar medium, a medium of sliced carrot and the like. In case the formation of ascospore is recognized, its morphological characteristics are to be described.

(c) Formation of radius spore

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Existence of radius spore is to be investigated by means of the culture using a malt extract-agar medium or MY-agar medium, and in case the formation thereof is observed, the morphological characteristics are to be described.

(d) Physiological properties

① Optimum growth conditions (pH and temperature), ② range of growable conditions (pH and temperature), ③ assimilation of nitrates, ④ decomposition of fat, ⑤ decomposition of urea, ⑥ gelatin liquefaction, ⑦ in case osmophility or osmotic resistance is observed, the optimum or maximum concentration of cane sugar or sodium chloride, ⑧ carotenoid production, ⑨ significant organic acid production, ⑩ starch-like substance production, ⑪ vitamin requirement, and ⑫ other characteristic physiological properties of species.

(e) Determination of the utilization of 15 or more compounds out of the following carbon sources (it is at least necessary to remark the existence of utilizability and fermentability of the sugars asterisked, and other compounds which are necessary for showing the characteristics of the species or strain are to be selected).

① D-arabinose, ② L-arabinose, ③ D-ribose, ④ D-xylose, ⑤ D-glucose*, ⑥ D-mannose*, ⑦ D-galactose, ⑧ L-rhamnose, ⑨ D-fructose, ⑩ L-sorbose, ⑪ maltose*, ⑫ sucrose*, ⑬ lactose*, ⑭ melibiose, ⑮ cellubiose, ⑯ trehalose, ⑰ raffinose*, ⑱

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melizitose, ⑲ α-methyl-D-glucoside, ⑳ alubutin or esculin, ㉑ salicin, ㉒ soluble starch, ㉓ inulin, ㉔ ethanol, ㉕ adonitol, ㉖ erythritol, ㉗ inositol, ㉘ D-mannitol, ㉙ D-sorbitol, ㉚ dulcitol, ㉛ D-gluconate, ㉜ glycerine, ㉝ 2-keto-D-gluconate, ㉞ DL-lactate, ㉟ succinate, and ㊱ citrate.

b. In case a new species is such as belonging to molds or fungi, the following matters are to be described.

(a) Properties of a cultured product

(1) Growth condition in various media

① Mark (or malt extract)-agar medium, ② potato-dextrose agar medium, ③ Czapek's agar medium, ④ Sabouraud's agar medium, ⑤ oatmeal-agar medium, ⑥ synthetic Mucor-agar medium, ⑦ YpSs-agar medium, and ⑧ yeast-sucrose-agar medium (for mycorrhiza-forming fungi).

Among these media, two or more media are selected and the growth condition in the media is observed to describe the morphological properties of fructification organ, asexual spore and vegetative hypha, and shape and color shade of the surface and reverse of colony. In addition thereto, particularly such media as may be capable of remarkably displaying the characteristics of the strain are to be described as much as possible.

(2) Physiological and ecological properties

① Optimum growth conditions (pH, temperature, etc.), ② range of growable conditions (pH, temperature,

Japan - continued

etc.), ③ phenoloxidase reaction (only wood-rotting fungi), and ④ other remarkable characteristics.

(b) When the cultural properties on various media are not sufficient to decide the mold or fungus as being a new species, the following properties are to be described with reference to a dried specimen or slide specimen.

Morphological properties of a type specimen (morphological properties of fructification organ, asexual spore and vegetative hypha, and shape, color, etc. on a substrate). Furthermore, it is desirable to describe the storage location and number of the type specimen.

C. When a new species is such as belonging to bacteria, the following properties thereof are to be mentioned.

(a) Morphological characteristics

The following points are to be mentioned with regard to a cell which has grown in an agar medium and liquid medium. The medium to be used is composed basically of meat extract and meat extract-agar, but suitable media having another composition may be used for those which do not grow in the aforesaid media.

① Shape and size of cell; ② existence of polymorphous cell and, if any, its detail; ③ existence of mobility and if any, growth state of flagellum; ④ existence of spore and, if any, shape and size of spore and sporangium, and location of spore; ⑤ Gram's stain, and ⑥ acid resistance.

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(b) Cultural growth condition in the following media

① Meat extract-agar plate culture; ② meat extract-agar slant culture; ③ meat extract liquid culture, ④ meat extract-gelatine stab culture, and ⑤ litmus milk.

There should be mentioned an aspect of growth, color, luster, diffusible pigment and the like in the case of agar medium; existence of surface growth, turbidity and the like in the case of liquid medium; growth condition, gelatine liquefaction and the like in the case of gelatine stab culture; and reaction (alkaline or acidic), coagulation, liquefaction and the like in the case of litmus milk.

Furthermore, in the case of bacteria, which do not grow in the above-mentioned media, their growth condition in other media suitable for their growth are to be mentioned.

(c) Physiological properties

There should be mentioned ① nitrate reduction, ② denitrification reaction, ③ MR test, ④ VP test, ⑤ indole production, ⑥ hydrogen sulfide production, ⑦ starch hydrolysis, ⑧ utilization of citric acid (Koser's medium and Christensen's medium are to be used in combination), ⑨ utilization of inorganic nitrogen sources (nitrates and ammonium salts), ⑩ pigment production (to be mentioned whether the pigment is water-soluble or

Japan - continued

not). (11) urease, (12) oxidase, (13) catalase, (14) range of growth conditions (pH, temperature, etc.), (15) behavior toward oxygen (distinction of aerobic or anaerobic property), (16) O-F test (according to Hugh Leifson method), and (17) existence of production of acids and gas from the following sugars. (1) L-arabinose, (2) D-xylose, (3) D-glucose, (4) D-mannose, (5) D-fructose, (6) D-galactose, (7) maltose, (8) sucrose, (9) lactose, (10) trehalose, (11) D-sorbitol, (12) D-mannitol, (13) inositol, (14) glycerine and (15) starch.

(d) From the following properties, those which are necessary for showing the characteristics of a new species are selected to be mentioned.

(1) Decomposition products of sugars, (2) gluconic acid oxidation, (3) alcohol oxidation, (4) dioxyacetone production, (5) esculin decomposition, (6) cellulose decomposition, (7) hippuric acid decomposition, (8) utilization of malonic acid, (9) arginine decomposition (10) decarboxylation reaction of lysine, (11) decarboxylation reaction of ornithine, (12) deamination reaction of phenylalanin, (13) coagulase, (14) hemolytic property, (15) temperature resistance, (16) ~~resistance~~ tolerance of sodium chloride, (17) ~~resistance~~ tolerance of potassium cyanide, (18) phosphatase, (19) pectinase, (20) lipase, (21) lecithinase, (22) nutrition requirement, and (23) other properties to be considered necessary.

Japan - continued

(e) With respect to absolute anaerobic bacteria, inorganic nutrition bacteria, photosynthesis bacteria and the like, the properties thereof are to be described in accordance with the foregoing (d) by referring Bergey's Manual or recent studies.

d. When a new species is such as belonging to actinomyces, the following matters are to be mentioned.

(a) Morphological characteristics

There are to be mentioned branching (distinction of simple branching or axle branching) and form (distinction of straight, curve, loop or spiral shape) of spore-forming hypha, the number of spore (distinction of ~~spore-forming hypha, the number of spore~~ (distinction of monospore or more, dispore or more, or 10 spores or more), surface structure and size of spore, existence of flagellated spore, existence of sporangium, growth location of sporophore (distinction of location on basal hypha or aerial hypha) and, if necessary, fission condition of hypha (mode of fission and time) and existence of formability of sclerotium.

(b) Growth condition on various media

(1) Sucrose-nitrate-agar medium, (2) glucose-asparagine-agar medium, (3) glycerine-asparagine-agar medium, (4) starch-agar medium, (5) tyrosine-agar medium, (6) nutrient agar medium, (7) yeast-malt-agar medium, and (8) oatmeal-agar medium.

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With regard to growth condition on those media, there are to be mentioned color of the surface of colony, color of the surface and reverse of basal hypha, diffusible pigment into medium and so on.

(c) Physiological properties

① Range of growth temperature conditions, ② liquefaction of gelatine (on glucose-peptone-gelatine medium), ③ starch hydrolysis (on starch-agar medium), ④ coagulation and peptonization of skim milk, ⑤ melanin-like pigment production (on tyrosine-agar medium and peptone-yeast-iron agar medium).

(d) Utilization of the following carbon sources (on Pridham-Gottlieb's agar medium)

① L-arabinose, ② D-xylose, ③ D-glucose, ④ D-fructose, ⑤ sucrose, ⑥ inositol, ⑦ L-rhamnose, ⑧ raffinose, and ⑨ D-mannitol.

Furthermore, examples of typical compositions of media to be used for identification of the above-mentioned yeasts, molds, fungi, bacteria and actinomyces are given as in the following.

(a) Yeasts

(1) MY medium

5 g of peptone, 3 g of yeast extract (commercially available), 3 g of malt extract (commercially available), 10 g of D-glucose and 1000 ml of distilled water.

(2) Potato-agar medium

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100 g of potato is grated, [illegible] of water and allowed to stand in a [illegible] for several hours, and then filtered through a cloth and boiled at 120°C for 1 hour. After cooling, the resulting liquid is made to 1 l. to which are added 10 g of D-glucose and 20 g of agar.

(3) Golodkova medium

1% peptone, 1% bouillon, 0.25% D-glucose, 0.5% sodium chloride and 2.5% agar.

(4) Sodium acetate medium

0.4% sodium acetate and 1.5% agar (0.04% raffinose).

(5) Malt extract-agar medium

20 g malt extract powder, 12 g of agar and 400 ml of distilled water.

(6) Vegetable broth-agar medium

500 ml of vegetable broth (commercially available), 10 g of baker's yeast, 20 g of agar and 500 ml of distilled water, pH 7.0.

(7) Gypsum medium

To a sintered gypsum is added an equal amount of water, and the mixture is stirred to give a paste-like product. The product is poured in a suitable frame work (a copper-made conical frame, of which the inside is coated with vaseline) and immediately thereafter, a gas present in the blocked gypsum is purged off by tapping

Japan - continued

the whole assembly on a desk and the block is allowed to stand for about 30 minutes. The solidified block is taken out, and the surface is made smooth and at the same time a small hole is provided on the surface into which the test yeast cells are to be placed. After sufficiently solidifying the block, the vaseline is wiped off, and the block is boiled for about 30 minutes while replacing water 1 to 2 times. The block is taken out using a sterilized pincette and placed in a large size petri dish which has previously been sterilized, and sterilized water is poured in the dish until about one half of the block is immersed in the water. The test yeast is precultured 2 to 3 times in malt broth, koji broth, MY or Miller medium, and the supernatant liquid is flown out. The remaining fresh cells are placed in the small hole on the block using a platinum loop or microspoon. The culture is effected at 20-25°C.

(b) Molds and fungi

(1) Malt extract-agar medium

20 g of malt extract, 20 g of dextrose 1 g of peptone, 25 g of agar and 1000 ml of water.

(2) Potato-dextrose-agar medium

200 g of potato (peeled off and cut into cubes), and 1000 ml of distilled water are used to give a decoction. To the decoction are added 20 g of sucrose and 15 g of agar.

(3) Czapek's agar medium

3 g of [illegible], 1 g of K_2HPO_4, 0.5 g of $MgSO_4$

Japan - continued

$7H_2O$, 0.5 g of KCl, 0.01 g of $FeSO_4 \cdot 7H_2O$, 30 g of sucrose, 15 g of agar and 1000 ml of distilled water.

(4) Sabouraud's agar medium

40 g of maltose, 10 g of peptone, 15 g of agar and 1000 ml of distilled water.

(5) Oatmeal-agar medium

30 g of oatmeal and 1000 ml of distilled water are used to give a decoction to which is added 20 g of agar.

( ) Synthetic Mucor-agar medium

40 g of dextrose, 2 g of asparagine, 0.5 g of KH_2PO_4, 0.025 g of $MgSO_4 7H_2O$, 0.5 mg of thiamine chloride, 15 g of agar and 1000 ml of distilled water.

(7) YpSs medium

15 g of soluble starch, 4 g of yeast extract, 1 g of K_2HPO_4, 0.5 g of $MgSO_4 7H_2O$, 20 g of agar and 1000 ml of distilled water.

(8) Sugar-yeast-agar medium (only for mycorrhiza-forming fungi)

20 g of dextrose, 5 g of dry yeast, 20 g of agar and 1000 ml of tap water (or well water), pH 5.0.

(9) Phenoloxidase reaction determination medium

0.5% each of tannic acid and gallic acid are added to a malt broth-agar medium or potato-dextrose-agar medium.

(c) Bacteria

(1) Meat extract medium

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10 g of meat extract, 10 g of peptone, 5 g of NaCl and 1000 ml of distilled water, pH 7.2.

(2) Meat extract-agar medium

10 g of meat extract, 10 g of peptone, 5 g of NaCl, 15-20 g of agar and 1000 ml of distilled water, pH 7.2.

(3) Meat extract-gelatine medium

10 g of meat extract, 10 g of peptone, 5 g of NaCl, 100-300 g of gelatine and 1000 ml of distilled water, pH 7.2.

(4) Litmus milk

To a fresh skim milk or powdered skim milk, which has been adjusted to the same concentration as in the raw milk, is added a suitable amount of litmus liquid.

(d) Actinomyces

(1) Sucrose-nitrate-agar medium

30 g of sucrose, 2 g of $NaNO_3$, 1 g of K_2HpO_4, 0.5 g of $MgSO_4 7H_2O$, 0.5 g of KCl, 0.01 g of $FeSO_4 7H_2O$, 10-20 g of agar and 1000 ml of distilled water, pH 7.0-7.3.

(2) Glucose-asparagine-agar medium

10 g of glucose, 0.5 g of asparagine, 0.5 g of K_2HPO_4, 15-20 g of agar and 1000 ml of distilled water, pH 6.8-7.0.

(3) Glycerine-asparagine-agar medium

10 g of glycerine, 1 g of L-asparagine, 1 g of K_2HPO_4, 1000 ml of distilled water, 1 ml of a solution of trace amounts of salts (0.1 g of $FeSO_4 \cdot 7H_2O$, 0.1 g of

Japan - continued

$MnCl_2 \cdot 4H_2O$, 0.1 g of $ZnSO_4 \cdot 7H_2O$ and 100 ml of distilled water) pH 7.0-7.4, and 15-20 g of agar.

(Note) The above medium is prepared in accordance with Medium No. 5 of International Streptomyces Project (hereinafter referred to as "ISP").

(4) Starch-inorganic salt-agar medium

Liquid I: 10 g of soluble starch is charged with a small amount of cold distilled water to give a paste-like product and the product is diluted to make 500 ml. Liquid II: 1 g of K_2HPO_4, 1 g of $MgSO_4 \cdot 7H_2O$, 1 g of NaCl, 2 g of $(NH_4)_2SO_4$, 2 g of $CaCO_3$, 500 ml of distilled water, 1 ml of a solution of trace amounts of salts (0.1 g of $FeSO_4 \cdot 7H_2O$, 0.1 g of $MnCl_2 \cdot 4H_2O$, 0.1 g of $ZnSO_4 \cdot 7H_2O$ and 100 ml of distilled water). Liquids I and II are mixed together, and thereto is added 15-20 g of agar.

(Note) The above medium is prepared inaccordance with Medium No. 4 of ISP.

(5) Tyrosine-agar medium

15 g of glycerine, 0.5 g of L-tyrosine, 1 g of L-asparagine, 0.5 g of K_2HPO_4, 0.5 of $MgSO_4 \cdot 7H_2O$, 0.5 g of NaCl, 0.01 g of $FeSO_4 \cdot 7H_2O$, 1000 ml of distilled water and 1 ml of a solution of trace amounts of salts (0.1 g of $FeSO_4 \cdot 7H_2O$, 0.1 g of $MnCl_2 \cdot 4H_2O$, 0.1 g of $ZnSO_4 \cdot 7H_2O$ and 100 ml of distilled water), pH 7.2-7.4, and 15-20 g of agar.

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(6) Nutrient agar medium

5 g of peptone, 5 g of meat extract, 5 g of NaCl, 15-20 g of agar, and 1000 ml of distilled water, pH 7.0-7.2.

(7) Yeast-malt-agar medium

4 g of yeast extract, 10 g of malt extract, 4 g of glucose and 1000 ml of distilled water and, after adjusting the pH to 7.3, thereto is added 15-20 g of agar.

(Note) The above medium is prepared in accordance with Medium No. 2 of ISP.

(8) Oatmeal-agar medium

20.0 g of oatmeal (20 g of oatmeal is boiled for 20 minutes in 1000 ml of distilled water, and then filtered through a cheese cloth and the loss in weight is compensated with distilled water), 1 ml of a solution of trace amounts of salts (0.1 g of $FeSO_4 \cdot 7H_2O$, 0.1 g of $MnCl_2 \cdot 4H_2O$, 0.1 g of $ZnSO_4 \cdot 7H_2O$ and 100 ml of distilled water) and 18.0 g of agar.

(9) Glucose-peptone-gelatine medium

20 g of glucose, 5 g of peptone, 200 g of gelatine and 1000 ml of distilled water. The mixture is sterilized by heating.

(10) Skim milk medium

100 g of unfortified powdered skim cow milk and 1000 ml of distilled water.

(11) Pridham-Gottlieb agar medium

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2.64 g of $(NH_4)_2SO_4$, 2.33 g of KH_2PO_4, 5.65 g of $K_2HPO_4 \cdot 3H_2O$, 1 g of $MgSO_4 \cdot 7H_2O$ and 1 ml of Pridham-Gottlieb solution of trace amounts of salts (0.64 g of $CuSO_4 \cdot 5H_2O$, 0.11 g of $FeSO_4 \cdot 7H_2O$, 0.79 g of $MnCl_2 \cdot 4H_2O$, 0.15 g of $ZnSO_4 \cdot 7H_2O$ and 100 ml of distilled water). The mixture is kept at 3-5°C, and is taken out when used. The mixture is prepared afresh every month. When a precipitate is formed during storage, the mixture is not used. After dissolving the whole content, the pH of the solution is adjusted to 6.8-7.0. (If necessary, 1 N NaOH or 1 N HCl may be used.) 15-20 g of rinsed and purified agar is added thereto, and the resulting mixture in sterilized.

(Note) In carrying out a test on utilization of carbon sources, the above-mentioned sterilized agar is dissolved and cooled to 60°C, and then 10% each of various carbon sources, which have been separately sterilized (according to filter sterilization, ether sterilization, ethylene oxide sterilization or the like), is added in an amount of 1/10 of the above-mentioned agar medium.

(12) Peptone-yeast-iron agar medium

① 36 g of peptone-iron agar e.g. Bacto-Peptone Iron Agar dehydrated (Difco), 15 g of peptone, 0.5 g of animal meat papain digestive peptone e.g. Proteose peptone (Difco) or Proteose peptone W (Nissui), 0.5 g of ammonium iron citrate, 1 g of K_2HPO_4, 0.03 g of $Na_2S_2O_3$ and 15 g of agar; ② 1 g of yeast extract;

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③ 1000 ml of distilled water, ① , ② and ③ are mixed together, sterilized and adjusted to pH 7.0-7.2.

B Substance produced

(A) When a substance produced is considered to be a known substance, the grounds for the confirmation are made clear desirably by referring to a literature in which the known substance is disclosed.

(B) When a substance produced is considered new, the following physico-chemical properties should be specified in order to make clear the reason for that consideration.

① Elementary analysis
② Molecular weight
③ Melting point (melting points of salts also are acceptable)
④ Specific rotation
⑤ Ultraviolet absorption spectrum
⑥ Infrared absorption spectrum
⑦ Solubility in solvents
⑧ Color reaction
⑨ Distinction on basic, acidic or neutral properties
⑩ Color of substance produced

Of the above-mentioned physico-chemical properties, if there are those which cannot be specified depending upon a kind of substances, the reason why they cannot be specified should be mentioned and, if necessary, other physico-chemical properties should be supplemented to make definite the substance produced.

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According to a kind of substance, for example, a melting point may not be determined due to carbonization or softening even when a crystallized product is obtained. In that case, the reason as above should be mentioned.

(C) When a substance produced is a new enzyme, the following 11 items should be referred to in order to make clear the reason why the enzyme is considered new.

① Activity
② Specificity on substrate
③ Optimum pH range and stable pH range
④ Determination method for potency
⑤ Range of temperature appropriate for activity
⑥ Condition of deactivation due to pH, temperature, etc.
⑦ Inhibition, activation and stabilization
⑧ Purification method
⑨ Molecular weight
⑩ Crystal structure
⑪ Elementary analysis

Of the above physico-chemical properties, if there are those which cannot be specified depending upon a kind of enzyme, the reason why they cannot be specified should be mentioned and at the same time, if necessary, other physico-chemical properties should be supplemented to make definite the enzyme produced.

A number of enzymes difficultly crystallize even when they are purified and so determination of crystal

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structure sometimes is impossible. In that case, degree of mobility on filter paper electrophoresis may be referred to in order to define enzyme.

(D) When a substance produced is a new high molecular weight substance and some of the physico-chemical properties as referred to in the above 3.41-(3)B-(B) cannot be specified as to said new high molecular weight substance, the reason for this should be mentioned and at the same time, if necessary, other physico-chemical properties should be supplemented to define the high molecular weight substance.

(E) When a substance produced is an antibiotic, in addition to the physico-chemical properties as referred to in the above 3.41-(3)B-(B), the resistance to the following bacteria as mentioned below and actual utility (including presence or absence of toxicity) should in principle be mentioned.

a. Bacteria

(a) Gram positive bacteria, for example, ① Staphylococcus aureus, ② Streptococcus pyogenes, ③ Diplococcus pneumoniae, ④ Corynebacterium diphtheriae, ⑤ Bacillus subtilis, etc.

(b) Gram negative bacteria, for example, ① Hemophilus pertussis, ② Neisseria meningitidis, ③ Escherichia coli, ④ Salmonella typhi, ⑤ Shigella dysenteriae, ⑥ Pseudomonas aeruginosa, etc.

(c) Acid-resistant bacteria, for example, ① Mycobacterium

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tuberculosis, etc.

b. Molds, for example, ① Aspergillus oryzae, ② Aspergillus niger, ③ Penicillium notatum, ④ Penicillium chrysogenum, etc.

c. Yeasts, for example, ① Hansenula anomala, ② Saccharomyces cerevisiae, ③ Torula utili, ④ Willia anomala, etc.

d. Others, for example, ① Virus, ② Rickettsia, ③ Protozoa, ④ Onco-cyte, etc.

C. Cultivation and Recovery

It is always necessary to give a concrete explanation on the procedures (cultivation method, step for recovery and the like) necessary for producing a substance even when there is no characteristic aspect.

4 Judgement of Change in Gist (= New Matters)

When the technical matters set forth in the claim deviate, as a result of amendment made to the specification, from the extent of the matters described in the specification as first filed, said amendment shall be deemed to change the gist of the specification or, in other words, to constitute new matter.

4.1 Microorganisms utilized

4.11 An amendment made to the name of microorganism utilized shall not be deemed to constitute new matter unless a deposit number (or receipt number) described in the specification as first filed is changed.

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4.12 In case no change is made as to a deposit number (or receipt number) described in the specification as first filed and the conditions stipulated in 3.13(3) are recognized as being satisfactorily fulfilled, any supplement thereto of other microbiological properties shall not be deemed to constitute new matter.

4.13 When an invention is recognized as incomplete in view of 3.13(2), amendment of a deposit number shall be deemed to constitute new matter.

4.14 In case an invention is recognized as incomplete in view of 3.13(3), any amendment made to the disclosed microbiological properties shall be deemed to constitute new matter.

4.15 When a deposit number described in the specification as first filed is subjected to amendment, such amendment deemed, in principle, to constitute new matter.

4.2 Substances produced

4.21 An amendment to a name of substance produced shall not be deemed as changing the gist of the specification only when it is clear that the properties of the substance referred to in the specification as first filed are not substantially changed thereby.

4.22 An amendment to physico-chemical properties shall not be deemed as constituting new matter, only when the amendment is slight and recognized as not changing in substance the substance produced.

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4.23 When a substance produced is new and at least the following three physico-chemical properties, i.e. (1) elementary analysis, (2) infrared absorption spectrum and (3) any one of molecular weight, melting point and characteristic color reaction, among ten physico-chemical properties listed in the above 3.41-(3)B(B) are specified in the specification as first filed so that confirmation of the substance is presumed as practically possible, addition of un-specified other physico-chemical properties among said ten shall not be deemed as constituting new matter.

Further, when either one of the above three physico-chemical properties is lacking but some properties instead are fully described or the reason why said properties cannot be specified depending upon the type of substance is made clear and confirmation of the substance is presumed as practically possible, addition of un-specified physico-chemical properties among the ten as listed up in the above 3.41-(3)B(B) shall not be deemed as constituting new matter.

4.24 Amendment to the structural formula of a substance produced shall not be deemed to constitute new matter, only when it is clarified that a compound having the newly determined structural formula is the same substance as that specified in the specification as first filed by a credible technical publication, credible experimental report or the like.

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4.25 When a substance produced is a new enzyme and at least three physico-chemical properties, i.e. 1 activity, 2 specificity on substrate and 3 Optimum pH value and stable pH range, among the eleven kinds of properties defined in the above 3.41-(3)B(C) are specified in the specification as first filed and when confirmation of the enzyme is presumed to be practically possible, addition of un-specified properties among said eleven kinds of physico-chemical properties shall not be deemed to constitute new matter.

Further, when either one of the above three physico-chemical properties is lacking but some properties instead are fully specified or the reason why said property cannot be specified depending upon the type of enzyme is made clear and confirmation of the enzyme is presumed practically possible, addition of un-specified properties among said eleven kinds of physico-chemical properties defined in the above 3.41-(3)B(C) shall not be deemed to constitute new matter.

4.26 When an invention is recognized as incomplete in view of 3.13(4) and 3.13(5), any supplement thereto of microbiological properties shall be deemed to constitute new matter.

Therefore, if the respective 3 items of 4.23 and 4.25 have not been described and hence the invention is recognized as incomplete in view of 3.13(4) and 3.13(5),

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no amendment is allowed to be effected. The application of said invention will inevitably come to be refiled afresh.

5 Supplementary Regulations

5.1 This Examination Standard shall be applied to a patent application as filed on and after January, 1971.

5.2 "Fermentation Research Institute, Agency of Industrial Science & Technology" is designated as an authentic depository in Japan, with which a microorganism utilized is to be deposited, as referred to in 3.14(1).

(Original)

MONACO

With reference to your Circular No. 1795/453 of November 20, 1973, relating to patent procedure with respect to inventions concerning microbiological processes or products thereof, I have the honor to inform you that Article 2 of Law No. 606 of June 20, 1955, requires that new patented products have industrial character; in principle this requirement should rule out biological inventions. However, considering the negligible importance of such inventions in 1955, and its incessant growth since that date, it is not unlikely that the courts will take a liberal attitude, but as yet no judicial decision has been rendered in this field.

Furthermore, the legislation of Monaco contains no specific provisions on the patentability of inventions concerning microorganisms. If an application for such a patent were to be filed with the Industrial Property Department, the latter would be unable to demand, in addition to the description, a deposit of the micro-organism with a reference to the deposit in the description.

(Translation)

NIGERIA

I (1) A valid patent may be obtained in respect of micro-organisms

(2) No

II (1) A description in writing is sufficient. No deposit is required.

(2) (3) & (4) Not applicable.

III No further information is available.

(Original)

ROMANIA

I. Patentability of Inventions Involving Microorganisms

The law of the Socialist Republic of Romania contains no provisions on the protection of inventions concerning microorganisms. The procedure followed in such cases is based on the general provisions regarding patentability and on the fundamental principles of our law.

1. According to the practice in our country a valid patent may be obtained for:

(a) a process involving the action, under specific conditions, of a microorganism; the microorganism must be officially registered on the date of filing of the application, and made available to the public;

(b) a product of a process referred to under (a) (the product patent is granted only to a Romanian State enterprise to which the inventor--or his successor in title--has assigned the rights attaching to the invention, pursuant to Article 7(b));

(c) No: a new microorganism existing in nature is not patentable;

(d) No: a new strain of an existing microorganism, regardless of the process by which it is obtained, is not patentable.

2. The law of our country contains no provisions relating to the patentability of inventions involving microorganisms.

II. Disclosure and Making Available to the Public

1. If a patent application is filed in our country for an invention involving new microorganisms, a description in writing of the microorganism has to be submitted (giving morphological and taxonomic characteristics), and a deposit of the new microorganism has to be made in a culture collection, with a reference to the deposit in the description.

2.(a) The deposit of the new microorganism must be made only in a recognized culture collection.

(b) The deposit may be made in a culture collection outside the country.

3. The deposit of the new microorganism in a recognized culture collection must be made on the priority date (the date of first filing of the patent application).

4. The new microorganism has to be made available to the public.

(a) The new microorganism, being the subject either of a patent application the owner of which is a Romanian State enterprise, or of an expired patent, is made available to the public through the obligation of the laboratory keeping the specimen to sell a sample to the Romanian State on request.

(b)(i) The new microorganism must be made available to the public on the filing date, provided that the instrument of filing contains an offer of assignment to a Romanian State enterprise.

(ii) No.

(iii) No.

(iv) On the date of expiration of the patent where the rights under the respective patent have not been assigned to a Romanian State enterprise.

(c) There are no provisions in our law determining the conditions and the relevant restrictions on the basis of which the new microorganism is made available to third parties. However, infringement of the exclusive rights conferred on the owners of patents for inventions involving microorganisms is punished according to the Law on the Protection of Patentable Technology.

(Translation)

SOUTH AFRICA

I. Patentability of Inventions involving Micro-organisms

1. a) A valid patent may be obtained under the South African Patent legislative for a process involving the action of a micro-organism not already known and available to the public.

b) It can also be obtained for a product of a process referred to under (a).

c) It seems highly probable that no protection can be obtained for a new micro-organism which is found in nature and is taken from where it was found, but that depending on the particular circumstances of each case, valid protection might well be obtainable for that micro-organism when "manufactured", provided of course, that it is possible artificially to produce such a micro-organism.

d) It is probable that a patent may be obtained for a new strain of an existing micro-organism obtained by a process such as mutation.

2. The South African legislation and court decisions contain no other provisions relating to patentability of inventions involving micro-organisms.

II. Disclosure and Making Available to the Public

1. There is no legislation or case law on this point. If the new micro-organism can be identified fully and clearly by way of description only, there seems no reason why this should not be sufficient. However, it might well be necessary for positive identification to make a deposit in a culture collection and to refer to that deposit in the description.

2. a) A definite answer cannot be given, but if a deposit is required it is highly probable that

South Africa - continued

it will be necessary for the deposit to be made in a recognised culture collection.

b) A definite answer cannot be given, but it is probable that if a deposit in a culture collection is required, a deposit in such a collection outside South Africa may be acceptable.

3. In the absence of legislative and presedent it is difficult to give a definite answer, but it is probable that the deposit will have to be made at the "effective" date of the application, i.e. at the priority date in the case of a Convention application and on the filing date in the case of a non-Convention application.

4. There is no legislative or case law on the point, but if a deposit is required, it is probable that the micro-organism will have to be made available to the public.

a) An answer to this question cannot be given at this stage.

b) No definite answer is possible, but if the micro-organism is to be made available, it is probable that it will have to be made available on the date of publication of the description.

c) There is no legislation or case law on this point.

III. In the absence of legislation and case law in respect of inventions concerning microbiological processes or products thereof, no further information can be furnished.

(Original)

UGANDA

My country does not examine Patents either as to patentability or as to novelty. We do a kind of rubber-stamping by registering only those Patents which have been registered in England. In the circumstances, I would say that whatever is registered in England as a Patent, is registrable in Uganda as well. I agree this is an anomaly, but there are a lot of facts that do contribute to this practice which are not necessary in this letter.

I hope that your request is complied with, especially as I think that it is not worthwhile touching point by point in your Questionnaire.

(Original)

/End of Annex
and of document/